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[Proposed Rules]

[Page 24079-24686]

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[[Page 24079]]

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Part II

Book 2 of 2 Books

Pages 24079-24694

Department of Health and Human Services

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Centers for Medicare & Medicaid Services

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42 CFR Parts 412, 413, 415 et al.

Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates; Proposed Rule

[[Page 24080]]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 415, and 489

[CMS-1406-P]

RIN 0938-AP39

Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

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SUMMARY: We are proposing to revise the Medicare hospital inpatient

prospective payment systems (IPPS) for operating and capital-related

costs of acute care hospitals to implement changes arising from our

continuing experience with these systems, and to implement certain

provisions made by the Medicare Improvements for Patients and Providers

Act of 2008 (MIPPA, Pub. L. 110-275) and the American Recovery and

Reinvestment Act of 2009 (ARRA, Pub. L. 111-5). In addition, in the

Addendum to this proposed rule, we describe the proposed changes to the

amounts and factors used to determine the rates for Medicare acute care

hospital inpatient services for operating costs and capital-related

costs. These proposed changes would be applicable to discharges

occurring on or after October 1, 2009. We also are setting forth the

proposed update to the rate-of-increase limits for certain hospitals

excluded from the IPPS that are paid on a reasonable cost basis subject

to these limits. The proposed updated rate-of-increase limits would be

effective for cost reporting periods beginning on or after October 1,

2009.

In addition, we are proposing to update the annual payment rates

for the Medicare prospective payment system (PPS) for inpatient

hospital services provided by long-term care hospitals (LTCHs). In the

Addendum to this proposed rule, we also set forth the proposed changes

to the payment rates, factors, and other payment rate policies under

the LTCH PPS for rate year 2010. These proposed changes would be

applicable to discharges occurring on or after October 1, 2009. In this

proposed rule, we also note those provisions of the ARRA that amended

provisions of the Medicare, Medicaid, and SCHIP Extension Act of 2007

(MMSEA, Pub. L. 110-173) relating to payments to LTCHs and new LTCHs

and LTCH satellite facilities, and increases in beds in existing LTCHs

and LTCH satellite facilities under the LTCH PPS that will be

implemented in the final rule issued for this proposed rule.

DATES: To be assured consideration, comments must be received at one of

the addresses provided below, no later than 5 p.m. E.S.T. on June 30,

2009.

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comments on this document's paperwork requirements by following the

instructions at the end of the ``Collection of Information

Requirements'' section in this document.

For information on viewing public comments, see the beginning of

the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION, CONTACT: Tzvi Hefter, (410) 786-4487,

Operating Prospective Payment, MS-DRGs, Wage Index, New Medical Service

and Technology Add-On Payments, Hospital Geographic Reclassifications,

Capital Prospective Payment, Excluded Hospitals, Direct and Indirect

Graduate Medical Education Payments, EMTALA, Hospital Emergency

Services, and Hospital-Within-Hospital Issues.

Michele Hudson, (410) 786-4487, Long-Term Care Hospital Prospective

Payment System and MS-LTC-DRGs Issues.

Siddhartha Mazumdar, (410) 786-6673, Rural Community Hospital

Demonstration Program Issues.

Sheila Blackstock, (410) 786-3502, Quality Data for Annual Payment

Update Issues.

Thomas Valuck, (410) 786-7479, Hospital-Acquired Conditions.

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[[Page 24081]]

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Acronyms

3M 3M Health Information System

AAHKS American Association of Hip and Knee Surgeons

AAMC Association of American Medical Colleges

ACGME Accreditation Council for Graduate Medical Education

AHA American Hospital Association

AHIC American Health Information Community

AHIMA American Health Information Management Association

AHRQ Agency for Healthcare Research and Quality

ALOS Average length of stay

ALTHA Acute Long Term Hospital Association

AMA American Medical Association

AMGA American Medical Group Association

AOA American Osteopathic Association

APR DRG All Patient Refined Diagnosis Related Group System

ARRA American Recovery and Reinvestment Act of 2009, Public Law 111-

5

ASC Ambulatory surgical center

ASCA Administrative Simplification Compliance Act of 2002, Public

Law 107-105

ASITN American Society of Interventional and Therapeutic

Neuroradiology

BBA Balanced Budget Act of 1997, Public Law 105-33

BBRA Medicare, Medicaid, and SCHIP [State Children's Health

Insurance Program] Balanced Budget Refinement Act of 1999, Public

Law 106-113

BIPA Medicare, Medicaid, and SCHIP [State Children's Health

Insurance Program] Benefits Improvement and Protection Act of 2000,

Public Law 106-554

BLS Bureau of Labor Statistics

CAH Critical access hospital

CARE [Medicare] Continuity Assessment Record & Evaluation

[Instrument]

CART CMS Abstraction & Reporting Tool

CBSAs Core-based statistical areas

CC Complication or comorbidity

CCR Cost-to-charge ratio

CDAC [Medicare] Clinical Data Abstraction Center

CDAD Clostridium difficile-associated disease

CIPI Capital input price index

CMI Case-mix index

CMS Centers for Medicare & Medicaid Services

CMSA Consolidated Metropolitan Statistical Area

COBRA Consolidated Omnibus Reconciliation Act of 1985, Public Law

99-272

COLA Cost-of-living adjustment

CoP [Hospital] condition of participation

CPI Consumer price index

CY Calendar year

DPP Disproportionate patient percentage

DRA Deficit Reduction Act of 2005, Public Law 109-171

DRG Diagnosis-related group

DSH Disproportionate share hospital

ECI Employment cost index

EMR Electronic medical record

EMTALA Emergency Medical Treatment and Labor Act of 1986, Public Law

99-272

FAH Federation of Hospitals

FDA Food and Drug Administration

FFY Federal fiscal year

FHA Federal Health Architecture

FIPS Federal information processing standards

FQHC Federally qualified health center

FTE Full-time equivalent

FY Fiscal year

GAAP Generally Accepted Accounting Principles

GAF Geographic Adjustment Factor

GME Graduate medical education

HACs Hospital-acquired conditions

HCAHPS Hospital Consumer Assessment of Healthcare Providers and

Systems

HCFA Health Care Financing Administration

HCO High-cost outlier

HCRIS Hospital Cost Report Information System

HHA Home health agency

HHS Department of Health and Human Services

HIPAA Health Insurance Portability and Accountability Act of 1996,

Public Law 104-191

HIPC Health Information Policy Council

HIS Health information system

HIT Health information technology

HMO Health maintenance organization

HPMP Hospital Payment Monitoring Program

HSA Health savings account

HSCRC [Maryland] Health Services Cost Review Commission

HSRV Hospital-specific relative value

HSRVcc Hospital-specific relative value cost center

HQA Hospital Quality Alliance

HQI Hospital Quality Initiative

HwH Hospital-Within-a-Hospital

ICD-9-CM International Classification of Diseases, Ninth Revision,

Clinical Modification

ICR Information collection requirement

IHS Indian Health Service

IME Indirect medical education

I-O Input-Output

IOM Institute of Medicine

IPF Inpatient psychiatric facility

IPPS [Acute care hospital] inpatient prospective payment system

IRF Inpatient rehabilitation facility

LAMCs Large area metropolitan counties

LOS Length of stay

LTC-DRG Long-term care diagnosis-related group

LTCH Long-term care hospital

MA Medicare Advantage

MAC Medicare Administrative Contractor

MCC Major complication or comorbidity

MCE Medicare Code Editor

MCO Managed care organization

MCV Major cardiovascular condition

MDC Major diagnostic category

MDH Medicare-dependent, small rural hospital

MedPAC Medicare Payment Advisory Commission

MedPAR Medicare Provider Analysis and Review File

MEI Medicare Economic Index

MGCRB Medicare Geographic Classification Review Board

MIEA-TRHCA Medicare Improvements and Extension Act, Division B of

the Tax Relief and Health Care Act of 2006, Public Law 109-432

MIPPA Medicare Improvements for Patients and Providers Act of 2008,

Public Law 110-275

MMA Medicare Prescription Drug, Improvement, and Modernization Act

of 2003, Public Law 108-173

MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public

Law 110-173

MPN Medicare provider number

MRHFP Medicare Rural Hospital Flexibility Program

MRSA Methicillin-resistant Staphylococcus aureus

MSA Metropolitan Statistical Area

MS-DRG Medicare severity diagnosis-related group

MS-LTC-DRG Medicare severity long-term care diagnosis-related group

NAICS North American Industrial Classification System

NALTH National Association of Long Term Hospitals

NCD National coverage determination

NCHS National Center for Health Statistics

NCQA National Committee for Quality Assurance

NCVHS National Committee on Vital and Health Statistics

NECMA New England County Metropolitan Areas

NQF National Quality Forum

NTIS National Technical Information Service

NVHRI National Voluntary Hospital Reporting Initiative

OACT [CMS'] Office of the Actuary

OBRA 86 Omnibus Budget Reconciliation Act of 1996, Public Law 99-509

OES Occupational employment statistics

OIG Office of the Inspector General

OMB Executive Office of Management and Budget

OPM U.S. Office of Personnel Management

[[Page 24082]]

O.R. Operating room

OSCAR Online Survey Certification and Reporting [System]

PIP Periodic interim payment

PLI Professional liability insurance

PMSAs Primary metropolitan statistical areas

POA Present on admission

PPI Producer price index

PPS Prospective payment system

PRM Provider Reimbursement Manual

ProPAC Prospective Payment Assessment Commission

PRRB Provider Reimbursement Review Board

PSF Provider-Specific File

PS&R Provider Statistical and Reimbursement (System)

QIG Quality Improvement Group, CMS

QIO Quality Improvement Organization

RCE Reasonable compensation equivalent

RHC Rural health clinic

RHQDAPU Reporting hospital quality data for annual payment update

RNHCI Religious nonmedical health care institution

RPL Rehabilitation psychiatric long-term care (hospital)

RRC Rural referral center

RTI Research Triangle Institute, International

RUCAs Rural-urban commuting area codes

RY Rate year

SAF Standard Analytic File

SCH Sole community hospital

SFY State fiscal year

SIC Standard Industrial Classification

SNF Skilled nursing facility

SOCs Standard occupational classifications

SOM State Operations Manual

SSO Short-stay outlier

TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law

97-248

TEP Technical expert panel

TMA TMA [Transitional Medical Assistance], Abstinence Education, and

QI [Qualifying Individuals] Programs Extension Act of 2007, Public

Law 110-90

TJA Total joint arthroplasty

UHDDS Uniform hospital discharge data set

VAP Ventilator-associated pneumonia

Table of Contents

I. Background

A. Summary

1. Acute Care Hospital Inpatient Prospective Payment System

(IPPS)

2. Hospitals and Hospital Units Excluded from the IPPS

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

4. Critical Access Hospitals (CAHs)

5. Payments for Graduate Medical Education (GME)

B. Provisions of the Medicare Improvements for Patients and

Providers Act of 2008 (MIPPA)

C. Provisions of the American Recovery and Reinvestment Act of

2009 (ARRA)

D. Major Contents of This Proposed Rule

1. Proposed Changes to MS-DRG Classifications and Recalibrations

of Relative Weights

2. Proposed Changes to the Hospital Wage Index for Acute Care

Hospitals

3. Proposed Rebasing and Revision of the Hospital Market Basket

for Acute Care Hospitals

4. Other Decisions and Proposed Changes to the IPPS for

Operating Costs and GME Costs

5. FY 2010 Policy Governing the IPPS for Capital-Related Costs

6. Proposed Changes to the Payment Rates for Certain Excluded

Hospitals: Rate-of-Increase Percentages

7. Proposed Changes to the LTCH PPS

8. Determining Proposed Prospective Payment Operating and

Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

9. Determining Proposed Prospective Payments Rates for LTCHs

10. Impact Analysis

11. Recommendation of Update Factors for Operating Cost Rates of

Payment for Hospital Inpatient Services

12. Discussion of Medicare Payment Advisory Commission

Recommendations

E. Public Comments Received on Two LTCH PPS Interim Final Rules

with Comment Period Issued in 2008

II. Proposed Changes to Medicare Severity Diagnosis-Related Group

(MS-DRG) Classifications and Relative Weights

A. Background

B. MS-DRG Reclassifications

1. General

2. Yearly Review for Making MS-DRG Changes

C. Adoption of the MS-DRGs in FY 2008

D. Proposed FY 2010 MS-DRG Documentation and Coding Adjustment,

Including the Applicability to the Hospital-Specific Rates and the

Puerto Rico-Specific Standardized Amount

1. Background on the Prospective MS-DRG Documentation and Coding

Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110-90

2. Prospective Adjustment to the Average Standardized Amounts

Required by Section 7(b)(1)(A) of Public Law 110-90

3. Recoupment or Repayment Adjustments in FYs 2010 through 2012

Required by Public Law 110-90

4. Retrospective Evaluation of FY 2008 Claims Data

5. Proposed Adjustments for FY 2010 and Subsequent Years

Authorized by Section 7(b)(1)(A) of Public Law 110-90 and Section

1886(d)(3)(vi) of the Act

6. Additional Adjustment for FY 2010 Authorized by Section

7(b)(1)(B) of Public Law 110-90

7. Background on the Application of the Documentation and Coding

Adjustment to the Hospital-Specific Rates

8. Proposed Documentation and Coding Adjustment to the Hospital-

Specific Rates for FY 2010 and Subsequent Years

9. Background on the Application of the Documentation and Coding

Adjustment to the Puerto Rico-Specific Standardized Amount

10. Proposed Documentation and Coding Adjustment to the Puerto

Rico-Specific Standardized Amount

E. Refinement of the MS-DRG Relative Weight Calculation

1. Background

a. Summary of the RTI Study of Charge Compression and CCR

Refinement

b. Summary of the Rand Corporation Study of Alternative Relative

Weight Methodologies

2. Summary of FY 2009 Changes and Discussion for FY 2010

3. Timeline for Revising the Medicare Cost Report

F. Preventable Hospital-Acquired Conditions (HACs), Including

Infections

1. Statutory Authority

2. HAC Selection Process

3. Collaborative Process

4. Selected HAC Categories

5. Public Input Regarding Selected and Potential Candidate HACs

6. POA Indicator Reporting

G. Proposed Changes to Specific MS-DRG Classifications

1. MDC 5 (Diseases and Disorders of the Circulatory System):

Intraoperative Fluorescence Vascular Angiography (IFVA)

2. MDC 8 (Diseases and Disorders of the Musculoskeletal System

and Connective Tissue): Infected Hip and Knee Replacements

3. Proposed Medicare Code Editor (MCE) Changes

a. Diagnoses Allowed for Males Only Edit

b. Manifestation Codes as Principal Diagnosis Edit

c. Invalid Diagnosis or Procedure Code

d. Unacceptable Principal Diagnosis

e. Proposed Creation of New Edit Titled ``Wrong Surgeries''

f. Procedures Allowed for Females Only Edit

4. Surgical Hierarchies

5. Complication or Comorbidity (CC) Exclusions List

a. Background

b. CC Exclusions List for FY 2010

6. Review of Procedure Codes in MS-DRGs 981 through 983, 984

through 986, and 987 through 989

a. Moving Procedure Codes from MS-DRGs 981 through 983 or MS-

DRGs 987 through 989 to MDCs

b. Reassignment of Procedures among MS-DRGs 981 through 983, 984

through 986, and 987 through 989

c. Adding Diagnosis or Procedure Codes to MDCs

7. Changes to the ICD-9-CM Coding System

H. Recalibration of MS-DRG Weights

I. Proposed Add-On Payments for New Services and Technologies

1. Background

2. Public Input Before Publication of a Notice of Proposed

Rulemaking on Add-On Payments

3. FY 2010 Status of Technologies Approved for FY 2009 Add-On

Payments

4. FY 2010 Applications for New Technology Add-On Payments

a. The AutoLITTTM System

b. CLOLAR[supreg] (clofarabine) Injection

c. LipiScanTM Coronary Imaging System

d. Spiration[supreg] IBV[supreg] Valve System

e. TherOx Downstream[supreg] System

5. Technical Correction

III. Proposed Changes to the Hospital Wage Index for Acute Care

Hospitals

[[Page 24083]]

A. Background

B. Requirements of Section 106 of the MIEA-TRHCA

1. Wage Index Study Required Under the MIEA-TRHCA

a. Legislative Requirement

b. Interim and Final Reports on Results of Acumen's Study

2. FY 2009 Policy Changes in Response to Requirements Under

Section 106(b) of the MIEA-TRHCA

a. Reclassification Average Hourly Wage Comparison Criteria

b. Within-State Budget Neutrality Adjustment for the Rural and

Imputed Floors

C. Core-Based Statistical Areas for the Hospital Wage Index

D. Proposed Occupational Mix Adjustment to the Proposed FY 2010

Wage Index

1. Development of Data for the Proposed FY 2010 Occupational Mix

Adjustment Based on the 2007-2008 Occupational Mix Survey

2. Calculation of the Proposed Occupational Mix Adjustment for

FY 2010

E. Worksheet S-3 Wage Data for the Proposed FY 2010 Wage Index

1. Included Categories of Costs

2. Excluded Categories of Costs

3. Use of Wage Index Data by Providers Other Than Acute Care

Hospitals Under the IPPS

F. Verification of Worksheet S-3 Wage Data

G. Method for Computing the Proposed FY 2010 Unadjusted Wage

Index

H. Analysis and Implementation of the Proposed Occupational Mix

Adjustment and the Proposed FY 2010 Occupational Mix Adjusted Wage

Index

I. Revisions to the Wage Index Based on Hospital Redesignations

1. General

2. Effects of Reclassification/Redesignation

3. FY 2010 MGCRB Reclassifications

4. Redesignations of Hospitals Under Section 1886(d)(8)(B) of

the Act

5. Reclassifications Under Section 1886(d)(8)(B) of the Act

6. Reclassifications Under Section 508 of Public Law 108-173

J. Proposed FY 2010 Wage Index Adjustment Based on Commuting

Patterns of Hospital Employees

K. Process for Requests for Wage Index Data Corrections

IV. Proposed Rebasing and Revision of the Hospital Market Baskets

for Acute Care Hospitals

A. Background

B. Rebasing and Revising the IPPS Market Basket

1. Development of Cost Categories and Weights

a. Medicare Cost Reports

b. Other Data Sources

2. Final Cost Category Computation

3. Selection of Price Proxies

a. Wages and Salaries

b. Employment Benefits

c. Fuel, Oil, and Gasoline

d. Electricity

e. Water and Sewage

f. Professional Liability Insurance

g. Pharmaceuticals

h. Food: Direct Purchase

i. Food: Contract Services

j. Chemicals

k. Blood and Blood Products

l. Medical Instruments

m. Photographic Supplies

n. Rubber and Plastics

o. Paper and Printing Products

p. Apparel

q. Machinery and Equipment

r. Miscellaneous Products

s. Professional Fees: Labor-Related

t. Administrative and Business Support Services

u. All Other: Labor-Related Services

v. Professional Fees: Nonlabor-Related

w. Financial Services

x. Telephone Services

y. Postage

z. All Other: Nonlabor-Related Services

4. Labor-Related Share

C. Separate Market Basket for Certain Hospitals Presently

Excluded From the IPPS

D. Rebasing and Revising the Capital Input Price Index (CIPI)

V. Other Decisions and Proposed Changes to the IPPS for Operating

Costs and GME Costs

A. Reporting of Hospital Quality Data for Annual Hospital

Payment Update

1. Background

a. Overview

b. Hospital Quality Data Reporting Under Section 501(b) of

Public Law 108-173

c. Hospital Quality Data Reporting Under Section 5001(a) of

Public Law 109-171

2. Retirement of RHQDAPU Program Measures

3. Quality Measures for the FY 2011 Payment Determination and

Subsequent Years

a. Considerations in Expanding and Updating Quality Measures

Under the RHQDAPU Program

b. Proposed RHQDAPU Program Quality Measures for the FY 2011

Payment Determination

3. Possible New Quality Measures for the FY 2012 Payment

Determination and Subsequent Years

4. Possible New Quality Measures for the FY 2012 Payment

Determination and Subsequent Years

5. Form, Manner, and Timing of Quality Data Submission

a. Proposed RHQDAPU Program Procedures for the FY 2011 Payment

Determination

b. RHQDAPU Program Disaster Extensions and Waivers

c. HACHPS Requirements for the FY 2011 Payment Determination

6. Proposed Chart Validation Requirements

a. Proposed Chart Validation Requirements and Methods for the FY

2011 Payment Determination

b. Proposed Chart Validation Requirements and Methods for the FY

2012 Payment Determination and Subsequent Years

c. Possible Supplements to the Chart Validation Process for the

FY 2013 Payment Determination and Subsequent Years

7. Data Accuracy and Completeness Acknowledgement Requirements

for the FY 2011 Payment Determination and Subsequent Years

8. Public Display Requirements for the FY 2011 Payment

Determination and Subsequent Years

9. Proposed Reconsideration and Appeal Procedures for the FY

2010 Payment Determination

10. RHQDAPU Program Withdrawal Deadlines

11. Electronic Health Records

a. Background

b. EHR Testing of Quality Measures Submission

c. HITECH Act EHR Provisions

B. Sole Community Hospitals (SCHs) and Medicare-Dependent, Small

Rural Hospitals (MDHs): Budget Neutrality Adjustment Factors for FY

2002-Based Hospital-Specific Rate for MDHs

1. Background

2. FY 2002-Based Hospital-Specific Rate

C. Rural Referral Centers (RRCs)

1. Case-Mix Index

2. Discharges

D. Indirect Medical Education (IME) Adjustment

1. Background

2. IME Adjustment Factor for FY 2010

3. IME-Related Proposed Changes in Other Sections of this

Proposed Rule

E. Payment Adjustment for Medicare Disproportionate Share

Hospitals (DSHs)

1. Background

2. Proposed Policy Change Relating to the Inclusion of Labor and

Delivery Patient Days in the Medicare DSH Calculation

a. Background

b. Proposed Policy Change

3. Proposed Policy Change Relating to Calculation of Inpatient

Days in the Medicaid Fraction in the Medicare DSH Calculation

a. Background

b. Proposed Policy Change

4. Proposed Policy Change Relating to the Exclusion of

Observation Beds and Patient Days From the Medicare DSH Calculation

a. Background

b. Proposed Policy Change

F. Technical Correction to Regulations on Payments for

Anesthesia Services Furnished by Hospital or CAH Employed

Nonphysician Anesthetists or Obtained Under Arrangements

G. Payments for Direct Graduate Medical Education (GME) Costs

1. Background

2. Clarification of Definition of New Medical Residency Training

Program

3. Participation of New Teaching Hospitals in Medicare GME

Affiliated Groups

4. Technical Corrections to Regulations

H. Hospital Emergency Services Under EMTALA

1. Background

2. Proposed Changes Relating to Applicability of Sanctions Under

EMTALA

I. Rural Community Hospital Demonstration Program

J. Technical Correction to Regulations Relating to Calculation

of the Federal Rate Under the IPPS

VI. Proposed Changes to the IPPS for Capital-Related Costs

[[Page 24084]]

A. Overview

B. Exception Payments

C. New Hospitals

D. Hospitals Located in Puerto Rico

E. Proposed Changes

1. Proposed FY 2010 MS-DRG Documentation and Coding Adjustment

a. Background on the Prospective MS-DRG Documentation and Coding

Adjustments for FY 2008 and FY 2009

b. Proposed Prospective MS-DRG Documentation and Coding

Adjustment to the National Capital Federal Rate for FY 2010 and

Subsequent Years

c. Proposed Documentation and Coding Adjustment to the Puerto

Rico-Specific Capital Rate

2. Revision to the FY 2009 IME Adjustment Factor

3. Other Proposed Changes for FY 2010

VII. Proposed Changes for Hospitals Excluded From the IPPS

A. Excluded Hospitals

B. Criteria for Satellite Facilities of Hospitals

C. Critical Access Hospitals (CAHs)

1. Background

2. Payment for Clinical Diagnostic Laboratory Tests Furnished by

CAHs

3. CAH Optional Method of Payment for Outpatient Services

D. Provider-Based Status of Facilities and Organizations:

Proposed Policy Changes

1. Background

2. Proposed Changes to the Scope of the Provider-Based Status

Regulations for CAHs

a. CAH-Based Clinical Diagnostic Laboratory Facilities

b. CAH-Based Ambulance Services

3. Technical Correction to Regulations

VIII. Proposed Changes to the Long-Term Care Hospital Prospective

Payment System (LTCH PPS) for RY 2010

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

2. Criteria for Classification as a LTCH

a. Classification as a LTCH

b. Hospitals Excluded from the LTCH PPS

3. Limitation on Charges to Beneficiaries

4. Administrative Simplification Compliance Act (ASCA) and

Health Insurance Portability and Accountability Act (HIPAA)

Compliance

B. Proposed Medicare Severity Long-Term Care Diagnosis-Related

Group (MS-LTC-DRG) Classifications and Relative Weights

1. Background

2. Patient Classifications Into MS-LTC-DRGs

a. Background

b. Proposed Changes to the MS-LTC-DRGs for RY 2010

3. Development of the Proposed RY 2010 MS-LTC-DRG Relative

Weights

a. General Overview of the Development of the MS-LTC-DRG

Relative Weights

b. Data

c. Hospital-Specific Relative Value (HSRV) Methodology

d. Treatment of Severity Levels in Developing the Proposed MS-

LTC-DRG Relative Weights

e. Low-Volume MS-LTC-DRGs

f. Steps for Determining the Proposed RY 2010 MS-LTC-DRG

Relative Weights

C. Proposed Changes to the LTCH Payment Rates and Other Changes

to the RY 2010 LTCH PPS

1. Overview of Development of the LTCH Payment Rates

2. Market Basket for LTCHs Reimbursed under the LTCH PPS

a. Overview

b. Proposed Market Basket under the LTCH PPS for RY 2010

c. Proposed Market Basket Update for LTCHs for RY 2010

d. Proposed Labor-Related Share under the LTCH PPS for RY 2010

3. Proposed Adjustment for Changes in LTCHs' Case-Mix Due to

Changes in Documentation and Coding Practices That Occurred in a

Prior Period

a. Background

b. Evaluation of FY 2007 Claims Data

c. Evaluation of FY 2008 Claims Data

d. Proposed RY 2010 Documentation and Coding Adjustment

D. Monitoring

E. Research Conducted by the Research Triangle Institute,

International (RTI)

F. Proposed Technical Corrections of LTCH PPS Regulations

IX. MedPAC Recommendations

X. Other Required Information

A. Requests for Data from the Public

B. Collection of Information Requirements

C. Additional Information Collection Requirements

1. Present on Admission (POA) Indicator Reporting

2. Proposed Add-On Payments for New Services and Technologies

3. Reporting of Hospital Quality Data for Annual Hospital

Payment Update

4. Occupational Mix Adjustment to the FY 2010 Index (Hospital

Wage Index Occupational Mix Survey)

5. Hospital Applications for Geographic Reclassifications by the

MGCRB

C. Response to Public Comments

Regulation Text

Addendum--Proposed Schedule of Standardized Amounts, Update

Factors, and Rate-of-Increase Percentages Effective With Cost

Reporting Periods Beginning on or after October 1, 2009

I. Summary and Background

II. Proposed Changes to the Prospective Payment Rates for Hospital

Inpatient Operating Costs for Acute Care Hospitals for FY 2010

A. Calculation of the Adjusted Standardized Amount

B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

C. Proposed MS-DRG Relative Weights

D. Calculation of the Proposed Prospective Payment Rates

III. Proposed Changes to Payment Rates for Acute Care Hospital

Inpatient Capital-Related Costs for FY 2010

A. Determination of Proposed Federal Hospital Inpatient Capital-

Related Prospective Payment Rate Update

B. Calculation of the Proposed Inpatient Capital-Related

Prospective Payments for FY 2010

C. Capital Input Price Index

IV. Proposed Changes to Payment Rates for Certain Excluded

Hospitals: Rate-of-Increase Percentages

V. Proposed Changes to the Payment Rates for the LTCH PPS for RY

2010

A. Proposed LTCH PPS Standard Federal Rate for RY 2010

B. Proposed Adjustment for Area Wage Levels under the LTCH PPS

for RY 2010

C. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO)

Cases

D. Computing the Proposed Adjusted LTCH PPS Federal Prospective

Payments for RY 2010

VI. Tables

Table 1A.--National Adjusted Operating Standardized Amounts,

Labor/Nonlabor (67.1 Percent Labor Share/32.9 Percent Nonlabor Share

If Wage Index Is Greater Than 1)

Table 1B.--National Adjusted Operating Standardized Amounts,

Labor/Nonlabor (62 Percent Labor Share/38 Percent Nonlabor Share If

Wage Index Is Less Than or Equal to 1)

Table 1C.--Adjusted Operating Standardized Amounts for Puerto

Rico, Labor/Nonlabor

Table 1D.--Capital Standard Federal Payment Rate

Table 1E.--LTCH Standard Federal Prospective Payment Rate

Table 2.--Acute Care Hospitals Case-Mix Indexes for Discharges

Occurring in Federal Fiscal Year 2008; Hospital Wage Indexes for

Federal Fiscal Year 2010; Hospital Average Hourly Wages for Federal

Fiscal Years 2008 (2004 Wage Data), 2009 (2005 Wage Data), and 2010

(2006 Wage Data); and 3-Year Average of Hospital Average Hourly

Wages

Table 3A.--FY 2010 and 3-Year Average Hourly Wage for Acute Care

Hospitals in Urban Areas by CBSA

Table 3B.--FY 2010 and 3-Year Average Hourly Wage for Acute Care

Hospitals in Rural Areas by CBSA

Table 4A.--Wage Index and Capital Geographic Adjustment Factor

(GAF) for Acute Care Hospitals in Urban Areas by CBSA and by State--

FY 2010

Table 4B.--Wage Index and Capital Geographic Adjustment Factor

(GAF) for Acute Care Hospitals in Rural Areas by CBSA and by State--

FY 2010

Table 4C.--Wage Index and Capital Geographic Adjustment Factor

(GAF) for Acute Care Hospitals That Are Reclassified by CBSA and by

State--FY 2010

Table 4D-1.--Rural Floor Budget Neutrality Factors for Acute

Care Hospitals--FY 2010

Table 4D-2.--Urban Areas with Acute Care Hospitals Receiving the

Statewide Rural Floor or Imputed Floor Wage Index--FY 2010

Table 4E.--Urban CBSAs and Constituent Counties for Acute Care

Hospitals--FY 2010

Table 4F.--Puerto Rico Wage Index and Capital Geographic

Adjustment Factor (GAF) for Acute Care Hospitals by CBSA--FY 2010

Table 4J.--Out-Migration Adjustment for Acute Care Hospitals--FY

2010

[[Page 24085]]

Table 5.--List of Medicare Severity Diagnosis-Related Groups

(MS-DRGs), Relative Weighting Factors, and Geometric and Arithmetic

Mean Length of Stay--FY 2010

Table 6A.--New Diagnosis Codes

Table 6B.--New Procedure Codes

Table 6C.--Invalid Diagnosis Codes

Table 6D.--Invalid Procedure Codes

Table 6E.--Revised Diagnosis Code Titles

Table 6F.--Revised Procedure Code Titles

Table 6G.--Additions to the CC Exclusions List (Available

through the Internet on the CMS Web site at: http://www.cms.hhs.gov/

AcuteInpatientPPS/)

Table 6H.--Deletions from the CC Exclusions List (Available

through the Internet on the CMS Web site at: http://www.cms.hhs.gov/

AcuteInpatientPPS/)

Table 6I.--Complete List of Complication and Comorbidity (CC)

Exclusions (Available only through the Internet on the CMS Web site

at: http://www.cms.hhs.gov/AcuteInpatientPPS/)

Table 6J.--Major Complication and Comorbidity (MCC) List

(Available through the Internet on the CMS Web site at: http://

www.cms.hhs.gov/AcuteInpatientPPS/)

Table 6K.--Complication and Comorbidity (CC) List (Available

through the Internet on the CMS Web site at: http://www.cms.hhs.gov/

AcuteInpatientPPS/)

Table 7A.--Medicare Prospective Payment System Selected

Percentile Lengths of Stay: FY 2008 MedPAR Update--December 2008

GROUPER V26.0 MS-DRGs

Table 7B.--Medicare Prospective Payment System Selected

Percentile Lengths of Stay: FY 2008 MedPAR Update--December 2008

GROUPER V27.0 MS-DRGs

Table 8A.--Proposed Statewide Average Operating Cost-to-Charge

Ratios (CCRs) for Acute Care Hospitals--March 2009

Table 8B.--Proposed Statewide Average Capital Cost-to-Charge

Ratios (CCRs) for Acute Care Hospitals--March 2009

Table 8C.--Proposed Statewide Average Total Cost-to-Charge

Ratios (CCRs) for LTCHs--March 2009

Table 9A.--Hospital Reclassifications and Redesignations--FY

2010

Table 9C.--Hospitals Redesignated as Rural under Section

1886(d)(8)(E) of the Act--FY 2010

Table 10.--Geometric Mean Plus the Lesser of .75 of the National

Adjusted Operating Standardized Payment Amount (Increased to Reflect

the Difference Between Costs and Charges) or .75 of One Standard

Deviation of Mean Charges by Medicare Severity Diagnosis-Related

Groups (MS-DRGs)--March 2009

Table 11.--Proposed MS-LTC-DRGs, Relative Weights, Geometric

Average Length of Stay, and Short-Stay Outlier Threshold for

Discharges Occurring from October 1, 2009 through September 30, 2010

under the LTCH PPS

Table 12A.--LTCH PPS Wage Index for Urban Areas for Discharges

Occurring from October 1, 2009 through September 30, 2010

Table 12B.--LTCH PPS Wage Index for Rural Ares for Discharges

Occurring from October 1, 2009 through September 30, 2010

Appendix A--Regulatory Impact Analysis

I. Overall Impact

II. Objectives of the IPPS

III. Limitations of Our Analysis

IV. Hospitals Included in and Excluded From the IPPS

V. Effects on Hospitals Excluded from the IPPS

VI. Quantitative Effects of the Policy Changes under the IPPS for

Operating Costs

A. Basis and Methodology of Estimates

B. Analysis of Table I

C. Effects of the Proposed Changes to the MS-DRG

Reclassifications and Relative Cost-Based Weights (Column 1)

D. Effects of the Application of Recalibration Budget Neutrality

(Column 2)

E. Effects of Proposed Wage Index Changes (Column 3)

F. Application of the Wage Budget Neutrality Factor (Column 4)

G. Combined Effects of Proposed MS-DRG and Wage Index Changes

(Column 5)

H. Effects of MGCRB Reclassifications (Column 6)

I. Effects of the Proposed Rural Floor and Imputed Floor,

Including the Transition To Apply Budget Neutrality at the State

Level (Column 7)

J. Effects of the Proposed Wage Index Adjustment for Out-

Migration (Column 8)

K. Effects of All Proposed Changes Prior to Documentation and

Coding (or CMI) Adjustment (Column 9)

L. Effects of All Proposed Changes With Documentation and Coding

(or CMI) Adjustment (Column 10)

M. Effects of Policy on Payment Adjustments for Low-Volume

Hospitals

N. Impact Analysis of Table II

VII. Effects of Other Proposed Policy Changes

A. Effects of Proposed Policy on HACs, Including Infections

B. Effects of Proposed Policy Change Relating to New Medical

Service and Technology Add-On Payments

C. Effects of Proposed Requirements for Hospital Reporting of

Quality Data for Annual Hospital Payment Update

D. Effects of Correcting the FY 2002-Based Hospital-Specific

Rates for MDHs

E. Effects of Proposed Policy Changes Relating to DSH Payment

Adjustment

F. Effects of Proposed Policy Changes Related to Direct GME

G. Effects of Proposed Policy Changes Relating to Hospital

Emergency Services under EMTALA

H. Effects of Proposed Policy Changes Relating to Payments to

CAHs

I. Effects of Proposed Policy Changes Relating to Provider-Based

Status of Facilities and Organizations

J. Effects of Proposed Policy Changes Relating to Criteria for

Satellite Facilities of Hospitals

K. Effects of Implementation of Rural Community Hospital

Demonstration Program

VIII. Effects of Proposed Changes in the Capital IPPS

A. General Considerations

B. Results

IX. Effects of Proposed Payment Rate Changes and Policy Changes

Under the LTCH PPS

A. Introduction and General Considerations

B. Impact on Rural Hospitals

C. Anticipated Effects of Proposed LTCH PPS Payment Rate Change

and Policy Changes

D. Effect on the Medicare Program

E. Effect on Medicare Beneficiaries

X. Alternatives Considered

XI. Overall Conclusion

A. Acute Care Hospitals

B. LTCHs

XII. Accounting Statements

A. Acute Care Hospitals

B. LTCHs

XIII. Executive Order 12866

Appendix B--Recommendation of Update Factors for Operating Cost Rates

of Payment for Inpatient Hospital Services

I. Background

II. Inpatient Hospital Update for FY 2010

III. Secretary's Recommendation

IV. MedPAC Recommendation for Assessing Payment Adequacy and

Updating Payments in Traditional Medicare

I. Background

A. Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a

system of payment for the operating costs of acute care hospital

inpatient stays under Medicare Part A (Hospital Insurance) based on

prospectively set rates. Section 1886(g) of the Act requires the

Secretary to pay for the capital-related costs of hospital inpatient

stays under a prospective payment system (PPS). Under these PPSs,

Medicare payment for hospital inpatient operating and capital-related

costs is made at predetermined, specific rates for each hospital

discharge. Discharges are classified according to a list of diagnosis-

related groups (DRGs).

The base payment rate is comprised of a standardized amount that is

divided into a labor-related share and a nonlabor-related share. The

labor-related share is adjusted by the wage index applicable to the

area where the hospital is located. If the hospital is located in

Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-

living adjustment factor. This base payment rate is multiplied by the

DRG relative weight.

If the hospital treats a high percentage of low-income patients, it

receives a percentage add-on payment applied to the DRG-adjusted base

payment rate.

[[Page 24086]]

This add-on payment, known as the disproportionate share hospital (DSH)

adjustment, provides for a percentage increase in Medicare payments to

hospitals that qualify under either of two statutory formulas designed

to identify hospitals that serve a disproportionate share of low-income

patients. For qualifying hospitals, the amount of this adjustment may

vary based on the outcome of the statutory calculations.

If the hospital is an approved teaching hospital, it receives a

percentage add-on payment for each case paid under the IPPS, known as

the indirect medical education (IME) adjustment. This percentage

varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new

technologies or medical services that have been approved for special

add-on payments. To qualify, a new technology or medical service must

demonstrate that it is a substantial clinical improvement over

technologies or services otherwise available, and that, absent an add-

on payment, it would be inadequately paid under the regular DRG

payment.

The costs incurred by the hospital for a case are evaluated to

determine whether the hospital is eligible for an additional payment as

an outlier case. This additional payment is designed to protect the

hospital from large financial losses due to unusually expensive cases.

Any eligible outlier payment is added to the DRG-adjusted base payment

rate, plus any DSH, IME, and new technology or medical service add-on

adjustments.

Although payments to most hospitals under the IPPS are made on the

basis of the standardized amounts, some categories of hospitals are

paid in whole or in part based on their hospital-specific rate based on

their costs in a base year. For example, sole community hospitals

(SCHs) receive the higher of a hospital-specific rate based on their

costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY

2006) or the IPPS Federal rate based on the standardized amount.

Through and including FY 2006, a Medicare-dependent, small rural

hospital (MDH) received the higher of the Federal rate or the Federal

rate plus 50 percent of the amount by which the Federal rate is

exceeded by the higher of its FY 1982 or FY 1987 hospital-specific

rate. As discussed below, for discharges occurring on or after October

1, 2007, but before October 1, 2011, an MDH will receive the higher of

the Federal rate or the Federal rate plus 75 percent of the amount by

which the Federal rate is exceeded by the highest of its FY 1982, FY

1987, or FY 2002 hospital-specific rate. SCHs are the sole source of

care in their areas, and MDHs are a major source of care for Medicare

beneficiaries in their areas. Specifically, section 1886(d)(5)(D)(iii)

of the Act defines an SCH as a hospital that is located more than 35

road miles from another hospital or that, by reason of factors such as

isolated location, weather conditions, travel conditions, or absence of

other like hospitals (as determined by the Secretary), is the sole

source of hospital inpatient services reasonably available to Medicare

beneficiaries. In addition, certain rural hospitals previously

designated by the Secretary as essential access community hospitals are

considered SCHs. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as

a hospital that is located in a rural area, has no more than 100 beds,

is not an SCH, and has a high percentage of Medicare discharges (not

less than 60 percent of its inpatient days or discharges in its cost

reporting year beginning in FY 1987 or in two of its three most

recently settled Medicare cost reporting years). Both of these

categories of hospitals are afforded this special payment protection in

order to maintain access to services for beneficiaries.

Section 1886(g) of the Act requires the Secretary to pay for the

capital-related costs of inpatient hospital services ``in accordance

with a prospective payment system established by the Secretary.'' The

basic methodology for determining capital prospective payments is set

forth in our regulations at 42 CFR 412.308 and 412.312. Under the

capital IPPS, payments are adjusted by the same DRG for the case as

they are under the operating IPPS. Capital IPPS payments are also

adjusted for IME and DSH, similar to the adjustments made under the

operating IPPS. We began phasing out the capital IPPS IME adjustment in

FY 2008, as discussed in section VI.B.2. of this preamble. However,

section 4301(b)(1) of the American Recovery and Reinvestment Act of

2009 (Pub. L. 111-5), enacted on February 17, 2009, requires that the

50-percent reduction in the capital IPPS teaching adjustment for FY

2009 specified in the regulations at Sec. 412.322(c) shall not be

applied. Section 4301(b)(2) of Public Law 111-5 specifies that, for

subsequent years, the change made by section 4301(b)(1) has no effect

on the capital teaching adjustment. Therefore, beginning in FY 2010,

there will no longer be a capital teaching adjustment under the capital

IPPS. The provisions of section 4301(b) of Public Law 111-5 are

discussed in sections VI.A. and E. of this preamble. In addition,

hospitals may receive outlier payments for those cases that have

unusually high costs.

The existing regulations governing payments to hospitals under the

IPPS are located in 42 CFR Part 412, Subparts A through M.

2. Hospitals and Hospital Units Excluded from the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain

hospitals and hospital units are excluded from the IPPS. These

hospitals and units are: Rehabilitation hospitals and units; long-term

care hospitals (LTCHs); psychiatric hospitals and units; children's

hospitals; and cancer hospitals. Religious nonmedical health care

institutions (RNHCIs) are also excluded from the IPPS. Various sections

of the Balanced Budget Act of 1997 (BBA, Pub. L. 105-33), the Medicare,

Medicaid and SCHIP [State Children's Health Insurance Program] Balanced

Budget Refinement Act of 1999 (BBRA, Pub. L. 106-113), and the

Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act

of 2000 (BIPA, Pub. L. 106-554) provide for the implementation of PPSs

for rehabilitation hospitals and units (referred to as inpatient

rehabilitation facilities (IRFs)), LTCHs, and psychiatric hospitals and

units (referred to as inpatient psychiatric facilities (IPFs)). (We

note that the proposed annual updates to the LTCH PPS are now included

as part of the IPPS annual update document (for RY 2010, in this

proposed rule). Updates to the IRF PPS and IPF PPS are issued as

separate documents.) Children's hospitals, cancer hospitals, and RNHCIs

continue to be paid solely under a reasonable cost-based system subject

to a rate-of-increase ceiling on inpatient operating costs per

discharge.

The existing regulations governing payments to excluded hospitals

and hospital units are located in 42 CFR Parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to

hospitals described in section 1886(d)(1)(B)(iv) effective for cost

reporting periods beginning on or after October 1, 2002. The LTCH PPS

was established under the authority of sections 123(a) and (c) of

Public Law 106-113 and section 307(b)(1) of Public Law 106-554. During

the 5-year (optional) transition period, a LTCH's payment under the PPS

was based on an increasing proportion of the LTCH Federal rate with a

corresponding decreasing proportion based on reasonable cost

principles. Effective for

[[Page 24087]]

cost reporting periods beginning on or after October 1, 2006, all LTCHs

are paid 100 percent of the Federal rate. The existing regulations

governing payment under the LTCH PPS are located in 42 CFR Part 412,

Subpart O. Beginning with RY 2010, we are issuing the annual updates to

the LTCH PPS in the same documents that update the IPPS (73 FR 26797

through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments are

made to critical access hospitals (CAHs) (that is, rural hospitals or

facilities that meet certain statutory requirements) for inpatient and

outpatient services are generally based on 101 percent of reasonable

cost. Reasonable cost is determined under the provisions of section

1861(v)(1)(A) of the Act and existing regulations under 42 CFR Parts

413 and 415.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational

activities are excluded from the operating costs of inpatient hospital

services. Hospitals with approved graduate medical education (GME)

programs are paid for the direct costs of GME in accordance with

section 1886(h) of the Act. The amount of payment for direct GME costs

for a cost reporting period is based on the hospital's number of

residents in that period and the hospital's costs per resident in a

base year. The existing regulations governing payments to the various

types of hospitals are located in 42 CFR Part 413.

B. Provisions of the Medicare Improvements for Patients and Providers

Act of 2008 (MIPPA)

Section 148 of the MIPPA (Pub. L. 110-275) changes the payment

rules regarding outpatient clinical diagnostic laboratory tests

furnished by a CAH. The statutory change applies to services furnished

on or after July 1, 2009. In section VI.C.2. of the preamble of this

proposed rule, we discuss our proposal to codify policies in the

Medicare regulations to implement this provision.

C. Provisions of the American Recovery and Reinvestment Act of 2009

(ARRA)

Section 4301(b) of the American Recovery and Reinvestment Act of

2009 (AARA), Public Law 111-5, enacted on February 17, 2009, requires

that the phase-out of the capital IPPS teaching adjustment at Sec.

412.322(c) (that is, the 50-percent reduction for FY 2009) shall be

applied, as if such paragraph had not been in effect. Section 4301(b)

of Public Law 111-5 also specifies that there will be no effect on the

phase-out of the capital teaching adjustment for subsequent years, such

that, for discharges occurring during FY 2010 and thereafter, there

will no longer be a teaching adjustment under the capital IPPS as is

currently specified at Sec. 412.322(d). We discuss the proposed

implementation of these provisions in section VI.A. and E. of the

preamble of this proposed rule.

Section 4302 of Public Law 111-5 included several amendments to

provisions of section 114 of the MMSEA relating to (1) the 3-year delay

in the application of certain provisions of the payment adjustments for

short-stay outliers and revision to the RY 2008 standard Federal rate

for LTCHs; and (2) the 3-year moratorium on the establishment of new

LTCHs and LTCH satellite facilities and on increases in beds in

existing LTCHs and LTCH satellite facilities. We discuss the proposed

implementation of these provisions in sections I.E. and VIII. of the

preamble of this proposed rule.

D. Major Contents of this Proposed Rule

In this proposed rule, we are setting forth proposed changes to the

Medicare IPPS for operating costs and for capital-related costs of

acute care hospitals in FY 2010. We also are setting forth proposed

changes relating to payments for IME costs and payments to certain

hospitals and units that continue to be excluded from the IPPS and paid

on a reasonable cost basis. In addition, we are setting forth proposed

changes to the payment rates, factors, and other payment rate policies

under the LTCH PPS for RY 2010.

The following is a summary of the major changes that we are

proposing to make:

1. Proposed Changes to MS-DRG Classifications and Recalibrations of

Relative Weights

In section II. of the preamble of this proposed rule, we are

including--

Proposed changes to MS-DRG classifications based on our

yearly review.

Proposed application of the documentation and coding

adjustment to hospital-specific rates for FY 2010 resulting from

implementation of the MS-DRG system.

A discussion of the Research Triangle International, Inc.

(RTI) and RAND Corporation reports and recommendations relating to

charge compression, including a solicitation of public comments on the

``over'' standardization of hospital charges.

Proposed recalibrations of the MS-DRG relative weights.

We are also presenting a listing and discussion of hospital-

acquired conditions (HACs), including infections, that are subject to

the statutorily required quality adjustment in MS-DRG payments for FY

2010.

We are presenting our evaluation and analysis of the FY 2010

applicants for add-on payments for high-cost new medical services and

technologies (including public input, as directed by Pub. L. 108-173,

obtained in a town hall meeting).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to this proposed rule, we are

proposing revisions to the wage index for acute care hospitals and the

annual update of the wage data. Specific issues addressed include the

following:

Second year of the 3-year transition from national to

within-State budget neutrality for the rural floor and imputed floor.

Final year of the 2-year transition for changes in the

average hourly wage criterion for geographic reclassifications.

Changes to the CBSA designations.

The proposed FY 2010 wage index update using wage data

from cost reporting periods that began during FY 2007.

Analysis and implementation of the proposed FY 2010

occupational mix adjustment to the wage index for acute care hospitals,

including the use of data from the 2007-2008 occupational mix survey.

Proposed revisions to the wage index for acute care

hospitals based on hospital redesignations and reclassifications.

The proposed adjustment to the wage index for acute care

hospitals for FY 2010 based on commuting patterns of hospital employees

who reside in a county and work in a different area with a higher wage

index.

The timetable for reviewing and verifying the wage data

used to compute the proposed FY 2010 wage index for acute care

hospitals.

3. Proposed Rebasing and Revision of the Hospital Market Basket for

Acute Care Hospitals

In section IV. of the preamble of this proposed rule, we are

proposing to rebase and revise the acute care hospital operating and

capital market baskets to be used in developing the FY 2010 update

factor for the operating and capital prospective payment rates and the

FY 2010 update factor for the

[[Page 24088]]

excluded hospital rate-of-increase limits. We also are setting forth

the data sources used to determine the proposed revised market basket

relative weights.

4. Other Decisions and Proposed Changes to the IPPS for Operating Costs

and GME Costs

In section V. of the preamble of this proposed rule, we discuss a

number of the provisions of the regulations in 42 CFR Parts 412, 413,

and 489, including the following:

The reporting of hospital quality data as a condition for

receiving the full annual payment update increase.

Discussion of applying the correct budget neutrality

adjustment for the FY 2002-based hospital-specific rates for MDHs.

The proposed updated national and regional case-mix values

and discharges for purposes of determining RRC status.

The statutorily-required IME adjustment factor for FY

2010.

Proposed changes to the policies governing payments to

Medicare disproportionate share hospitals, including proposed policies

relating to the inclusion of labor and delivery patient days in the

calculation of the DSH payment adjustment, calculation of inpatient

days in the Medicaid fraction for the Medicare DSH calculation, and

exclusion of observation beds and patient days from the Medicare DSH

calculation and from the bed count for the IME adjustment.

Proposed changes to the policies governing payment for

direct GME.

Proposed changes to policies on hospital emergency

services under EMTALA relating to the applicability of sanctions under

EMTALA.

Discussion of the implementation of the Rural Community

Hospital Demonstration Program in FY 2010.

Proposed technical correction to the regulations governing

the calculation of the Federal rate under the IPPS.

5. FY 2010 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble to this proposed rule, we discuss

the payment policy requirements for capital-related costs and capital

payments to hospitals for FY 2010. We also are proposing to remove a

section of the regulations relating to the phase-out of the capital IME

adjustment for FY 2009 to implement the provisions of section 4301(b)

of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5).

6. Proposed Changes to the Payment Rates for Certain Excluded

Hospitals: Rate-of-Increase Percentages

In section VII. of the preamble of this proposed rule, we discuss--

Proposed changes to payments to excluded hospitals.

Proposed changes to the regulations governing satellite

facilities of hospitals.

Proposed changes relating to payments to CAHs, including

payment for clinical laboratory tests furnished by CAHs and payment for

outpatient facility services when a CAH elects the optional payment

method.

Proposed changes to the rules governing provider-based

status of facilities and a proposed technical correction to the

regulations governing provider-based entities.

7. Proposed Changes to the LTCH PPS

In section VIII.A. through C. and F. of the preamble of this

proposed rule, we set forth proposed changes to the payment rates,

factors, and other payment rate policies under the LTCH PPS for RY

2010, including the annual update of the MS-LTC-DRG classifications and

relative weights for use under the LTCH PPS for RY 2010, the proposed

use of the FY 2002-based RPL market basket for LTCHs, and proposed

technical corrections to the LTCH PPS regulations.

In section VIII.D. of the preamble of this proposed rule, we

discuss our ongoing monitoring protocols under the LTCH PPS. In section

VIII.E., we discuss the Research Triangle Institute, International

(RTI) Phase III Report on its evaluation of the feasibility of

establishing facility and patient criteria for LTCHs, as recommended by

MedPAC in its June 2004 Report to Congress.

8. Determining Proposed Prospective Payment Operating and Capital Rates

and Rate-of-Increase Limits for Acute Care Hospitals

In the Addendum to this proposed rule, we set forth proposed

changes to the amounts and factors for determining the proposed FY 2010

prospective payment rates for operating costs and capital-related costs

for acute care hospitals. We also establish the proposed threshold

amounts for outlier cases. In addition, we address the proposed update

factors for determining the rate-of-increase limits for cost reporting

periods beginning in FY 2010 for hospitals excluded from the IPPS.

9. Determining Proposed Prospective Payment Rates for LTCHs

In the Addendum to this proposed rule, we set forth proposed

changes to the amounts and factors for determining the proposed RY 2010

prospective standard Federal rate. We also establish the proposed

adjustments for wage levels, the labor-related share, the cost-of-

living adjustment, and high-cost outliers, including the fixed-loss

amount, and the LTCH cost-to-charge ratios (CCRs) under the LTCH PPS.

10. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of

the impact that the proposed changes would have on affected acute care

hospitals and LTCHs.

11. Recommendation of Update Factors for Operating Cost Rates of

Payment for Hospital Inpatient Services

In Appendix B of this proposed rule, as required by sections

1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the

appropriate percentage changes for FY 2010 for the following:

A single average standardized amount for all areas for

hospital inpatient services paid under the IPPS for operating costs of

acute care hospitals (and hospital-specific rates applicable to SCHs

and MDHs).

Target rate-of-increase limits to the allowable operating

costs of hospital inpatient services furnished by certain hospitals

excluded from the IPPS.

The standard Federal rate for hospital inpatient services

furnished by LTCHs.

12. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a

report to Congress, no later than March 1 of each year, in which MedPAC

reviews and makes recommendations on Medicare payment policies.

MedPAC's March 2008 recommendations concerning hospital inpatient

payment policies address the update factor for hospital inpatient

operating costs and capital-related costs under the IPPS, for hospitals

and distinct part hospital units excluded from the IPPS, and for LTCHs.

We address these recommendations in Appendix B of this proposed rule.

For further information relating specifically to the MedPAC March 2008

report or to obtain a copy of the report, contact MedPAC at (202) 220-

3700 or visit MedPAC's Web site at: http://www.medpac.gov.

[[Page 24089]]

E. Public Comments Received on Two LTCH PPS Interim Final Rules With

Comment Period Issued in 2008

On May 6, 2008 and May 22, 2008, we issued in the Federal Register

two interim final rules with comment periods relating to the LTCH PPS

(73 FR 24871 and 73 FR 29699, respectively), which implement section

114 of Public Law 110-173 (MMSEA). The May 6, 2008 interim final rule

with comment period implemented provisions of section 114 of Public Law

110-173 relating to a 3-year delay in the application of certain

provisions of the payment adjustment for short-stay outliers and

revisions to the RY 2008 standard Federal rate for LTCHs. The May 22,

2008 interim final rule with comment period implemented certain

provisions of section 114 of Public Law 110-173 relating to a 3-year

moratorium on the establishment of new LTCHs and LTCH satellite

facilities and on increases in beds in existing LTCHs and LTCH

satellite facilities. The May 22, 2008 interim final rule with comment

period also implemented a 3-year delay in the application of certain

payment policies that apply to payment adjustments for discharges from

LTCHs and LTCH satellite facilities that were admitted from certain

referring hospitals in excess of various percentage thresholds.

Section 4302 of the American Recovery and Reinvestment Act of 2009

(ARRA, Pub. L. 111-5) included several amendments to section 114 of

Public Law 110-173. We have issued instructions to the fiscal

intermediaries and Medicare administrative contractors (MACs) to

interpret these amendments (Change Request 6444). We intend to

implement the provisions of section 4302 of Public Law 111-5 by issuing

an interim final rule with comment period along with the FY 2010 IPPS

and RY 2010 LTCH PPS final rule that is scheduled for publication in

August 2009. In the FY 2010 IPPS and RY 2010 LTCH PPS final rule, we

also intend to respond to the public comments that we received on the

two interim final rules with comment period noted above and finalize

those provisions, as appropriate.

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS-

DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall

establish a classification system (referred to as DRGs) for inpatient

discharges and adjust payments under the IPPS based on appropriate

weighting factors assigned to each DRG. Therefore, under the IPPS, we

pay for inpatient hospital services on a rate per discharge basis that

varies according to the DRG to which a beneficiary's stay is assigned.

The formula used to calculate payment for a specific case multiplies an

individual hospital's payment rate per case by the weight of the DRG to

which the case is assigned. Each DRG weight represents the average

resources required to care for cases in that particular DRG, relative

to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the

DRG relative weights periodically to account for changes in resource

consumption. Accordingly, section 1886(d)(4)(C) of the Act requires

that the Secretary adjust the DRG classifications and relative weights

at least annually. These adjustments are made to reflect changes in

treatment patterns, technology, and any other factors that may change

the relative use of hospital resources.

B. MS-DRG Reclassifications

1. General

As discussed in the preamble to the FY 2008 IPPS final rule with

comment period (72 FR 47138), we focused our efforts in FY 2008 on

making significant reforms to the IPPS consistent with the

recommendations made by MedPAC in its ``Report to the Congress,

Physician-Owned Specialty Hospitals'' in March 2005. MedPAC recommended

that the Secretary refine the entire DRG system by taking severity of

illness into account and applying hospital-specific relative value

(HSRV) weights to DRGs.\1\ We began this reform process by adopting

cost-based weights over a 3-year transition period beginning in FY 2007

and making interim changes to the DRG system for FY 2007 by creating 20

new CMS DRGs and modifying 32 other DRGs across 13 different clinical

areas involving nearly 1.7 million cases. As described in more detail

below, these refinements were intermediate steps towards comprehensive

reform of both the relative weights and the DRG system as we undertook

further study. For FY 2008, we adopted 745 new Medicare Severity DRGs

(MS-DRGs) to replace the CMS DRGs. We refer readers to section II.D. of

the FY 2008 IPPS final rule with comment period for a full detailed

discussion of how the MS-DRG system, based on severity levels of

illness, was established (72 FR 47141).

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\1\ Medicare Payment Advisory Commission: Report to the

Congress, Physician-Owned Specialty Hospitals, March 2005, page

viii.

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Currently, cases are classified into MS-DRGs for payment under the

IPPS based on the following information reported by the hospital: The

principal diagnosis, up to eight additional diagnoses, and up to six

procedures performed during the stay. In a small number of MS-DRGs,

classification is also based on the age, sex, and discharge status of

the patient. The diagnosis and procedure information is reported by the

hospital using codes from the International Classification of Diseases,

Ninth Revision, Clinical Modification (ICD-9-CM).

The process of developing the MS-DRGs was begun by dividing all

possible principal diagnoses into mutually exclusive principal

diagnosis areas, referred to as Major Diagnostic Categories (MDCs). The

MDCs were formulated by physician panels to ensure that the DRGs would

be clinically coherent. The diagnoses in each MDC correspond to a

single organ system or etiology and, in general, are associated with a

particular medical specialty. Thus, in order to maintain the

requirement of clinical coherence, no final MS-DRG could contain

patients in different MDCs. For example, MDC 6 is Diseases and

Disorders of the Digestive System. This approach is used because

clinical care is generally organized in accordance with the organ

system affected. However, some MDCs are not constructed on this basis

because they involve multiple organ systems (for example, MDC 22

(Burns)). For FY 2009, cases are assigned to one of 746 MS-DRGs in 25

MDCs. The table below lists the 25 MDCs.

Major Diagnostic Categories (MDCs)

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1............................... Diseases and Disorders of the Nervous

System.

2............................... Diseases and Disorders of the Eye.

3............................... Diseases and Disorders of the Ear,

Nose, Mouth, and Throat.

4............................... Diseases and Disorders of the

Respiratory System.

5............................... Diseases and Disorders of the

Circulatory System.

6............................... Diseases and Disorders of the

Digestive System.

7............................... Diseases and Disorders of the

Hepatobiliary System and Pancreas.

8............................... Diseases and Disorders of the

Musculoskeletal System and Connective

Tissue.

9............................... Diseases and Disorders of the Skin,

Subcutaneous Tissue and Breast.

10.............................. Endocrine, Nutritional and Metabolic

Diseases and Disorders.

11.............................. Diseases and Disorders of the Kidney

and Urinary Tract.

12.............................. Diseases and Disorders of the Male

Reproductive System.

[[Page 24090]]

13.............................. Diseases and Disorders of the Female

Reproductive System.

14.............................. Pregnancy, Childbirth, and the

Puerperium.

15.............................. Newborns and Other Neonates with

Conditions Originating in the

Perinatal Period.

16.............................. Diseases and Disorders of the Blood

and Blood Forming Organs and

Immunological Disorders.

17.............................. Myeloproliferative Diseases and

Disorders and Poorly Differentiated

Neoplasms.

18.............................. Infectious and Parasitic Diseases

(Systemic or Unspecified Sites).

19.............................. Mental Diseases and Disorders.

20.............................. Alcohol/Drug Use and Alcohol/Drug

Induced Organic Mental Disorders.

21.............................. Injuries, Poisonings, and Toxic

Effects of Drugs.

22.............................. Burns.

23.............................. Factors Influencing Health Status and

Other Contacts with Health Services.

24.............................. Multiple Significant Trauma.

25.............................. Human Immunodeficiency Virus

Infections.

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In general, cases are assigned to an MDC based on the patient's

principal diagnosis before assignment to an MS-DRG. However, under the

most recent version of the Medicare GROUPER (Version 26.0), there are

13 MS-DRGs to which cases are directly assigned on the basis of ICD-9-

CM procedure codes. These MS-DRGs are for heart transplant or implant

of heart assist systems; liver and/or intestinal transplants; bone

marrow transplants; lung transplants; simultaneous pancreas/kidney

transplants; pancreas transplants; and tracheostomies. Cases are

assigned to these MS-DRGs before they are classified to an MDC. The

table below lists the 13 current pre-MDCs.

Pre-Major Diagnostic Categories (Pre-MDCs)

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MS-DRG 001........................ Heart Transplant or Implant of Heart

Assist System with MCC.

MS-DRG 002........................ Heart Transplant or Implant of Heart

Assist System without MCC.

MS-DRG 003........................ ECMO or Tracheostomy with Mechanical

Ventilation 96+ Hours or Principal

Diagnosis Except for Face, Mouth,

and Neck Diagnosis with Major O.R.

MS-DRG 004........................ Tracheostomy with Mechanical

Ventilation 96+ Hours or Principal

Diagnosis Except for Face, Mouth,

and Neck Diagnosis with Major O.R.

MS-DRG 005........................ Liver Transplant with MCC or

Intestinal Transplant.

MS-DRG 006........................ Liver Transplant without MCC.

MS-DRG 007........................ Lung Transplant.

MS-DRG 008........................ Simultaneous Pancreas/Kidney

Transplant.

MS-DRG 009........................ Bone Marrow Transplant.

MS-DRG 010........................ Pancreas Transplant.

MS-DRG 011........................ Tracheostomy for Face, Mouth, and

Neck Diagnoses with MCC.

MS-DRG 012........................ Tracheostomy for Face, Mouth, and

Neck Diagnoses with CC.

MS-DRG 013........................ Tracheostomy for Face, Mouth, and

Neck Diagnoses without CC/MCC.

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Once the MDCs were defined, each MDC was evaluated to identify

those additional patient characteristics that would have a consistent

effect on hospital resource consumption. Because the presence of a

surgical procedure that required the use of the operating room would

have a significant effect on the type of hospital resources used by a

patient, most MDCs were initially divided into surgical DRGs and

medical DRGs. Surgical DRGs are based on a hierarchy that orders

operating room (O.R.) procedures or groups of O.R. procedures by

resource intensity. Medical DRGs generally are differentiated on the

basis of diagnosis and age (0 to 17 years of age or greater than 17

years of age). Some surgical and medical DRGs are further

differentiated based on the presence or absence of a complication or

comorbidity (CC) or a major complication or comorbidity (MCC).

Generally, nonsurgical procedures and minor surgical procedures

that are not usually performed in an operating room are not treated as

O.R. procedures. However, there are a few non-O.R. procedures that do

affect MS-DRG assignment for certain principal diagnoses. An example is

extracorporeal shock wave lithotripsy for patients with a principal

diagnosis of urinary stones. Lithotripsy procedures are not routinely

performed in an operating room. Therefore, lithotripsy codes are not

classified as O.R. procedures. However, our clinical advisors believe

that patients with urinary stones who undergo extracorporeal shock wave

lithotripsy should be considered similar to other patients who undergo

O.R. procedures. Therefore, we treat this group of patients similar to

patients undergoing O.R. procedures.

Once the medical and surgical classes for an MDC were formed, each

diagnosis class was evaluated to determine if complications or

comorbidities would consistently affect hospital resource consumption.

Each diagnosis was categorized into one of three severity levels. These

three levels include a major complication or comorbidity (MCC), a

complication or comorbidity (CC), or a non-CC. Physician panels

classified each diagnosis code based on a highly iterative process

involving a combination of statistical results from test data as well

as clinical judgment. As stated earlier, we refer readers to section

II.D. of the FY 2008 IPPS final rule with comment period for a full

detailed discussion of how the MS-DRG system was established based on

severity levels of illness (72 FR 47141).

A patient's diagnosis, procedure, discharge status, and demographic

information is entered into the Medicare claims processing systems and

subjected to a series of automated screens called the Medicare Code

Editor (MCE). The MCE screens are designed to identify cases that

require further review before classification into an MS-DRG.

After patient information is screened through the MCE and any

further development of the claim is conducted, the cases are classified

into the appropriate MS-DRG by the Medicare GROUPER software program.

The GROUPER program was developed as a means of classifying each case

into an MS-DRG on the basis of the diagnosis and procedure codes and,

for a limited number of MS-DRGs, demographic information (that is, sex,

age, and discharge status).

After cases are screened through the MCE and assigned to an MS-DRG

by the GROUPER, the PRICER software calculates a base MS-DRG payment.

The PRICER calculates the payment for each case covered by the IPPS

based on the MS-DRG relative weight and additional factors associated

with each hospital, such as IME and DSH payment adjustments. These

additional factors increase the payment amount to hospitals above the

base MS-DRG payment.

The records for all Medicare hospital inpatient discharges are

maintained in the Medicare Provider Analysis and Review (MedPAR) file.

The data in this file are used to evaluate possible MS-DRG

classification changes and to recalibrate the MS-DRG weights. However,

in the FY 2000 IPPS final rule (64 FR 41500), we discussed a process

for considering non-MedPAR data in the recalibration process. In order

for us to consider using particular non-MedPAR data, we must have

sufficient time to evaluate and test the data. The time necessary to do

so depends upon the

[[Page 24091]]

nature and quality of the non-MedPAR data submitted. Generally,

however, a significant sample of the non-MedPAR data should be

submitted by mid-October for consideration in conjunction with the next

year's proposed rule. This date allows us time to test the data and

make a preliminary assessment as to the feasibility of using the data.

Subsequently, a complete database should be submitted by early December

for consideration in conjunction with the next year's proposed rule.

As we indicated above, for FY 2008, we made significant

improvements in the DRG system to recognize severity of illness and

resource usage by adopting MS-DRGs that were reflected in the FY 2008

GROUPER, Version 25.0, and were effective for discharges occurring on

or after October 1, 2007. Our MS-DRG analysis for the FY 2009 final

rule was based on data from the March 2008 update of the FY 2007 MedPAR

file, which contained hospital bills received through March 31, 2008,

for discharges occurring through September 30, 2007. For this proposed

rule, for FY 2010, our MS-DRG analysis is based on data from the

September 2008 update of the FY 2008 MedPAR file, which contains

hospital bills received through September 30, 2008, for discharges

occurring through September 30, 2008.

2. Yearly Review for Making MS-DRG Changes

Many of the changes to the MS-DRG classifications we make annually

are the result of specific issues brought to our attention by

interested parties. We encourage individuals with comments about MS-DRG

classifications to submit these comments no later than early December

of each year so they can be carefully considered for possible inclusion

in the annual proposed rule and, if included, may be subjected to

public review and comment. Therefore, similar to the timetable for

interested parties to submit non-MedPAR data for consideration in the

MS-DRG recalibration process, comments about MS-DRG classification

issues should be submitted no later than early December in order to be

considered and possibly included in the next annual proposed rule

updating the IPPS.

The actual process of forming the MS-DRGs was, and will likely

continue to be, highly iterative, involving a combination of

statistical results from test data combined with clinical judgment. In

the FY 2008 IPPS final rule (72 FR 47140 through 47189), we described

in detail the process we used to develop the MS-DRGs that we adopted

for FY 2008. In addition, in deciding whether to make further

modification to the MS-DRGs for particular circumstances brought to our

attention, we considered whether the resource consumption and clinical

characteristics of the patients with a given set of conditions are

significantly different than the remaining patients in the MS-DRG. We

evaluated patient care costs using average charges and lengths of stay

as proxies for costs and relied on the judgment of our medical advisors

to decide whether patients are clinically distinct or similar to other

patients in the MS-DRG. In evaluating resource costs, we considered

both the absolute and percentage differences in average charges between

the cases we selected for review and the remainder of cases in the MS-

DRG. We also considered variation in charges within these groups; that

is, whether observed average differences were consistent across

patients or attributable to cases that were extreme in terms of charges

or length of stay, or both. Further, we considered the number of

patients who will have a given set of characteristics and generally

preferred not to create a new MS-DRG unless it would include a

substantial number of cases.

C. Adoption of the MS-DRGs in FY 2008

In the FY 2006, FY 2007, and FY 2008 IPPS final rules, we discussed

a number of recommendations made by MedPAC regarding revisions to the

DRG system used under the IPPS (70 FR 47473 through 47482; 71 FR 47881

through 47939; and 72 FR 47140 through 47189). As we noted in the FY

2006 IPPS final rule, we had insufficient time to complete a thorough

evaluation of these recommendations for full implementation in FY 2006.

However, we did adopt severity-weighted cardiac DRGs in FY 2006 to

address public comments on this issue and the specific concerns of

MedPAC regarding cardiac surgery DRGs. We also indicated that we

planned to further consider all of MedPAC's recommendations and

thoroughly analyze options and their impacts on the various types of

hospitals in the FY 2007 IPPS proposed rule.

For FY 2007, we began this process. In the FY 2007 IPPS proposed

rule, we proposed to adopt Consolidated Severity DRGs (CS DRGs) for FY

2008 (if not earlier). Based on public comments received on the FY 2007

IPPS proposed rule, we decided not to adopt the CS DRGs. In the FY 2007

IPPS final rule (71 FR 47906 through 47912), we discussed several

concerns raised by commenters regarding the proposal to adopt CS DRGs.

We acknowledged the many comments suggesting the logic of Medicare's

DRG system should continue to remain in the public domain as it has

since the inception of the PPS. We also acknowledged concerns about the

impact on hospitals and software vendors of moving to a proprietary

system. Several commenters suggested that CMS refine the existing DRG

classification system to preserve the many policy decisions that were

made over the last 20 years and were already incorporated into the DRG

system, such as complexity of services and new device technologies.

Consistent with the concerns expressed in the public comments, this

option had the advantage of using the existing DRGs as a starting point

(which was already familiar to the public) and retained the benefit of

many DRG decisions that were made in recent years. We stated our belief

that the suggested approach of incorporating severity measures into the

existing DRG system was a viable option that would be evaluated.

Therefore, we decided to make interim changes to the existing DRGs

for FY 2007 by creating 20 new DRGs involving 13 different clinical

areas that would significantly improve the CMS DRG system's recognition

of severity of illness. We also modified 32 DRGs to better capture

differences in severity. The new and revised DRGs were selected from 40

existing CMS DRGs that contained 1,666,476 cases and represented a

number of body systems. In creating these 20 new DRGs, we deleted 8

existing DRGs and modified 32 existing DRGs. We indicated that these

interim steps for FY 2007 were being taken as a prelude to more

comprehensive changes to better account for severity in the DRG system

by FY 2008.

In the FY 2007 IPPS final rule (71 FR 47898), we indicated our

intent to pursue further DRG reform through two initiatives. First, we

announced that we were in the process of engaging a contractor to

assist us with evaluating alternative DRG systems that were raised as

potential alternatives to the CMS DRGs in the public comments. Second,

we indicated our intent to review over 13,000 ICD-9-CM diagnosis codes

as part of making further refinements to the current CMS DRGs to better

recognize severity of illness based on the work that CMS (then HCFA)

did in the mid-1990's in connection with adopting severity DRGs. We

describe below the progress we have made on these two initiatives, our

actions for FY 2008 and FY 2009, and our proposals for FY 2010 based on

our continued analysis of reform of the DRG system. We note that the

adoption of the MS-DRGs to better recognize severity of

[[Page 24092]]

illness has implications for the outlier threshold, the application of

the postacute care transfer policy, the measurement of real case-mix

versus apparent case-mix, and the IME and DSH payment adjustments. We

discuss these implications for FY 2010 in other sections of this

preamble and in the Addendum to this proposed rule.

In the FY 2007 IPPS proposed rule, we discussed MedPAC's

recommendations to move to a cost-based HSRV weighting methodology

using HSRVs beginning with the FY 2007 IPPS proposed rule for

determining the DRG relative weights. Although we proposed to adopt the

HSRV weighting methodology for FY 2007, we decided not to adopt the

proposed methodology in the final rule after considering the public

comments we received on the proposal. Instead, in the FY 2007 IPPS

final rule, we adopted a cost-based weighting methodology without the

HSRV portion of the proposed methodology. The cost-based weights were

adopted over a 3-year transition period in 1/3 increments between FY

2007 and FY 2009. In addition, in the FY 2007 IPPS final rule, we

indicated our intent to further study the HSRV-based methodology as

well as other issues brought to our attention related to the cost-based

weighting methodology adopted in the FY 2007 final rule. There was

significant concern in the public comments that our cost-based

weighting methodology does not adequately account for charge

compression--the practice of applying a higher percentage charge markup

over costs to lower cost items and services and a lower percentage

charge markup over costs to higher cost items and services. Further,

public commenters expressed concern about potential inconsistencies

between how costs and charges are reported on the Medicare cost reports

and charges on the Medicare claims. In the FY 2007 IPPS final rule, we

used costs and charges from the cost report to determine departmental

level cost-to-charge ratios (CCRs) which we then applied to charges on

the Medicare claims to determine the cost-based weights. The commenters

were concerned about potential distortions to the cost-based weights

that would result from inconsistent reporting between the cost reports

and the Medicare claims. After publication of the FY 2007 IPPS final

rule, we entered into a contract with RTI International (RTI) to study

both charge compression and to what extent our methodology for

calculating DRG relative weights is affected by inconsistencies between

how hospitals report costs and charges on the cost reports and how

hospitals report charges on individual claims. Further, as part of its

study of alternative DRG systems, the RAND Corporation analyzed the

HSRV cost-weighting methodology. We refer readers to section II.E. of

the preamble of this proposed rule for discussion of the issue of

charge compression and the HSRV cost-weighting methodology for FY 2010.

We believe that revisions to the DRG system to better recognize

severity of illness and changes to the relative weights based on costs

rather than charges are improving the accuracy of the payment rates in

the IPPS. We agree with MedPAC that these refinements should be

pursued. Although we continue to caution that any prospective payment

system based on grouping cases will always present some opportunities

for providers to specialize in cases they believe have higher margins,

we believe that the changes we have adopted and the continuing reforms

we are proposing to make in this proposed rule for FY 2010 will improve

payment accuracy and reduce financial incentives to create specialty

hospitals.

We refer readers to section II.D. of the FY 2008 IPPS final rule

with comment period for a full discussion of how the MS-DRG system was

established based on severity levels of illness (72 FR 47141).

D. Proposed FY 2010 MS-DRG Documentation and Coding Adjustment,

Including the Applicability to the Hospital-Specific Rates and the

Puerto Rico-Specific Standardized Amount

1. Background on the Prospective MS-DRG Documentation and Coding

Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110-90

As we discussed earlier in this preamble, we adopted the MS-DRG

patient classification system for the IPPS, effective October 1, 2007,

to better recognize severity of illness in Medicare payment rates for

acute care hospitals. The adoption of the MS-DRG system resulted in the

expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008

(currently, 746 DRGs, which include 1 additional MS-DRG created in FY

2009). By increasing the number of DRGs and more fully taking into

account patients' severity of illness in Medicare payment rates for

acute care hospitals, the use of MS-DRGs encourages hospitals to

improve their documentation and coding of patient diagnoses. In the FY

2008 IPPS final rule with comment period (72 FR 47175 through 47186),

we indicated that we believe the adoption of the MS-DRGs had the

potential to lead to increases in aggregate payments without a

corresponding increase in actual patient severity of illness due to the

incentives for additional documentation and coding. In that final rule

with comment period, we exercised our authority under section

1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget

neutrality by adjusting the national standardized amount to eliminate

the estimated effect of changes in coding or classification that do not

reflect real changes in case-mix. Our actuaries estimated that

maintaining budget neutrality required an adjustment of -4.8 percent to

the national standardized amount. We phased in this -4.8 percent

adjustment over 3 years. Specifically, we established prospective

documentation and coding adjustments of -1.2 percent for FY 2008, -1.8

percent for FY 2009, and -1.8 percent for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional

Medical Assistance], Abstinence Education, and QI [Qualifying

Individuals] Programs Extension Act of 2007, Public Law 110-90. Section

7(a) of Public Law 110-90 reduced the documentation and coding

adjustment made as a result of the MS-DRG system that we adopted in the

FY 2008 IPPS final rule with comment period to -0.6 percent for FY 2008

and -0.9 percent for FY 2009. Section 7(a) of Public Law 110-90 did not

adjust the FY 2010 -1.8 percent documentation and coding adjustment

promulgated in the FY 2008 IPPS final rule with comment period. To

comply with section 7(a) of Public Law 110-90, we promulgated a final

rule on November 27, 2007 (72 FR 66886) that modified the IPPS

documentation and coding adjustment for FY 2008 to -0.6 percent, and

revised the FY 2008 payment rates, factors, and thresholds accordingly.

These revisions were effective on October 1, 2007.

For FY 2009, section 7(a) of Public Law 110-90 required a

documentation and coding adjustment of -0.9 percent instead of the -1.8

percent adjustment established in the FY 2008 IPPS final rule with

comment period. As discussed in the FY 2009 IPPS final rule (73 FR

48447) and required by statute, we applied a documentation and coding

adjustment of -0.9 percent to the FY 2009 IPPS national standardized

amount. The documentation and coding adjustments established in the FY

2008 IPPS final rule with comment period, as amended by Public Law 110-

90, are cumulative. As a result, the -0.9 percent documentation and

coding

[[Page 24093]]

adjustment for FY 2009 was in addition to the -0.6 percent adjustment

for FY 2008, yielding a combined effect of -1.5 percent.

2. Prospective Adjustment to the Average Standardized Amounts Required

by Section 7(b)(1)(A) of Public Law 110-90

Section 7(b)(1)(A) of Public Law 110-90 requires that if the

Secretary determines that implementation of the MS-DRG system resulted

in changes in documentation and coding that did not reflect real

changes in case-mix for discharges occurring during FY 2008 or FY 2009

that are different than the prospective documentation and coding

adjustments applied under section 7(a) of Public Law 110-90, the

Secretary shall make an appropriate adjustment under section

1886(d)(3)(A)(vi) of the Act. Section 1886(d)(3)(A)(vi) of the Act

authorizes adjustments to the average standardized amounts for

subsequent fiscal years in order to eliminate the effect of such coding

or classification changes. These adjustments are intended to ensure

that future annual aggregate IPPS payments are the same as the payments

that otherwise would have been made had the prospective adjustments for

documentation and coding applied in FY 2008 and FY 2009 reflected the

change that occurred in those years.

3. Recoupment or Repayment Adjustments in FYs 2010 through 2012

Required by Public Law 110-90

If, based on a retroactive evaluation of claims data, the Secretary

determines that implementation of the MS-DRG system resulted in changes

in documentation and coding that did not reflect real changes in case-

mix for discharges occurring during FY 2008 or FY 2009 that are

different from the prospective documentation and coding adjustments

applied under section 7(a) of Public Law 110-90, section 7(b)(1)(B) of

Public Law 110-90 requires the Secretary to make an additional

adjustment to the standardized amounts under section 1886(d) of the

Act. This adjustment must offset the estimated increase or decrease in

aggregate payments for FYs 2008 and 2009 (including interest) resulting

from the difference between the estimated actual documentation and

coding effect and the documentation and coding adjustment applied under

section 7(a) of Public Law 110-90. This adjustment is in addition to

making an appropriate adjustment to the standardized amounts under

section 1886(d)(3)(A)(vi) of the Act as required by section 7(b)(1)(A)

of Public Law 110-90. That is, these adjustments are intended to recoup

(or repay) spending in excess of (or less than) spending that would

have occurred had the prospective adjustments for changes in

documentation and coding applied in FY 2008 and FY 2009 precisely

matched the changes that occurred in those years. Public Law 110-90

requires that the Secretary make these recoupment or repayment

adjustments for discharges occurring during FYs 2010, 2011, and 2012.

4. Retrospective Evaluation of FY 2008 Claims Data

In order to implement the requirements of section 7 of Public Law

110-90, we indicated in the FY 2009 IPPS final rule (73 FR 48450) that

we planned a thorough retrospective evaluation of our claims data. We

stated that the results of this evaluation would be used by our

actuaries to determine any necessary payment adjustments to the

standardized amounts under section 1886(d) of the Act beginning in FY

2010 to ensure the budget neutrality of the MS-DRGs implementation for

FY 2008 and FY 2009, as required by law. In the FY 2009 IPPS proposed

rule (73 FR 23541 through 23542), we described our preliminary plan for

a retrospective analysis of inpatient hospital claims data and invited

public input on our proposed methodology.

In that proposed rule, we indicated that we intended to measure and

corroborate the extent of the overall national average changes in case-

mix for FY 2008 and FY 2009. We expected that the two largest parts of

this overall national average change would be attributable to

underlying changes in actual patient severity and to documentation and

coding improvements under the MS-DRG system. In order to separate the

two effects, we planned to isolate the effect of shifts in cases among

base DRGs from the effect of shifts in the types of cases within-base

DRGs.

The MS-DRGs divide the base DRGs into three severity levels (with

MCC, with CC and without CC); the previously used CMS DRGs had only two

severity levels (with CC and without CC). Under the CMS DRG system, the

majority of hospital discharges had a secondary diagnosis which was on

the CC list, which led to the higher severity level. The MS-DRGs

significantly changed the code lists of what was classified as an MCC

or a CC. Many codes that were previously classified as a CC are no

longer included on the MS-DRG CC list because the data and clinical

review showed these conditions did not lead to a significant increase

in resource use. The addition of a new level of high severity

conditions, the MCC list, also provided a new incentive to code more

precisely in order to increase the severity level. We anticipated that

hospitals would examine the MS-DRG MCC and CC code lists and then work

with physicians and coders on documentation and coding practices so

that coders could appropriately assign codes from the highest possible

severity level. We note that there have been numerous seminars and

training sessions on this particular coding issue. The topic of

improving documentation practices in order to code conditions on the

MCC list was also discussed extensively by participants at the March

11-12, 2009 ICD-9-CM Coordination and Maintenance Committee meeting.

Participants discussed their hospitals' efforts to encourage physicians

to provide more precise documentation so that coders could

appropriately assign codes that would lead to a higher severity level.

Because we expected most of the documentation and coding changes under

the MS-DRG system would occur in the secondary diagnoses, we believed

that the shifts among base DRGs were less likely to be the result of

the MS-DRG system and the shifts within base DRGs were more likely to

be the result of the MS-DRG system. We also anticipated evaluating data

to identify the specific MS-DRGs and diagnoses that contributed

significantly to the documentation and coding payment effect and to

quantify their impact. This step entailed analysis of the secondary

diagnoses driving the shifts in severity within specific base DRGs.

In that same proposed rule, we also stated that, while we believe

that the data analysis plan described previously will produce an

appropriate estimate of the extent of case-mix changes resulting from

documentation and coding changes, we might decide, if feasible, to use

historical data from our Hospital Payment Monitoring Program (HPMP) to

corroborate the within-base DRG shift analysis. The HPMP is supported

by the Medicare Clinical Data Abstraction Center (CDAC).

In the FY 2009 IPPS proposed rule, we solicited public comments on

the analysis plans described above, as well as suggestions on other

possible approaches for performing a retrospective analysis to identify

the amount of case-mix changes that occurred in FY 2008 and FY 2009

that did not reflect real increases in patients' severity of illness.

A few commenters, including MedPAC, expressed support for the

[[Page 24094]]

analytic approach described in the FY 2009 IPPS proposed rule. A number

of other commenters expressed concerns about certain aspects of the

approach and/or suggested alternate analyses or study designs. In

addition, one commenter recommended that any determination or

retrospective evaluation by the actuaries of the impact of the MS-DRGs

on case-mix be open to public scrutiny prior to the implementation of

the payment adjustments beginning in FY 2010.

We took these comments into consideration as we developed our

proposed analysis plan (described in greater detail below) and in this

proposed rule are seeking comment on our methodology. We performed a

retrospective evaluation of the FY 2008 data for claims paid through

December 2008. Based on this evaluation, our actuaries have determined

that implementation of the MS-DRG system resulted in a 2.5 percent

change due to documentation and coding that did not reflect real

changes in case-mix for discharges occurring during FY 2008.

In performing this analysis, we first divided the case-mix index

(CMI) obtained by grouping the FY 2008 claims data through the FY 2008

GROUPER (Version 25.0) by the CMI obtained by grouping these same FY

2008 claims through the FY 2007 GROUPER (Version 24.0). This resulted

in a value of 1.028. Because these cases are the same FY 2008 cases

grouped using the Versions 24.0 and 25.0 of the GROUPER, we attribute

this increase primarily to two factors: (1) The effect of changes in

documentation and coding under the MS-DRG system; and (2) the

measurement effect from the calibration of the GROUPER. We estimated

the measurement effect from the calibration of the GROUPER by dividing

the CMI obtained by grouping cases in the FY 2007 claims data through

the FY 2008 GROUPER by the CMI obtained by grouping cases in these same

claims through the FY 2007 GROUPER. This resulted in a value of 1.003.

In order to isolate the documentation and coding effect, we then

divided the combined effect of the changes in documentation and coding

and measurement (1.028) by the measurement effect (1.003) to yield

1.025. Therefore, our estimate of the documentation and coding increase

is 2.5 percent.

We then sought to corroborate this 2.5 percent estimate by

examining the increases in the within-base DRGs as compared to the

increases in the across base DRGs as described earlier in our analysis

plan. In other words, we looked for improvements in code selection that

would lead to a secondary diagnosis increasing the severity level to

either a CC or an MCC level.

We found that the within-base DRG increases were almost entirely

responsible for the case-mix change, supporting our conclusion that the

2.5 percent estimate was an accurate reflection of the FY 2008 effect

of changes in documentation and coding under the MS-DRG system. In

fact, almost every base DRG that was split into different severity

levels under the MS-DRG system experienced increases in the within-base

DRGs. In Figure 1 below, we show that, between FY 2007 and FY 2008,

there was a 5 percentage point increase in the discharges with an MCC

from 21 percent to 26 percent and a corresponding decrease of 5

percentage points from 56 percent to 51 percent in discharges without a

CC or an MCC.

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We then further analyzed the changes in the within-base DRGs to

determine which MS-DRGs had the highest contributions to this increase.

Consistent with the expectations of our medical coding experts

concerning areas with potential for documentation and coding

improvements, the top contributors were heart failure, chronic

obstructive pulmonary disease, and simple pneumonia and pleurisy. In

fact, the coding of heart failure was discussed extensively at the

March 11-12, 2009 ICD-9-CM Coordination and Maintenance Committee

meeting. Heart failure is a very common secondary diagnosis among

Medicare hospital admissions. The heart failure codes are assigned to

all three severity levels. Some are classified as non-CCs, while others

are on the CC and MCC lists. By changing physician documentation to

more precisely identify the type of heart failure, coders are able to

appropriately change the severity level of cases from the lowest level

(non-CC) to a higher severity level (CC or MCC). This point was

stressed repeatedly at the March 11-12, 2009 ICD-9-CM Coordination and

Maintenance Committee meeting as coders discussed their work with

physicians on this coding issue. Many of the participants indicated

that

[[Page 24095]]

additional work was still needed with their physicians in order to

document conditions in the medical record more precisely.

The results of this analysis provides additional support for our

conclusion that the 2.5 percent estimate accurately reflects the FY

2008 increases in documentation and coding under the MS-DRG system.

While we attempted to use the CDAC data to distinguish real

increase in case-mix growth from documentation and coding in the

overall case-mix number, we found aberrant data and significant

variation across the FY 1999-FY 2007 analysis period. It was not

possible to distinguish changes in documentation and coding from

changes in real case-mix in the CDAC data. Therefore, we concluded that

the CDAC data would not support analysis of real case-mix growth that

could be used in our retrospective evaluation of the FY 2008 claims

data.

Although we could not use the CDAC data, we did examine the overall

growth in case-mix using the FY 2007 claims data in which we grouped

cases using the FY 2007 GROUPER and the FY 2008 data in which we

grouped cases using the FY 2008 GROUPER. We found the overall growth in

case-mix was 1.9 percent. The implication of overall FY 2008 case-mix

growth of 1.9 percent relative to our estimate of the FY 2008

documentation and coding effect and the GROUPER measurement effect is

that real case-mix declined between FY 2007 and FY 2008. After

additional data analysis, our actuaries determined that the 1.9 percent

growth in overall case-mix was consistent with our 2.5 percent estimate

of the FY 2008 documentation and coding effect for reasons that

included: (1) Our mathematical model for determining the 2.5 percent

documentation and coding effect was corroborated by the amount of case-

mix growth attributed to within-DRG improvements in secondary coding of

MCCs and CCs; (2) our data analysis confirmed the substitution of

specified diagnosis for unspecified diagnoses for such common

conditions as heart failure and chronic obstructive pulmonary disease;

and (3) there was a relative decline in above average cost short-stay

surgical cases that can be performed on an outpatient basis, such as

certain high volume pacemaker procedures.

We also examined the differences in case-mix between the FY 2008

claims data in which cases were grouped through the FY 2008 GROUPER

(Version 25.0) and the FY 2009 GROUPER (Version 26.0). This was to help

inform analysis of the potential for increase in the documentation and

coding effect in FY 2009. In FY 2008, we were transitioning to the

fully implemented MS-DRG relative weights and the fully implemented

cost-based weights. We found that the use of the transition weights

mitigated the FY 2008 documentation and coding effect on expenditures.

Using the FY 2009 relative weights, the documentation and coding effect

would have been an estimated 3.2 percent in FY 2008 instead of our

estimated 2.5 percent. Even assuming no continued improvement in

documentation and coding in FY 2009, we estimate that the use of the FY

2009 relative weights will result in an additional 0.7 percent

documentation and coding effect in FY 2009. After taking into account

the results of our FY 2008 analysis and the expertise of our coding

staff, our actuaries continue to estimate that the cumulative overall

effect of documentation and coding improvements under the MS-DRG system

will be 4.8 percent. However, our actuaries estimate that these

improvements will be substantially complete by the end of FY 2009.

Therefore, our current estimate of the FY 2009 MS-DRG documentation and

coding effect is 2.3 percent.

As in prior years, the FY 2008 MedPAR files are available to the

public to allow independent analysis of the FY 2008 documentation and

coding effect. Interested individuals may order these files by going to

the Web site at http://www.cms.hhs.gov/LimitedDataSets/ and clicking on

MedPAR Limited Data Set (LDS)-Hospital (National). This Web page will

describe the file and provide directions and further detailed

instructions for how to order.

Persons placing an order must send the following: a Letter of

Request, the LDS Data Use Agreement and Research Protocol (refer to the

Web site for further instructions), the LDS Form, and a check for

$3,655 to: Mailing address if using the U.S. Postal Service: Centers

for Medicare & Medicaid Services, RDDC Account, Accounting Division,

P.O. Box 7520, Baltimore, MD 21207-0520. Mailing address if using

express mail: Centers for Medicare & Medicaid Services, OFM/Division of

Accounting--RDDC, 7500 Security Boulevard, C3-07-11, Baltimore, MD

21244-1850.

We are seeking public comment on our methodology and analysis. We

intend to update our analysis with FY 2008 data on claims paid through

March 2008 in the FY 2010 IPPS final rule.

5. Proposed Adjustments for FY 2010 and Subsequent Years Authorized by

Section 7(b)(1)(A) of Public Law 110-90 and Section 1886(d)(3)(vi) of

the Act

The estimated 2.5 percent change in FY 2008 case-mix due to changes

in documentation and coding that did not reflect real changes in case-

mix for discharges occurring during FY 2008 exceeded the -0.6 percent

prospective documentation and coding adjustment applied under section

7(a) of Public Law 110-90 by 1.9 percentage points. Under section

7(B)(1)(a) of Public Law 119-90, the Secretary is required to make an

appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act to

the average standardized amounts for subsequent fiscal years in order

to eliminate the full effect of the documentation and coding changes.

In addition, we note that the Secretary has the authority to make this

prospective adjustment in FY 2010 under section 1886(d)(3)(A)(vi) of

the Act. As we have consistently stated since the initial

implementation of the MS-DRG system, we do not believe it is

appropriate for expenditures to increase due to MS-DRG-related changes

in documentation and coding that do not reflect real changes in case-

mix.

Therefore, we are proposing to change the average standardized

amounts under section 1886(d) of the Act in FY 2010 by -1.9 percent,

the difference between the changes in documentation and coding that do

not reflect real changes in case-mix for discharges occurring during FY

2008 and the prospective adjustment applied under section 7 of Public

Law 110-90. We are proposing to leave this adjustment in place for

subsequent fiscal years in order to ensure that changes in

documentation and coding resulting from the adoption of the MS-DRGs do

not lead to an increase in aggregate payments not reflective of an

increase in real case-mix.

We also estimate that the change in case-mix due to changes in

documentation and coding that do not reflect real changes in case-mix

for discharges occurring during FY 2009 will be 2.3 percent, which

would exceed by 1.4 percentage points the -0.9 percent prospective

documentation and coding adjustment for FY 2009 applied under section

7(a) of Public Law 100-90. We have the statutory authority to adjust

the FY 2010 rates for this estimated 1.4 percentage point increase.

However, given that Public Law 100-90 requires a retrospective claims

evaluation for the additional adjustments described in section II.D.6.

of this preamble, we believe our

[[Page 24096]]

evaluation of the extent of the overall national average changes in

case-mix for FY 2009 should also be based on a retrospective evaluation

of all FY 2009 claims data. Because we will not receive all FY 2009

claims data prior to publication of the final rule, we will address any

difference between the increase in FY 2009 case-mix due to changes in

documentation and coding that did not reflect real changes in case-mix

for discharges occurring during FY 2009 and the -0.9 percent

prospective documentation and coding adjustment applied under section

7(a) of Public Law 110-90 in the FY 2011 rulemaking cycle.

We are seeking public comment on the proposed -1.9 percent

prospective adjustment to the standardized amounts under section

1886(d) of the Act to address the effects of documentation and coding

changes unrelated to changes in real case-mix in FY 2008. In addition,

we are seeking public comments on addressing in the FY 2011 rulemaking

cycle any differences between the increase in FY 2009 case-mix due to

changes in documentation and coding changes that do not reflect real

changes in case-mix for discharges occurring during FY 2009 and the -

0.9 percent prospective documentation and coding adjustment applied

under section 7(a) of Public Law 110-90.

6. Additional Adjustment for FY 2010 Authorized by Section 7(b)(1)(B)

of Public Law 110-90

As indicated above, the 2.5 percent change due to documentation and

coding that did not reflect real changes in case-mix for discharges

occurring during FY 2008 exceeded the -0.6 percent prospective

documentation and coding adjustment applied under section 7(a) of

Public Law 110-90 by 1.9 percentage points. Our actuaries currently

estimate that this 1.9 percentage point increase resulted in an

increase in aggregate payments of approximately $2.2 billion. As

described earlier, section 7(b)(1)(B) of Public Law 110-90 requires an

additional adjustment for discharges occurring in FYs 2010, 2011, and/

or 2012 to offset the estimated amount of this increase in aggregate

payments (including interest).

Although section 7(b)(1)(B) of Public Law 110-90 requires us to

make this adjustment in FYs 2010, 2011, and/or 2012, we have discretion

as to when during this 3 year period we will apply the adjustment. For

example, we could make adjustments to the standardized amounts under

section 1886(d) of the Act in FY 2010, 2011, and 2012. Alternatively,

we could delay offsetting the increase in FY 2008 aggregate payments by

applying the adjustment required under section 7(b)(1)(B) of Public Law

110-90 only to FYs 2011 and 2012.

We are not proposing to make an adjustment to FY 2010 to offset, in

whole or in part, the estimated increase in aggregate payments for

discharges occurring in FY 2008, but intend to address this issue in

future rulemaking for FYs 2011 and 2012. That is, we will address

recouping the additional expenditures that occurred in FY 2008 as a

result of the 1.9 percentage point difference between the actual

changes in documentation and coding that do not reflect real changes in

case-mix, or 2.5 percent, and the -0.6 percent adjustment applied under

Public Law 110-90 in FY 2011 and/or FY 2012, as required by law. While

we have the statutory authority to make this -1.9 percent recoupment

adjustment entirely in FY 2010, we are proposing to delay the

adjustment until FY 2011 and FY 2012 because we do not have any data

yet on the magnitude of the documentation and coding effect in FY 2009.

If the documentation and coding effect were less in FY 2009 than our

current estimates, it could lessen the anticipated recoupment

adjustment that we currently estimate we would have to make for FY 2008

and FY 2009 combined. As we have the authority to recoup the aggregate

effect of this 1.9 percentage point difference in FY 2008 IPPS payments

in FY 2011 or FY 2012 (with interest), delaying this adjustment would

have no effect on Federal budget outlays. For this reason, we are

proposing to wait until we have a complete year of data on the FY 2009

documentation and coding effect before applying a recoupment adjustment

for IPPS spending that occurred in FY 2008 or we estimate will occur in

FY 2009.

As discussed above, section 7(b)(1)(B) of Public Law 110-90

requires the Secretary to make an additional adjustment to the

standardized amounts under section 1886(d) of the Act to offset the

estimated increase or decrease in aggregate payments for FY 2009

(including interest) resulting from the difference between the

estimated actual documentation and coding effect and the documentation

and coding adjustments applied under section 7(a) of Public Law 110-90.

This determination must be based on a retrospective evaluation of

claims data. Because we will not receive all FY 2009 claims data prior

to publication of the final rule, we intend to address any increase or

decrease in FY 2009 payments in future rulemaking for FY 2011 and 2012

after we perform a retrospective evaluation of the FY 2009 claims data.

Our actuaries currently estimate that this adjustment will be

approximately -3.3 percent. This reflects the difference between the

estimated 4.8 percent cumulative actual documentation and coding

changes for FY 2009 (2.5 percent for FY 2008 and an additional 2.3

percent for FY 2009) and the cumulative -1.5 percent documentation and

coding adjustments applied under section 7(a) of Public Law 110-90 (-

0.6 percent in FY 2008 and -0.9 percent in FY 2009). We note that the

actual adjustments are multiplicative and not additive. This estimated

4.8 percent cumulative actual documentation and coding changes for FY

2009 includes the impact of the changes in documentation and coping

first occurring in FY 2008 because we believe hospitals will continue

these changes in documentation and coding in subsequent fiscal years.

Consequently, these documentation and coding changes will continue to

impact payments under the IPPS absent a prospective adjustment to

account for the effect of these changes.

We note that unlike the proposed -1.9 adjustment to the

standardized amounts under section 7(b)(1)(A) of Public Law 110-90

described earlier, any adjustment to the standardized amounts under

section 7(b)(1)(B) of Public Law 110-90 would not be cumulative, but

would be removed for subsequent fiscal years once we have offset the

increase in aggregate payments for discharges occurring in FY 2008

expenditures and FY 2009 expenditures, if any.

We are seeking public comment on our proposal not to offset the 1.9

percent increase in aggregate payments (including interest) for

discharges occurring in FY 2008 resulting from the adoption of the MS-

DRGs, but to instead address this issue in future rulemaking for FYs

2011 and 2012.

To assist the public in commenting on this issue, the following

table shows our estimate of the adjustments required under section

7(b)(1) of Public Law 110-90. Column (A) and Column (C) show the

prospective adjustments discussed above in section II.D.5. of this

preamble. Column (B) and Column (D) show the retrospective adjustments

discussed above in section II.D.6. of this preamble. Column (E) shows

the -1.9 percent adjustment from Column (A) that we are proposing for

FY 2010. The estimated -6.6 percent adjustment in Column (F) reflects

the cumulative effect of the remaining -1.9 adjustment from Column (B),

the remaining -1.4 percent adjustment from Column (C), and the

remaining -3.3 adjustment from

[[Page 24097]]

Column (D) that are required by statute, but that we are not proposing

for FY 2010. Column (G) shows the combined effect of the -1.9 percent

adjustment in Column (E) that we are proposing for FY 2010 and the -6.6

percent adjustment in Column (F) that we currently estimate we will

need to propose in future years. As noted above, we are unable to

provide our final estimate of the documentation and coding changes in

FY 2009 that do not reflect real changes in case-mix, as we do not have

all FY 2009 claims data. The table instead reflects our current

estimate of the difference between changes in documentation and coding

in FY 2009 that do not reflect real changes in case-mix and the

prospective adjustment applied in FY 2009 under section 7(a) of Public

Law 110-90. If documentation and coding increases were to exceed

current projections for FY 2009, future adjustments would be greater

than those shown here. If documentation and coding adjustments were to

be less than current projections for FY 2009, future adjustments would

be less than those shown here.

FY 2010 MS-DRG Documentation and Coding Adjustment Range

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Estimated Total

Prospective Recoupment Prospective Recoupment Adjustment remaining adjustment

adjustment for FY adjustment for FY adjustment for FY adjustment for FY proposed adjustment FY 2010- FY

2008 2008 2009 \* 2009 \* for FY 2010 \* 2012 \*

(A)................ (B)............... (C)............... (D)............... (E) (F) (G)

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FY 2010 Proposal................ Proposed for FY Not Proposed for Not Proposed for Not Proposed for

2010. FY 2010. FY 2010. FY 2010.

Amount of Adjustment............ -1.9............... -1.9.............. -1.4.............. -3.3.............. -1.9 -6.6 -8.5

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\* Estimated. The actual percentage adjustment to the national standardized amounts for the purpose of offsetting the estimated $2.2 billion in increased

payments under IPPS in FY 2008 will depend on when we apply the adjustment. However, we believe this adjustment will be approximately -1.9 percent, or

the difference between the actual changes in documentation and coding that do not reflect real changes in case-mix in FY 2008 and the documentation

and coding adjustment applied under section 7(a) of Public Law 110-90. Similarly, we based our estimate of the percentage adjustment to the national

standardized amounts for the purpose of offsetting the expected increase in payments in FY 2009 on the estimated difference between the cumulative

actual changes in documentation and coding that do not reflect real changes in case-mix in FY 2009 and the documentation and coding adjustments

applied under section 7(a) of Public Law 110-90, or 3.3 percent. As discussed earlier, we are not permitted to apply a retroactive FY 2009 adjustment

until we have performed an analysis of the FY 2009 data.

7. Background on the Application of the Documentation and Coding

Adjustment to the Hospital-Specific Rates

Under section 1886(d)(5)(D)(i) of the Act, SCHs are paid based on

whichever of the following rates yields the greatest aggregate payment:

The Federal rate; the updated hospital-specific rate based on FY 1982

costs per discharge; the updated hospital-specific rate based on FY

1987 costs per discharge; the updated hospital-specific rate based on

FY 1996 costs per discharge; or the updated hospital-specific rate

based on FY 2006 costs per discharge. Under section 1886(d)(5)(G) of

the Act, MDHs are paid based on the Federal national rate or, if

higher, the Federal national rate plus 75 percent of the difference

between the Federal national rate and the updated hospital-specific

rate based on the greatest of the FY 1982, FY 1987, or FY 2002 costs

per discharge. In the FY 2008 IPPS final rule with comment period (72

FR 47152 through 47188), we established a policy of applying the

documentation and coding adjustment to the hospital-specific rates. In

that final rule with comment period, we indicated that because SCHs and

MDHs use the same DRG system as all other hospitals, we believe they

should be equally subject to the budget neutrality adjustment that we

are applying for adoption of the MS-DRGs to all other hospitals. In

establishing this policy, we relied on section 1886(d)(3)(A)(vi) of the

Act, which provides us with the authority to adjust ``the standardized

amount'' to eliminate the effect of changes in coding or classification

that do not reflect real change in case-mix.

However, in the final rule that appeared in the Federal Register on

November 27, 2007 (72 FR 66886), we rescinded the application of the

documentation and coding adjustment to the hospital-specific rates

retroactive to October 1, 2007. In that final rule, we indicated that,

while we still believe it would be appropriate to apply the

documentation and coding adjustment to the hospital-specific rates,

upon further review, we decided that the application of the

documentation and coding adjustment to the hospital-specific rates is

not consistent with the plain meaning of section 1886(d)(3)(A)(vi) of

the Act, which only mentions adjusting ``the standardized amount''

under section 1886(d) of the Act and does not mention adjusting the

hospital-specific rates.

In the FY 2009 IPPS proposed rule (73 FR 23540), we indicated that

we continued to have concerns about this issue. Because hospitals paid

based on the hospital-specific rate use the same MS-DRG system as other

hospitals, we believe they have the potential to realize increased

payments from documentation and coding changes that do not reflect real

increases in patients' severity of illness. In section

1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid

based on the standardized amount should not receive additional payments

based on the effect of documentation and coding changes that do not

reflect real changes in case-mix. Similarly, we believe that hospitals

paid based on the hospital-specific rates should not have the potential

to realize increased payments due to documentation and coding changes

that do not reflect real increases in patients' severity of illness.

While we continue to believe that section 1886(d)(3)(A)(vi) of the Act

does not provide explicit authority for application of the

documentation and coding adjustment to the hospital-specific rates, we

believe that we have the authority to apply the documentation and

coding adjustment to the hospital-specific rates using our special

exceptions and adjustment authority under section 1886(d)(5)(I)(i) of

the Act. The special exceptions and adjustment provision authorizes us

to provide ``for such other exceptions and adjustments to [IPPS]

payment amounts \* \* \* as the Secretary deems appropriate.'' In the FY

2009 IPPS final rule (73 FR 48448 through 48449), we indicated that,

for the FY 2010 rulemaking, we planned to examine our FY 2008 claims

data for hospitals paid based on the hospital-specific rate. We further

indicated that if we found evidence of significant increases in case-

mix for patients treated in these hospitals that do not reflect real

changes in case-mix, we would consider

[[Page 24098]]

proposing application of the documentation and coding adjustments to

the FY 2010 hospital-specific rates under our authority in section

1886(d)(5)(I)(i) of the Act.

In response to public comments received on the FY 2009 IPPS

proposed rule, we stated in the FY 2009 IPPS final rule that we would

consider whether such a proposal is warranted for FY 2010. To gather

information to evaluate these considerations, we indicated that we

planned to perform analyses on FY 2008 claims data to examine whether

there has been a significant increase in case-mix for hospitals paid

based on the hospital-specific rate. If we found that application of

the documentation and coding adjustment to the hospital-specific rates

for FY 2010 is warranted, we indicated that we would include a proposal

to do so in the FY 2010 IPPS proposed rule.

8. Proposed Documentation and Coding Adjustment to the Hospital-

Specific Rates for FY 2010 and Subsequent Fiscal Years

We performed a retrospective evaluation of the FY 2008 claims data

for SCHs and MDHs using the same methodology described earlier for

other IPPS hospitals. We found that, independently for both SCHs and

MDHs, the change due to documentation and coding that did not reflect

real changes in case-mix for discharges occurring during FY 2008

slightly exceeded the 2.5 percent result discussed earlier, but did not

significantly differ from that result.

Again, we found that the within-base DRG increases were almost

entirely responsible for the case-mix change. In Figure 2 below, we

show that, for SCHs, there was a 5 percentage point increase in the

discharges with an MCC from 17 percent to 22 percent and a

corresponding decrease of 5 percentage points from 59 percent to 54

percent in discharges without a CC or an MCC. In Figure 3 below, we

show that, for MDHs, there was a 5 percentage point increase in the

discharges with an MCC from 15 percent to 20 percent and a decrease of

6 percentage points from 60 percent to 54 percent in discharges without

a CC or an MCC.

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The largest within-base DRG contributors for both types of

hospitals are heart failure and shock, chronic obstructive pulmonary

disease, and simple pneumonia and pleurisy. For each of these

conditions, a significant decrease in the percentage of discharges

without a CC or an MCC was observed.

Therefore, consistent with our statements in prior IPPS rules, we

are proposing to use our authority under section 1886(d)(5)(I)(i) of

the Act to prospectively adjust the hospital-specific rates by -2.5

percent in FY 2010 to account for our estimated documentation and

coding effect in FY 2008 that does not reflect real changes in case-

mix. We are proposing to leave this adjustment in place for subsequent

fiscal years in order to ensure that changes in documentation and

coding resulting from the adoption of the MS-DRGs do not lead to an

increase in aggregate payments for SCHs and MDHs not reflective of an

increase in real case-mix. This proposed -2.5 percent adjustment to the

hospital-specific rates exceeds the proposed -1.9 percent adjustment to

the national standardized amount under section 7(b)(1)(A) of Public Law

110-90 because, unlike the national standardized rates, the FY 2008

hospital-specific rates were not previously reduced in order to account

for anticipated changes in documentation and coding that do not reflect

real changes in case-mix resulting from the adoption of the MS-DRGs.

Consistent with our proposed approach for IPPS hospitals discussed

earlier, we will address in the FY 2011 rulemaking cycle any changes in

documentation and coding that do not reflect real changes in case-mix

for discharges occurring during FY 2009. We note that, unlike the

national standardized rates, the FY 2009 hospital-specific rates were

not previously reduced in order to account for anticipated changes in

documentation and coding that do not reflect real changes in case-mix

resulting from the adoption of the MS-DRGs.

We are seeking public comment on the proposed -2.5 percent

prospective adjustment to the hospital-specific rates under section

1886(d)(5)(I)(i) of the Act and addressing in the FY 2011 rulemaking

cycle any changes in FY 2009 case-mix due to changes in documentation

and coding that do not reflect real changes in case-mix for discharges

occurring during FY 2009. We intend to update our analysis with FY 2008

data on claims paid through March 2008 for the FY 2010 IPPS final rule.

9. Background on the Application of the Documentation and Coding

Adjustment to the Puerto Rico-Specific Standardized Amount

Puerto Rico hospitals are paid based on 75 percent of the national

standardized amount and 25 percent of the Puerto Rico-specific

standardized amount. As noted previously, the documentation and coding

adjustment we adopted in the FY 2008 IPPS final rule with comment

period relied upon our authority under section 1886(d)(3)(A)(vi) of the

Act, which provides the Secretary the authority to adjust ``the

standardized amounts computed under this paragraph'' to eliminate the

effect of changes in coding or classification that do not reflect real

changes in case-mix. Section 1886(d)(3)(A)(vi) of the Act applies to

the national standardized amounts computed under section 1886(d)(3) of

the Act, but does not apply to the Puerto Rico-specific standardized

amount computed under section 1886(d)(9)(C) of the Act. In calculating

the FY 2008 payment rates, we made an inadvertent error and applied the

FY 2008 -0.6 percent documentation and coding adjustment to the Puerto

Rico-specific standardized amount, relying on our authority under

section 1886(d)(3)(A)(vi) of the Act. However, section

1886(d)(3)(A)(vi) of the Act authorizes application of a documentation

and coding adjustment to the national standardized amount and does not

apply to the Puerto Rico specific standardized amount. In the FY 2009

IPPS final rule (73 FR 48449), we corrected this inadvertent error by

removing the -0.6 percent documentation and coding adjustment from the

FY 2008 Puerto Rico-specific rates.

While section 1886(d)(3)(A)(vi) of the Act is not applicable to the

Puerto Rico-specific standardized amount, we believe that we have the

authority to apply the documentation and coding adjustment to the

Puerto Rico-specific standardized amount using our special exceptions

and adjustment authority under section 1886(d)(5)(I)(i) of the Act.

Similar to SCHs and MDHs that are paid based on the hospital-specific

rate, we believe that Puerto Rico hospitals that are paid based on the

Puerto Rico-specific standardized amount should not have the potential

to realize increased payments due to documentation and coding changes

that do not reflect real increases in patients' severity of illness.

Consistent with the approach described for SCHs and MDHs, in the FY

2009 IPPS final rule (73 FR 48449), we indicated that we planned to

examine our FY 2008 claims data for hospitals in Puerto Rico. We

indicated in the FY 2009 IPPS proposed rule (73 FR 23541), that if we

found evidence of significant increases in case-mix for patients

treated in these hospitals, we would consider proposing application of

the documentation and coding adjustments to the FY 2010 Puerto Rico-

specific standardized amount under our authority in section

1886(d)(5)(I)(i) of the Act.

10. Proposed Documentation and Coding Adjustment to the Puerto Rico-

Specific Standardized Amount

We performed a retrospective evaluation of the FY 2008 claims data

for Puerto Rico hospitals using the same methodology described earlier

for IPPS hospitals paid under the national standardized amounts under

section 1886(d) of the Act. We found that, for Puerto Rico hospitals,

the increase in payments for discharges occurring during FY 2008 due to

documentation and coding that did not reflect real changes in case-mix

for discharges occurring during FY 2008 was approximately 1.1 percent.

When we calculate the within-base DRG changes and the across-base DRG

changes for Puerto Rico hospitals, we find that responsibility for the

case-mix change between FY 2007 and FY 2008 is much more evenly shared.

Across-base DRG shifts account for 44 percent of the changes, and

within-base DRG shifts account for 56 percent. Thus, the change in the

percentage of discharges with an MCC is not as large as that for other

IPPS hospitals. In Figure 4 below, we show that, for Puerto Rico

hospitals, there was a 3 percentage point increase in the discharges

with an MCC from 22 percent to 25 percent and a corresponding decrease

of 3 percentage points from 58 percent to 55 percent in discharges

without a CC or an MCC.

[[Page 24101]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.003

The top contributing base DRGs to the case-mix change due to the

within-base DRG changes differ partially from those of other hospitals.

The top three are acute myocardial infarction, major small and large

bowel procedures, and chronic obstructive pulmonary disease.

Given these documentation and coding increases, consistent with our

statements in prior IPPS rules, we are proposing to use our authority

under section 1886(d)(5)(I)(i) of the Act to adjust the Puerto Rico-

specific standardized amount by -1.1 percent in FY 2010 to account for

the FY 2008 documentation and coding increase not due to changes in

real case-mix and to leave that adjustment in place for subsequent

fiscal years. The proposed -1.1 percent adjustment will be applied to

the Puerto Rico-specific rate that accounts for 25 percent of payments

to Puerto Rico hospitals, with the remaining 75 percent based on the

national standardized amount, which we are proposing to adjust as

described above. Consequently, the overall reduction to the payment

rates for Puerto Rico hospitals to account for documentation and coding

changes will be slightly less than the reduction for IPPS hospitals

paid based on 100 percent of the national standardized amount. We note

that, as with the hospital-specific rates, the Puerto Rico-specific

standardized amount had not previously been reduced based on estimated

changes in documentation and coding associated with the adoption of the

MS-DRGs.

Consistent with our proposed approach for IPPS hospitals discussed

above, we will address in the FY 2011 rulemaking cycle any change in FY

2009 case-mix due to documentation and coding that did not reflect real

changes in case-mix for discharges occurring during FY 2009. We note

that, unlike the national standardized rates, the FY 2009 hospital-

specific rates were not previously reduced in order to account for

anticipated changes in documentation and coding that do not reflect

real changes in case-mix resulting from the adoption of the MS-DRGs.

We are seeking public comment on the proposed -1.1 percent

prospective adjustment to the hospital-specific rates under section

1886(d)(5)(I)(i) of the Act and addressing in the FY 2011 rulemaking

cycle any changes in FY 2009 case-mix due to changes in documentation

and coding that did not reflect real changes in case-mix for discharges

occurring during FY 2009. We intend to update our analysis with FY 2008

data on claims paid through March 2008 for the FY 2010 IPPS final rule.

E. Refinement of the MS-DRG Relative Weight Calculation

1. Background

In the FY 2009 IPPS final rule (73 FR 48450), we continued to

implement significant revisions to Medicare's inpatient hospital rates

by completing our 3-year transition from charge-based relative weights

to cost-based relative weights. Beginning in FY 2007, we implemented

relative weights based on cost report data instead of based on charge

information. We had initially proposed to develop cost-based relative

weights using the hospital-specific relative value cost center (HSRVcc)

methodology as recommended by MedPAC. However, after considering

concerns expressed in the public comments we received on the proposal,

we modified MedPAC's methodology to exclude the hospital-specific

relative weight feature. Instead, we developed national CCRs based on

distinct hospital departments and engaged a contractor to evaluate the

HSRVcc methodology for future consideration. To mitigate payment

instability due to the adoption of cost-based relative weights, we

decided to transition cost-based weights over 3 years by blending them

with charge-based weights beginning in FY 2007. (We refer readers to

the FY 2007 IPPS final rule for details on the HSRVcc methodology and

the 3-year transition blend from charge-based relative weights to cost-

based relative weights (71 FR 47882 through 47898).)

In FY 2008, we adopted severity-based MS-DRGs, which increased the

number of DRGs from 538 to 745. Many commenters raised concerns as to

how the transition from charge-based weights to cost-based weights

would continue with the introduction of new MS-DRGs. We decided to

implement a 2-year transition for the MS-DRGs to coincide with the

remainder of the transition to cost-based relative weights. In FY 2008,

50 percent of the relative weight for each DRG was based on the CMS DRG

relative weight and 50 percent was based on the MS-DRG relative weight.

In FY 2009, the third and final year of the transition from charge-

based weights to cost-based weights, we calculated the MS-DRG relative

weights based on 100 percent of hospital costs. We refer readers to the

FY 2007 IPPS final rule (71 FR 47882) for a more

[[Page 24102]]

detailed discussion of our final policy for calculating the cost-based

DRG relative weights and to the FY 2008 IPPS final rule with comment

period (72 FR 47199) for information on how we blended relative weights

based on the CMS DRGs and MS-DRGs.

a. Summary of the RTI Study of Charge Compression and CCR Refinement

As we transitioned to cost-based relative weights, some commenters

raised concerns about potential bias in the weights due to ``charge

compression,'' which is the practice of applying a higher percentage

charge markup over costs to lower cost items and services, and a lower

percentage charge markup over costs to higher cost items and services.

As a result, the cost-based weights would undervalue high-cost items

and overvalue low-cost items if a single CCR is applied to items of

widely varying costs in the same cost center. To address this concern,

in August 2006, we awarded a contract to RTI to study the effects of

charge compression in calculating the relative weights and to consider

methods to reduce the variation in the CCRs across services within cost

centers. RTI issued an interim draft report in January 2007 with its

findings on charge compression (which was posted on the CMS Web site

at: http://www.cms.hhs.gov/reports/downloads/Dalton.pdf). In that

report, RTI found that a number of factors contribute to charge

compression and affect the accuracy of the relative weights. RTI's

findings demonstrated that charge compression exists in several CCRs,

most notably in the Medical Supplies and Equipment CCR.

In its interim draft report, RTI offered a number of

recommendations to mitigate the effects of charge compression,

including estimating regression-based CCRs to disaggregate the Medical

Supplies Charged to Patients, Drugs Charged to Patients, and Radiology

cost centers, and adding new cost centers to the Medicare cost report,

such as adding a ``Devices, Implants and Prosthetics'' line under

``Medical Supplies Charged to Patients'' and a ``CT Scanning and MRI''

subscripted line under ``Radiology-Diagnostics''. (For more details on

RTI's findings and recommendations, we refer readers to the FY 2009

IPPS final rule (73 FR 48452).) Despite receiving public comments in

support of the regression-based CCRs as a means to immediately resolve

the problem of charge compression, particularly within the Medical

Supplies and Equipment CCR, we did not adopt RTI's recommendation to

create additional regression-based CCRs for several reasons. We were

concerned that RTI's analysis was limited to charges on hospital

inpatient claims, while typically hospital cost report CCRs combine

both inpatient and outpatient services. Further, because both the IPPS

and the OPPS rely on cost-based weights, we preferred to introduce any

methodological adjustments to both payment systems at the same time.

RTI's analysis of charge compression has since been expanded to

incorporate outpatient services. RTI evaluated the cost estimation

process for the OPPS cost-based relative weights, including a

reassessment of the regression-based CCR models using both outpatient

and inpatient charge data. This interim report was made available in

April 2008 during the public comment period on the FY 2009 IPPS

proposed rule and can be found on RTI's Web site at: http://

www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining\_Cost\_to\_

Charge\_Ratios\_200804.pdf . The IPPS-specific chapters, which were

separately displayed in the April 2008 interim report, as well as the

more recent OPPS chapters, were included in the July 3, 2008 RTI final

report entitled, ``Refining Cost-to-Charge Ratios for Calculating APC

[Ambulatory Payment Classification] and DRG Relative Payment Weights,''

that became available at the time of the development of the FY 2009

IPPS final rule. The RTI final report can be found on RTI's Web site

at: http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining\_

Cost\_to\_Charge\_Ratios\_200807\_Final.pdf.

RTI's final report distinguished between two types of research

findings and recommendations: those pertaining to the accounting or

cost report data and those related to statistical regression analysis.

Importantly, RTI found that, under the IPPS and the OPPS, accounting

improvements to the cost reporting data reduce some of the sources of

aggregation bias without having to use regression-based adjustments. In

general, with respect to the regression-based adjustments, RTI

confirmed the findings of its March 2007 report that regression models

are a valid approach for diagnosing potential aggregation bias within

selected services for the IPPS and found that regression models are

equally valid for setting payments under the OPPS. RTI also suggested

that regression-based CCRs could provide a short-term correction until

accounting data could be sufficiently refined to support more accurate

CCR estimates under both the IPPS and the OPPS.

RTI also noted that cost-based weights are only one component of a

final prospective payment rate. There are other rate adjustments (wage

index, IME, and DSH) to payments derived from the revised cost-based

weights and the cumulative effect of these components may not improve

the ability of final payment to reflect resource cost. With regard to

APCs and MS-DRGs that contain substantial device costs, RTI cautioned

that the other rate adjustments largely offset the effects of charge

compression among hospitals that receive these adjustments. RTI

endorsed short-term regression-based adjustments, but also concluded

that more refined and accurate accounting data are the preferred long-

term solution to mitigate charge compression and related bias in

hospital cost-based weights.

As a result of this research, RTI made 11 recommendations. For a

more detailed summary of RTI's findings, recommendations, and public

comments we received on the report, we refer readers to the FY 2009

IPPS final rule (73 FR 48452 through 48453).

b. Summary of the RAND Corporation Study of Alternative Relative Weight

Methodologies

One of the reasons that we did not implement regression-based CCRs

at the time of the FY 2008 IPPS final rule with comment period was our

inability to investigate how regression-based CCRs would interact with

the implementation of MS-DRGs. In the FY 2008 final rule with comment

period (72 FR 47197), we stated that we engaged the RAND Corporation as

the contractor to evaluate the HSRV methodology in conjunction with

regression-based CCRs, and that we would consider its analysis as we

prepared for the FY 2009 IPPS rulemaking process. In the FY 2009 IPPS

final rule (73 FR 48453 through 48457), we provided a summary of the

RAND report and the public comments we received in response to the FY

2009 IPPS proposed rule. The report may be found on RAND's Web site at:

http://www.rand.org/pubs/working\_papers/WR560/.

RAND evaluated six different methods that could be used to

establish relative weights, CMS' current relative weight methodology of

15 national CCRs and 5 alternatives, including a method in which the 15

national CCRs are disaggregated using the regression-based methodology,

and a method using hospital-specific CCRs for the 15 cost center

groupings. In addition, RAND analyzed our standardization methodologies

that account for systematic cost differences across hospitals. The

purpose of standardization is to eliminate

[[Page 24103]]

systematic facility-specific differences in cost so that these cost

differences do not influence the relative weights. The three

standardization methodologies analyzed by RAND include: The ``hospital

payment factor'' methodology currently used by CMS, under which a

hospital's wage index factor, and IME and/or DSH factor, are divided

out of its estimated DRG cost; the HSRV methodology, which standardizes

the cost for a given discharge by the hospital's own costliness rather

than by the effect of the systematic cost differences across groups of

hospitals; and the HSRVcc methodology, which removes hospital-level

cost variation by calculating hospital-specific charge-based relative

values for each DRG at the cost center level and standardizing them for

differences in case-mix. Under the HSRVcc methodology, a national

average charge-based relative weight is calculated for each cost

center.

Overall, RAND found that none of the alternative methods of

calculating the relative weights represented a marked improvement in

payment accuracy over the current method, and there was little

difference across methods in their ability to predict cost at either

the discharge-level or the hospital-level. In their regression

analysis, RAND found that after controlling for hospital payment

factors, the relative weights are compressed (that is, understated).

However, RAND also found that the hospital payment factors are

overstated and increase more rapidly than cost. Therefore, while the

relative weights are compressed, these payment factors offset the

compression such that total payments to hospitals increase more rapidly

than hospitals' costs.

RAND found that relative weights using the 19 national

disaggregated regression-based CCRs result in significant

redistributions in payments among hospital groupings. However, RAND did

not believe the regression-based charge compression adjustments

significantly improve payment accuracy. With regard to standardization

methodologies, while RAND found that there is no clear advantage to the

HSRV method or the HSRVcc method of standardizing cost compared to the

current hospital payment factor standardization method, its analysis

did reveal significant limitations of CMS' current hospital payment

factor standardization method. The current standardization method has a

larger impact on the relative weights and payment accuracy than any of

the other alternatives that RAND analyzed because the method ``over-

standardizes'' by removing more variability for hospitals receiving a

payment factor than can be empirically supported as being cost-related

(particularly for IME and DSH). RAND found that instead of increasing

proportionately with cost, the payment factors CMS currently uses (some

of which are statutory) increase more rapidly than cost, thereby

reducing payment accuracy. RAND concluded that further analysis is

needed to isolate the cost-related component of the IPPS payment

adjustments (some of which has already been done by MedPAC), use them

to standardize cost, and revise the analysis of payment accuracy to

reflect only the cost-related component.

2. Summary of FY 2009 Changes and Discussion for FY 2010

In the FY 2009 IPPS final rule (73 FR 48458 through 48467), in

response to the RTI's recommendations concerning cost report

refinements, and because of RAND's finding that regression-based

adjustments to the CCRs do not significantly improve payment accuracy,

we discussed our decision to pursue changes to the cost report to split

the cost center for Medical Supplies Charged to Patients into one line

for ``Medical Supplies Charged to Patients'' and another line for

``Implantable Devices Charged to Patients.'' We acknowledged, as RTI

had found, that charge compression occurs in several cost centers that

exist on the Medicare cost report. However, as we stated in the final

rule, we focused on the CCR for Medical Supplies and Equipment because

RTI found that the largest impact on the MS-DRG relative weights could

result from correcting charge compression for devices and implants. In

determining what should be reported in these respective cost centers,

we adopted the commenters' recommendation that hospitals should use

revenue codes established by AHA's National Uniform Billing Committee

to determine what should be reported in the ``Medical Supplies Charged

to Patients'' and the ``Implantable Devices Charged to Patients'' cost

centers.

When we developed the FY 2009 IPPS final rule, we considered all of

the public comments we received both for and against adopting

regression-based CCRs. Also noteworthy is RAND's belief that

regression-based CCRs may not significantly improve payment accuracy,

and that it is equally, if not more, important to consider revisions to

the current IPPS hospital payment factor standardization method in

order to improve payment accuracy. We continue to believe that,

ultimately, improved and more precise cost reporting is the best way to

minimize charge compression and improve the accuracy of the cost

weights. Accordingly, we are not proposing to adopt regression-based

CCRs for the calculation of the FY 2010 IPPS relative weights.

However, we are concerned about RAND's finding that there are

significant limitations of CMS' current hospital payment factor

standardization method. As summarized above, RAND found that the

current standardization method ``over-standardizes'' by removing more

variability for hospitals receiving a payment factor than can be

empirically supported as being cost-related (particularly for IME and

DSH). RAND found that instead of increasing proportionately with cost,

the payment factors CMS currently uses (some of which are statutory)

increase more rapidly than cost, thereby reducing payment accuracy.

Further analysis is needed to isolate the cost-related component of the

IPPS payment adjustments, use them to standardize cost, and revise the

analysis of payment accuracy to reflect only the cost-related

component. However, RAND cautions that ``re-estimating'' these payment

factors ``raises important policy issues that warrant additional

analyses'' (page 49 of RAND's report, which is available on the Web

site at: http://www.rand.org/pubs/working\_papers/WR560/), particularly

to ``determine the analytically justified-levels using the MS-DRGs''

(page 86 of the RAND report). In addition, we note that RTI, in its

July 2008 final report, also observed that the adjustment factors under

the IPPS (the wage index, IME, and DSH adjustments) complicate the

determination of cost and these factors ``within the rate calculation

may offset the effects of understated weights due to charge

compression'' (page 109 of RTI's final report, which is available at

the Web site at: http://www.rti.org/reports/cms/HHSM-500-2005-0029I/

PDF/Refining\_Cost\_to\_Charge\_Ratios\_200807\_Final.pdf). While it

may be more accurate to standardize using the empirically justified

levels of the IME and DSH adjustments, consideration needs to be given

to the extent to which these payment factors offset the compression of

the relative weights.

We understand that MedPAC has performed an analysis to identify

empirically justifiable formulas for determining appropriate IME and

DSH adjustments. For example, in its March 2007 report (and reiterated

in its March 2009 report), MedPAC asserts that the current level of the

IME adjustment factor, 5.5 percent for every 10 percent increase in

resident-to-bed ratio, overstates IME payments by more than

[[Page 24104]]

twice the empirically justified level, resulting in approximately $3

billion in overpayments. The empirical level of the IME adjustment is

estimated to be 2.2 percent for every 10 percent increase in the

resident-to-bed ratio. We cannot propose to change the IME and DSH

factors used for actual payment under the IPPS because these factors

are mandated by law. However, under section 1886(d)(4) of the Act, we

have the authority to determine the appropriate weighting factor for

each MS-DRG (including which factors or method we will employ in making

annual adjustments to the MS-DRGs so as to reflect changes in the

relative use of hospital resources). In addition, section 1886(d)(7)(B)

of the Act precludes judicial review of our methodology for determining

the appropriate weighting factors. Therefore, we do have some

flexibility in what factors may be used for standardization purposes.

For purposes of standardization only, one option may be for CMS to use

the empirically justified IME adjustment of 2.2 percent, such that only

the cost-related component of teaching hospitals is removed from the

claim charges prior to calculating the relative weights. Similarly, for

the DSH adjustment, in its March 2007 report, MedPAC found that costs

per case increase about 0.4 percent for each 10 percent increase in the

low income patient percentage. This is significantly less than the

percentage increase expressed by the current factors used in the DSH

payment formulas. (According to MedPAC, in FY 2004, about $5.5 billion

in DSH payments were made above the empirically justified level.) In

looking only at urban hospitals with greater than 100 beds, which

manifest the strongest positive correlation between cost and low income

patient share, MedPAC found that costs increase about 1.4 percent for

every 10 percent increment of the low-income patient percentage. MedPAC

did not find a positive cost relationship between low-income patient

percentage and costs per case for urban hospitals with less than 100

beds and/or for rural hospitals. Therefore, for purposes of

standardizing for the DSH adjustment, an option we may consider is to

incorporate an adjustment factor of 1.4 percent for urban hospitals

with greater than 100 beds, and to remove the DSH payment adjustment

altogether for other hospitals that otherwise currently qualify for DSH

payment. While we cannot predict the effect of using the empirical

factors for IME and DSH in the standardized methodology on the relative

weights without further analysis, dividing out (that is, excluding)

reduced IME and DSH payment factors from a hospital's total payment

would result in a greater share of teaching and DSH hospitals' costs

used in calculating the relative weights. With respect to the wage

index, because there are multiple wage index factors, one for each

geographic area, determining the true cost associated with geographic

location and standardizing for those costs is much more challenging.

While we are not proposing changes for FY 2010, in light of the

previous discussion of the current IME and DSH adjustments in the

standardization process, we are interested in receiving public comments

as to how the standardization process can be improved to more precisely

remove cost differences across hospitals, thereby improving the

accuracy of the relative weights in subsequent fiscal years.

3. Timeline for Revising the Medicare Cost Report

As mentioned in the FY 2009 IPPS final rule (73 FR 48467), we are

currently in the process of comprehensively reviewing the Medicare

hospital cost report, and the finalized policy from the FY 2009 IPPS

final rule to split the current cost center for Medical Supplies

Charged to Patients into one line for ``Medical Supplies Charged to

Patients'' and another line for ``Implantable Devices Charged to

Patients,'' as part of our initiative to update and revise the hospital

cost report. Under an effort initiated by CMS to update the Medicare

hospital cost report to eliminate outdated requirements in conjunction

with provisions of the Paperwork Reduction Act (PRA), we have been

planning to propose the actual changes to the cost reporting form, the

attending cost reporting software, and the cost reporting instructions

in Chapter 40 of the Medicare Provider Reimbursement Manual (PRM), Part

II. Under the effort to update the cost report and eliminate outdated

requirements in conjunction with the provisions of the PRA, changes to

the cost reporting form and cost reporting instructions would be made

available to the public for comment. Thus, the public would have an

opportunity to suggest comprehensive reforms (which they had advocated

in the FY 2009 IPPS final rule in response to our proposals), and would

similarly be able to make suggestions for ensuring that these reforms

are made in a manner that is not disruptive to hospitals' billing and

accounting systems, and are within the guidelines of GAAP, Medicare

principles of reimbursement, and sound accounting practices.

In the FY 2009 IPPS final rule (73 FR 48468), we stated that we

expect the revised cost reporting forms that reflect one cost center

for ``Medical Supplies Charged to Patients'' and one cost center for

``Implantable Devices Charged to Patients'' would not be available

until cost reporting periods beginning after the Spring of 2009. At

this time, we anticipate that the transmittal to create this new cost

center will be issued in June 2009. Because there is approximately a 3-

year lag between the availability of cost report data for IPPS and OPPS

ratesetting purposes in a given fiscal year or calendar year, we may be

able to derive two distinct CCRs, one for medical supplies and one for

devices, for use in calculating the FY 2013 IPPS relative weights and

the CY 2013 OPPS relative weights. Until the revised cost reporting

forms are published, hospitals must include costs and charges of

separately chargeable medical supplies and implantable medical devices

in the cost center for ``Medical Supplies Charged to Patients''

(section 2202.8 of the PRM-I), and effective for cost reporting periods

specified in the revised cost reporting forms, hospitals must include

costs and charges of separately chargeable medical supplies in the cost

center for ``Medical Supplies Charged to Patients'' and of separately

chargeable implantable medical devices in the new ``Implantable Devices

Charged to Patients'' cost center.

F. Preventable Hospital-Acquired Conditions (HACs), Including

Infections

1. Statutory Authority

Section 1886(d)(4)(D) of the Act addresses certain hospital-

acquired conditions (HACs), including infections. By October 1, 2007,

the Secretary was required to select, in consultation with CDC, at

least two conditions that: (a) Are high cost, high volume, or both; (b)

are assigned to a higher paying MS-DRG when present as a secondary

diagnosis (that is, conditions under the MS-DRG system that are CCs or

MCCs); and (c) could reasonably have been prevented through the

application of evidence-based guidelines. The list of conditions can be

revised from time to time, again in consultation with CDC, as long as

the list contains at least two conditions.

Medicare continues to assign a discharge to a higher paying MS-DRG

if a selected condition is present on admission (POA). However, since

October 1, 2008, Medicare no longer assigns an inpatient hospital

discharge to a higher paying MS-DRG if a selected

[[Page 24105]]

condition is not POA. That is, if there is a HAC, the case is paid as

though the secondary diagnosis was not present. However, if any

nonselected CC/MCC appears on the claim, the claim will be paid at the

higher MS-DRG rate; to cause a lower MS-DRG payment, all CCs/MCCs on

the claim must be selected conditions for the HAC payment provision.

Since October 1, 2007, hospitals have been required to submit

information on Medicare claims specifying whether diagnoses were POA.

The POA indicator reporting requirement and the HAC payment provision

apply to IPPS hospitals only. Non-IPPS hospitals, including CAHs,

LTCHs, IRFs, IPFs, cancer hospitals, children's hospitals, hospitals in

Maryland operating under waivers, rural health clinics, federally

qualified health centers, RNHCIs, and Department of Veterans Affairs/

Department of Defense hospitals, are exempt from POA reporting and the

HAC payment provision. Throughout this section, the term ``hospital''

refers to IPPS hospitals.

2. HAC Selection Process

In the FY 2007 IPPS proposed rule (71 FR 24100), we sought public

input regarding conditions with evidence-based prevention guidelines

that should be selected in implementing section 1886(d)(4)(D) of the

Act. The public comments we received were summarized in the FY 2007

IPPS final rule (71 FR 48051 through 48053).

In the FY 2008 IPPS proposed rule (72 FR 24716 through 24726), we

sought public comment on conditions that we proposed to select. In the

FY 2008 IPPS final rule with comment period (72 FR 47200 through

47218), we selected 8 categories to which the HAC payment provisions

would apply.

In the FY 2009 IPPS proposed rule (73 FR 23547), we proposed

several additional candidate HACs and proposed refinements to the

previously selected HACs. In the FY 2009 IPPS final rule (73 FR 48471),

we expanded and refined several of the previously-selected HACs and we

selected 2 additional categories of HACs. A complete list of the 10

current categories of HACs is included in section II.F.4. of this

preamble.

3. Collaborative Process

CMS experts have worked closely with public health and infectious

disease professionals from the CDC to identify the candidate

preventable HACs, review comments, and select HACs. CMS and CDC staff

have also collaborated on the process for hospitals to submit a POA

indicator for each diagnosis listed on IPPS hospital Medicare claims

and on the payment implications of the various POA reporting options.

On December 17, 2007, CMS and CDC hosted a jointly sponsored HAC

and POA Listening Session to receive input from interested

organizations and individuals. On December 18, 2008, CMS and CDC again

hosted a jointly sponsored HAC and POA Listening Session to receive

input from interested organizations and individuals. Experts from AHRQ

also participated in the event. The agenda, presentations, audio file,

and written transcript of the December 18, 2008, Listening Session are

available on the CMS Web site at: http://www.cms.hhs.gov/

HospitalAcqCond/07\_EducationalResources.asp#TopOfPage.

4. Selected HAC Categories

The following table lists the current HACs.

------------------------------------------------------------------------

HAC CC/MCC (ICD-9-CM code)

------------------------------------------------------------------------

Foreign Object Retained After Surgery.. 998.4 (CC), 998.7 (CC).

Air Embolism........................... 999.1 (MCC).

Blood Incompatibility.................. 999.6 (CC).

Pressure Ulcer Stages III & IV......... 707.23 (MCC), 707.24 (MCC).

Falls and Trauma: Codes within these ranges on

--Fracture the CC/MCC list: 800-829, 830-

--Dislocation 839, 850-854, 925-929, 940-

--Intracranial Injury 949, 991-994.

--Crushing Injury

--Burn

--Electric Shock

Catheter-Associated Urinary Tract 996.64 (CC).

Infection (UTI).

Also excludes the following

from acting as a CC/MCC: 112.2

(CC), 590.10 (CC), 590.11

(MCC), 590.2 (MCC), 590.3

(CC), 590.80 (CC), 590.81

(CC), 595.0 (CC), 597.0 (CC),

599.0 (CC).

Vascular Catheter-Associated Infection. 999.31 (CC).

Manifestations of Poor Glycemic Control 250.10-250.13 (MCC), 250.20-

250.23 (MCC), 251.0 (CC),

249.10-249.11 (MCC), 249.20-

249.21 (MCC).

Surgical Site Infections:

Surgical Site Infection, Mediastinitis, 519.2 (MCC).

Following Coronary Artery Bypass Graft And one of the following

(CABG). procedure codes: 36.10-36.19.

Surgical Site Infection Following 996.67 (CC), 998.59 (CC).

Certain Orthopedic Procedures.

And one of the following

procedure codes: 81.01-81.08,

81.23-81.24, 81.31-81.38,

81.83, 81.85.

Surgical Site Infection Following Principal Diagnosis--278.01,

Bariatric Surgery for Obesity. 998.59 (CC).

And one of the following

procedure codes: 44.38, 44.39,

or 44.95.

Deep Vein Thrombosis and Pulmonary 415.11 (MCC), 415.19 (MCC),

Embolism Following Certain Orthopedic 453.40-453.42 (MCC).

Procedures. And one of the following

procedure codes: 00.85-00.87,

81.51-81.52, or 81.54.

------------------------------------------------------------------------

We refer readers to section II.F.6. of the FY 2008 IPPS final rule

with comment period (72 FR 47202 through 47218) and to section II.F.7.

of the FY 2009 IPPS final rule with comment period (73 FR 48474 through

48486) for detailed analyses supporting the selection of each of these

HACs.

The list of selected HAC categories is dependent upon CMS' list of

diagnoses designated as CC/MCCs. As changes and/or new diagnosis codes

are proposed and finalized to the list of CC/MCCs, these changes need

to be reflected in the list of selected HAC

[[Page 24106]]

categories. We refer readers to Table 6A in the Addendum to this

proposed rule for proposed changes. In Table 6A, we are proposing the

following changes that reflect the new diagnosis codes that are within

the fracture code range for the falls/trauma HAC category:

------------------------------------------------------------------------

Proposed CC/

ICD-9-CM code Code descriptor MCC

designations

------------------------------------------------------------------------

813.46.................... Torus fracture of ulna...... CC

813.47.................... Torus fracture of radius and CC

ulna.

------------------------------------------------------------------------

If these proposed CC designations for ICD-9-CM codes 813.46 and

813.47 are finalized, these codes will be adopted within the fracture

code range for the falls/trauma HAC category.

5. Public Input Regarding Selected and Potential Candidate HACs

We are not proposing to add or remove categories of HACs at this

time. However, we continue to encourage public dialogue about

refinements to the HAC list. During and after the December 18, 2008

Listening Session, we received many oral and written stakeholder

comments about both previously selected and potential candidate HACs.

Some stakeholders commented on previously selected HACs. For

example, one commenter requested a coding change to the Stages III and

IV Pressure Ulcer HAC. The commenter recommended that CMS include the

following ICD-9-CM codes to further define pressure ulcers as a HAC:

(1) 707.20 (Pressure ulcer, unspecified stage); and (2) 707.25

(Pressure ulcer, unstageable). However, these codes are not classified

as CCs or MCCs and, therefore, do not meet the statutory requirement of

causing a higher paying MS-DRG.

Commenters strongly supported using information gathered from early

experience with the HAC payment provision to inform maintenance of the

HAC list and consideration of future potential candidate HACs. Now that

we have early program data, we are focused on evaluating the impact of

the HAC payment provision through a joint program evaluation with CDC

and AHRQ. That evaluation process will provide valuable information for

future policymaking aimed at preventing HACs. Commenters emphasized

during the IPPS FY 2009 rulemaking and during and after the December

18, 2008 Listening Session the need for a robust program evaluation

prior to changing the HAC list.

As an early aspect of the program evaluation, we plan to analyze

the available POA data. This early analysis may be useful for future

HAC policymaking and for other purposes like identifying priorities for

the development of HAC prevention guidelines.

6. POA Indicator Reporting

Collection of POA indicator data is necessary to identify which

conditions were acquired during hospitalization for the HAC payment

provision as well as for broader public health uses of Medicare data.

Through Change Request No. 5679 (released on June 20, 2007), CMS issued

instructions requiring IPPS hospitals to submit POA indicator data for

all diagnosis codes on Medicare claims. CMS also issued Change Request

No. 6086 (released on June 13, 2008) regarding instructions for

processing non-IPPS claims. Specific instructions on how to select the

correct POA indicator for each diagnosis code are included in the ICD-

9-CM Official Guidelines for Coding and Reporting, available on the CDC

Web site at: http://www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/

icdguide07.pdf (the POA reporting guidelines begin on page 92).

Additional information regarding POA indicator reporting and

application of the POA reporting options is available on the CMS Web

site at: http://www.cms.hhs.gov/HospitalAcqCond. CMS has historically

not provided coding advice. Rather, CMS collaborates with the American

Hospital Association (AHA) through the Coding Clinic for ICD-9-CM. CMS

has been collaborating with the AHA to promote the Coding Clinic for

ICD-9-CM as the source for coding advice about the POA indicator.

There are five POA indicator reporting options, as defined by the

ICD-9-CM Official Guidelines for Coding and Reporting:

------------------------------------------------------------------------

Indicator Descriptor

------------------------------------------------------------------------

Y................................. Indicates that the condition was

present on admission.

W................................. Affirms that the provider has

determined based on data and

clinical judgment that it is not

possible to document when the onset

of the condition occurred.

N................................. Indicates that the condition was not

present on admission.

U................................. Indicates that the documentation is

insufficient to determine if the

condition was present at the time

of admission.

1................................. Signifies exemption from POA

reporting. CMS established this

code as a workaround to blank

reporting on the electronic 4010A1.

A list of exempt ICD-9-CM diagnosis

codes is available in the ICD-9-CM

Official Guidelines for Coding and

Reporting.

------------------------------------------------------------------------

In the FY 2009 IPPS final rule (73 FR 48487), we adopted our

proposal to: (1) Pay the CC/MCC MS-DRGs for those HACs coded with ``Y''

and ``W'' indicators; and (2) not pay the CC/MCC MS-DRGs for those HACs

coded with ``N'' and ``U'' indicators. We are not proposing changes to

the payment implications of the POA indicator reporting options at this

time.

As we have noted in previous IPPS rulemaking documents, most

recently in the FY 2009 IPPS final rule (73 FR 48487), the American

Health Information Management Association (AHIMA) has promulgated

Standards of Ethical Coding that require accurate coding regardless of

the payment implications of the diagnoses. Further, Medicare program

integrity initiatives closely monitor for inaccurate coding and coding

inconsistent with medical record documentation.

G. Proposed Changes to Specific MS-DRG Classifications

1. MDC 5 (Diseases and Disorders of the Circulatory System):

Intraoperative Fluorescence Vascular Angiography (IFVA)

We received a request to reassign cases reporting the use of

intraoperative fluorescence vascular angiography (IFVA) with coronary

artery bypass graft (CABG) procedures from MS-DRGs 235 and 236

(Coronary Bypass without Cardiac Catheterization with and without MCC,

respectively) into MS-DRG 233 (Coronary Bypass with Cardiac

Catheterization with MCC) and MS-DRG 234 (Coronary Bypass with Cardiac

Catheterization without MCC). Effective October 1, 2007, procedure code

88.59 (Intraoperative fluorescence vascular angiography (IFVA))

describes this technology.

IFVA technology consists of a mobile device imaging system with

software. The technology is used to test cardiac graft patency and

technical adequacy at the time of coronary artery bypass grafting

(CABG). While this system does not involve fluoroscopy or cardiac

catheterization, it has been suggested by the manufacturer and clinical

studies that it yields results that are similar to those achieved with

selective coronary

[[Page 24107]]

arteriography and cardiac catheterization. Intraoperative coronary

angiography provides information about the quality of the anastomosis,

blood flow through the graft, distal perfusion and durability. For

additional detailed information regarding IFVA technology, we refer

readers to the September 28-29, 2006 ICD-9-CM Coordination and

Maintenance Committee meeting handout at the following Web site: http:/

/www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/03\_

meetings.asp#TopOfPage.

We examined data on cases identified by procedure code 88.59 in MS-

DRGs 233, 234, 235, and 236 in the FY 2008 MedPAR file. As shown in the

table below, for both MS-DRGs 235 and 236, the cases utilizing IFVA

technology identified by procedure code 88.59 have a shorter length of

stay and lower average costs compared to all cases in MS-DRGs 235 and

236. There were a total of 10,312 cases in MS-DRG 235 with an average

length of stay of 11.12 days with average costs of $33,846. There were

88 cases in MS-DRG 235 identified by procedure code 88.59 with an

average length of stay of 9.82 days with average costs of $29,258. In

MS-DRG 236, there were a total of 24,799 cases with an average length

of stay of 6.52 days and average costs of $22,329. There were 159 cases

in MS-DRG 236 identified by procedure code 88.59 with an average length

of stay of 6.30 days and average costs of $20,404. The data clearly

demonstrate that the IFVA cases identified by procedure code 88.59 are

assigned appropriately to MS-DRGs 235 and 236. We also examined data on

cases identified by procedure code 88.59 in MS-DRGs 233 and 234.

Similarly, in MS-DRGs 233 and 234, cases identified by procedure code

88.59 reflect shorter lengths of stay and lower average costs compared

to all of the other cases in those MS-DRGs. There were a total of

17,453 cases in MS-DRG 233 with an average length of stay of 13.65 days

with average costs of $41,199. There were 60 cases in MS-DRG 233

identified by procedure code 88.59 with an average length of stay of

12.82 days and average costs of $38,842. In MS-DRG 234, there were a

total of 27,003 cases with an average length of stay of 8.70 days and

average costs of $28,327. There were 69 cases in MS-DRG 234 identified

by procedure code 88.59 with an average length of stay of 8.75 days and

average costs of $25,308. As a result of our analysis, the data

demonstrate that the IFVA cases identified by procedure code 88.59 are

appropriately assigned to MS-DRGs 233 and 234.

------------------------------------------------------------------------

Average

MS-DRG Number of length of Average

cases stay cost\*

------------------------------------------------------------------------

235--All cases................... 10,312 11.12 $33,846

235--Cases with code 88.59....... 88 9.82 29,258

235--Cases without code 88.59.... 10,224 11.14 33,886

236--All cases................... 24,799 6.52 22,329

236--Cases with code 88.59....... 159 6.30 20,404

236--Cases without code 88.59.... 24,640 6.52 22,341

------------------------------------------------------------------------

Average

MS-DRG Number of length of Average

cases stay cost\*

------------------------------------------------------------------------

233--All cases................... 17,453 13.65 $41,199

233--Cases with code 88.59....... 60 12.82 38,842

233--Cases without code 88.59.... 17,393 13.65 41,207

234--All cases................... 27,003 8.70 28,327

234--Cases with code 88.59....... 69 8.75 25,308

234--Cases without code 88.59.... 26,934 8.70 28,334

------------------------------------------------------------------------

\* In the FY 2007 IPPS final rule (71 FR 47882), we adopted a cost-based

weighting methodology. The cost-based weights were adopted over a 3-

year transition period in 1/3 increments between FY 2007 and FY 2009.

The average cost represents the average standardized charges on the

claims reduced to cost using the cost center-specific CCRs for a

specific DRG. The standardization process includes adjustments for

IME, DSH, and wage index as applied to individual hospitals. This

estimation of cost is the same method used in the computation of the

relative weights. We are using cost-based data instead of our

historical charge-based data to evaluate proposed MS-DRG

classification changes.

We believe that if the cases identified by procedure code 88.59

were proposed to be reassigned from MS-DRGs 235 and 236 to MS-DRGs 233

and 234, they would be significantly overpaid. In addition, because the

cases in MS-DRGs 235 and 236 did not actually have a cardiac

catheterization performed, a proposal to reassign cases identified by

procedure code 88.59 would result in lowering the relative weights of

MS-DRGs 233 and 234 where a cardiac catheterization is truly performed.

In summary, the data do not support moving IFVA cases identified by

procedure code 88.59 from MS-DRGs 235 and 236 into MS-DRGs 233 and 234.

We invite the public to submit comments on our proposal not to make any

MS-DRG modifications for cases reporting procedure code 88.59 for FY

2010.

2. MDC 8 (Diseases and Disorders of the Musculoskeletal System and

Connective Tissue): Infected Hip and Knee Replacements

We received a request that we examine the issue of patients who

have undergone hip or knee replacement procedures that have

subsequently become infected and who are then admitted for inpatient

services for removal of the prosthesis. The requestor stated that these

patients are presented with devastating complications and require

extensive resources to treat. The infection often results in the need

for multiple re-operations, prolonged use of intravenous and oral

antibiotics, extended rehabilitation, and frequent followups.

Furthermore, the requestor stated that, even with extensive treatment,

the outcomes can still be poor for some of these patients. The

requestor stated that patients who are admitted for inpatient services

with an infected hip or knee prosthesis must first undergo a procedure

to remove the prosthesis and to insert an antibiotic spacer to treat

the infection and maintain a space for the new prosthesis. The new

prosthesis cannot be inserted until after the infection has been

treated. Patients who are admitted for inpatient services with a hip or

knee infection and then undergo a removal of the prosthesis are

captured by the following procedure codes:

[[Page 24108]]

80.05 (Arthrotomy for removal of prosthesis, hip)

80.06 (Arthrotomy for removal of prosthesis, knee)

In addition, code 84.56 (Insertion or replacement of (cement)

spacer) would be used for any insertion of a spacer that would be

reported if an antibiotic spacer were inserted.

The issue of hip and knee infections and revisions was discussed in

the FY 2009 IPPS final rule (73 FR 48498 through 48507) in response to

a more complicated request that we received involving the creation and

modification of several joint DRGs. Because data did not support the

requestor's suggested changes, we did not make any modifications to the

joint DRGs at that time.

The current requestor asked that we move cases involving the

removal of hip and knee prostheses (procedure codes 80.05 and 80.06)

from their current assignment in MS-DRGs 480, 481, and 482 (Hip and

Femur Procedures Except Major Joint with MCC, with CC, without CC/MCC,

respectively) and in MS-DRGs 495, 496, and 497 (Local Excision of

Internal Fixation Device Except Hip and Femur with MCC, with CC, and

with CC/MCC, respectively) and assign them to MS-DRGs 463, 464, and 465

(Wound Debridement and Skin Graft Except Hand, for Musculo-Connective

Tissue Disease with MCC, with CC, without CC/MCC, respectively). MS-

DRGs 463, 464, and 465 include cases that are treated with a

debridement for infection. The requestor stated that these cases are

clinically similar to those captured by procedure codes 80.05 and 80.06

where the prosthesis is removed and a new prosthesis is not inserted

because of an infection.

The requestor specifically asked that we remove the hip arthrotomy

code 80.05 from MS-DRGs 480, 481, and 482, and assign it to MS-DRGs

463, 464, and 465. The requestor also recommended that we remove the

knee arthrotomy code 80.06 from MS-DRGs 495, 496, and 497 and assign it

to MS-DRGs 463, 464, and 465.

If we were to accept the requestor's suggestion, joint replacement

cases in which the patients were admitted for inpatient services to

remove the prosthesis because of an infection would be assigned to the

higher paying debridement MS-DRGs (MS-DRGs 463, 464, and 465). As

mentioned earlier, these MS-DRGs contain other cases involving

treatment for infections.

We examined hip replacement cases identified by procedure code

80.05 in MS-DRGs 480, 481, and 482, and knee replacement cases

identified by procedure code 80.06 in MS-DRGs 495, 496, and 497 using

the FY 2008 MedPAR file. Our data support the requestor's suggestion

that these cases have similar costs to those in MS-DRGs 463, 464, and

465, and that they are significantly more expensive to treat than those

in their current MS-DRG assignments. The following table summarizes

those findings:

------------------------------------------------------------------------

Average

MS-DRG Number of length of Average

cases stay cost\*

------------------------------------------------------------------------

463--All Cases................... 4,834 16.59 $26,696

464--All Cases................... 4,934 9.52 15,065

465--All Cases................... 1,696 5.45 9,041

480--All Cases................... 31,181 8.89 17,168

480--Cases with code 80.05....... 643 13.35 26,053

480--Cases without code 80.05.... 30,538 8.80 16,981

481--All Cases................... 72,406 5.68 11,259

481--Cases with code 80.05....... 871 8.34 17,202

481--Cases without code 80.05.... 71,535 5.65 11,187

482--All Cases................... 37,443 4.65 9,320

482--Cases with code 80.05....... 282 6.82 13,718

482--Cases without code 80.05.... 37,161 4.63 9,287

495--All Cases................... 2,140 10.40 18,729

495--Cases with code 80.06....... 513 11.53 23,508

495--Cases without code 80.06.... 1,627 10.04 17,432

496--All Cases................... 5,518 5.73 10,827

496--Cases with code 80.06....... 1,346 6.67 14,454

496--Cases without code 80.06.... 4,172 5.42 9,657

497--All Cases................... 5,856 2.84 7,148

497--Cases with code 80.06....... 688 5.08 12,234

497--Cases without code 80.06.... 5,168 2.54 6,470

------------------------------------------------------------------------

\* In the FY 2007 IPPS final rule (71 FR 47882), we adopted a cost-based

weighting methodology. The cost-based weights were adopted over a 3-

year transition period in 1/3 increments between FY 2007 and FY 2009.

The average cost represents the average standardized charges on the

claims reduced to cost using the cost center-specific CCRs for a

specific DRG. The standardization process includes adjustments for

IME, DSH, and wage index as applied to individual hospitals. This

estimation of cost is the same method used in the computation of the

relative weights. We are using cost-based data instead of our

historical charge-based data to evaluate proposed MS-DRG

classification changes.

The data show that hip replacement cases with procedure code 80.05

in MS-DRGs 480, 481, and 482 have average costs of $26,053, $17,202,

and $13,718, respectively, compared to overall average costs of $17,168

in MS-DRG 480; $11,259 in MS-DRG 481; and $9,320 in MS-DRG 482. The

data also show that knee replacement cases with procedure code 80.06 in

MS-DRGs 495, 496, and 497 have average costs of $23,508, $14,454, and

$12,234, respectively, compared to average costs of all cases of

$18,729 in MS-DRG 495, $10,827 in MS-DRG 496, and $7,148 in MS-DRG 497.

All cases in MS-DRGs 463, 464, and 465 had average costs of $26,696,

$15,065, and $9,041, respectively.

The results of this analysis of data support the reassignment of

procedure codes 80.05 and 80.06 to MS-DRGs 463, 464, and 465.

Therefore, we are proposing to move procedure codes 80.05 and 80.06

from their current assignments in MS-DRGs 480, 481, and 482 and 495,

496, and 497 and assign them to MS-DRGs 463, 464, and 465. We also are

proposing to revise the code title of procedure code 80.05 to read

``Arthrotomy for removal of prosthesis without replacement, hip'' and

the title of procedure code 80.06 to read ``Arthrotomy for removal of

prosthesis without replacement, knee'', effective October 1, 2009, as

is shown in Table

[[Page 24109]]

6F of the Addendum to this proposed rule.

3. Proposed Medicare Code Editor (MCE) Changes

As explained under section II.B.1. of the preamble of this final

rule, the Medicare Code Editor (MCE) is a software program that detects

and reports errors in the coding of Medicare claims data. Patient

diagnoses, procedure(s), and demographic information are entered into

the Medicare claims processing systems and are subjected to a series of

automated screens. The MCE screens are designed to identify cases that

require further review before classification into a DRG. For FY 2010,

we are proposing to make the following changes to the MCE edits:

a. Diagnoses Allowed for Males Only Edit

There are four diagnosis codes that were inadvertently left off of

the MCE edit titled ``Diagnoses Allowed for Males Only.'' These codes

are located in the chapter of the ICD-9-CM diagnosis codes entitled

``Diseases of Male Genital Organs.'' In the FY 2009 IPPS final rule, we

indicated that we were adding the following four codes to this MCE

edit:

603.0 (Encysted hydrocele)

603.1 (Infected hydrocele)

603.8 (Other specified types of hydrocele)

603.9 (Hydrocele, unspecified).

We had no reported problems or confusion with the omission of these

codes from this section of the MCE, but in order to have an accurate

product, we indicated that we were adding these codes for FY 2009.

However, through an oversight, we failed to implement the indicated FY

2009 changes to the MCE by adding codes 603.0, 603.1, 603.8, and 603.9

to the MCE edit of diagnosis allowed for males only. In this FY 2010

IPPS proposed rule, we are acknowledging this omission and are again

proposing to make the changes.

b. Manifestation Codes as Principal Diagnosis Edit

Manifestation codes describe the manifestation of an underlying

disease, not the disease itself. Therefore, manifestation codes should

not be used as a principal diagnosis. The National Center for Health

Statistics (NCHS) has removed the advice ``code first associated

disorder'' from three codes, thereby making them acceptable principal

diagnosis codes. These codes are:

365.41 (Glaucoma associated with chamber angle anomalies)

365.42 (Glaucoma associated with anomalies of iris)

365.43 (Glaucoma associated with other anterior segment

anomalies)

In order to make conforming changes to the MCE, we are proposing to

remove codes 365.41, 365.42, and 365.43 from the Manifestation Code as

Principal Diagnosis Edit.

c. Invalid Diagnosis or Procedure Code

The MCE checks each diagnosis, including the admitting diagnosis,

and each procedure against a table of valid ICD-9-CM codes. If an

entered code does not agree with any code on the list, it is assumed to

be invalid or that the 4th or 5th digit of the code is invalid or

missing.

An error was discovered in this edit. ICD-9-CM code 00.01

(Therapeutic ultrasound of vessels of head and neck) was inadvertently

left out of the MCE tables. The inclusion of this code in the MCE

tables would have generated an error message at the Medicare contractor

level, but we had instructed the Medicare contractors to override this

edit for discharges on or after October 1, 2008. To make a conforming

change to the MCE, we are proposing to add code 00.01 to the table of

valid codes.

d. Unacceptable Principal Diagnosis

There are selected codes that describe a circumstance that

influences an individual's health status but not a current illness or

injury and codes that are not specific manifestations but may describe

illnesses due to an underlying cause. These codes are considered

unacceptable as a principal diagnosis.

For FY 2008, a series of diagnostic codes were created at

subcategory 209, Neuroendocrine Tumors. An instructional note under

this subcategory stated that coders were to ``Code first any associated

multiple endocrine neoplasia syndrome (258.01-258.03)''. Medicare

contractors had interpreted this note to mean that none of the codes in

subcategory 209 were acceptable principal diagnoses and had entered

these codes on the MCE edit for unacceptable principal diagnoses. We

later deemed this interpretation to be incorrect. We had not intended

that the series of codes at subcategory 209 were only acceptable as

secondary diagnoses.

To avoid future misinterpretation, in this proposed rule, we are

proposing to remove the following codes from the MCE edit for

unacceptable principal diagnoses.

209.00 (Malignant carcinoid tumor of the small intestine,

unspecified portion)

209.01 (Malignant carcinoid tumor of the duodenum)

209.02 (Malignant carcinoid tumor of the jejunum)

209.03 (Malignant carcinoid tumor of the ileum)

209.10 (Malignant carcinoid tumor of the large intestine,

unspecified portion)

209.11 (Malignant carcinoid tumor of the appendix)

209.12 (Malignant carcinoid tumor of the cecum)

209.13 (Malignant carcinoid tumor of the ascending colon)

209.14 (Malignant carcinoid tumor of the transverse colon)

209.15 (Malignant carcinoid tumor of the descending colon)

209.16 (Malignant carcinoid tumor of the sigmoid colon)

209.17 (Malignant carcinoid tumor of the rectum)

209.20 (Malignant carcinoid tumor of unknown primary site)

209.21 (Malignant carcinoid tumor of the bronchus and

lung)

209.22 (Malignant carcinoid tumor of the thymus)

209.23 (Malignant carcinoid tumor of the stomach)

209.24 (Malignant carcinoid tumor of the kidney)

209.25 (Malignant carcinoid tumor of foregut, not

otherwise specified)

209.26 (Malignant carcinoid tumor of midgut, not otherwise

specified)

209.27 (Malignant carcinoid tumor of hindgut, not

otherwise specified)

209.29 (Malignant carcinoid tumor of other sites)

209.30 (Malignant poorly differentiated neuroendocrine

carcinoma, any site)

209.40 (Benign carcinoid tumor of the small intestine,

unspecified portion)

209.41 (Benign carcinoid tumor of the duodenum)

209.42 (Benign carcinoid tumor of the jejunum)

209.43 (Benign carcinoid tumor of the ileum)

209.50 (Benign carcinoid tumor of the large intestine,

unspecified portion)

209.51 (Benign carcinoid tumor of the appendix)

209.52 (Benign carcinoid tumor of the cecum)

209.53 (Benign carcinoid tumor of the ascending colon)

209.54 (Benign carcinoid tumor of the transverse colon)

209.55 (Benign carcinoid tumor of the descending colon)

209.56 (Benign carcinoid tumor of the sigmoid colon)

209.57 (Benign carcinoid tumor of the rectum)

209.60 (Benign carcinoid tumor of unknown primary site)

209.61 (Benign carcinoid tumor of the bronchus and lung)

209.62 (Benign carcinoid tumor of the thymus)

[[Page 24110]]

209.63 (Benign carcinoid tumor of the stomach)

209.64 (Benign carcinoid tumor of the kidney)

209.65 (Benign carcinoid tumor of foregut, not otherwise

specified)

209.66 (Benign carcinoid tumor of midgut, not otherwise

specified)

209.67 (Benign carcinoid tumor of hindgut, not otherwise

specified)

209.69 (Benign carcinoid tumor of other sites)

In the meantime, CMS has issued instructions in the form of an

interim working document called a joint signature memorandum to the

Medicare contractors to override this edit and process claims

containing codes from the subcategory 209 series as acceptable

principal diagnoses.

e. Proposed Creation of New Edit Titled ``Wrong Surgeries''

On January 15, 2009, CMS issued three National Coverage Decision

memoranda on the coverage of erroneous surgeries on Medicare patients:

Wrong Surgical or Other Invasive Procedure Performed on a Patient (CAG-

00401N); Surgical or Other Invasive Procedure Performed on the Wrong

Body Part (CAG-00402N); and Surgical or Other Invasive Procedure

Performed on the Wrong Patient (CAG-00403N). We refer readers to the

following CMS Web sites to view the memoranda in their entirety: For

the decision memorandum on surgery on the wrong body part: https://

www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=222. For the decision

memorandum on surgery on the wrong patient: https://www.cms.hhs.gov/

mcd/viewdecisionmemo.asp?id=221. For the decision memorandum on the

wrong surgery performed on a patient: https://www.cms.hhs.gov/mcd/

viewdecisionmemo.asp?id=223.

To conform to these new coverage decisions, in this proposed rule,

we are proposing to create a new edit to identify cases in which wrong

surgeries occurred. The NCHS has revised the title of one E-code and

created two new E-codes to identify cases in which incorrect surgeries

have occurred. The revised E-code title is:

E876.5 (Performance of wrong operation (procedure) on

correct patient).

The two new E-codes are as follows:

E876.6 (Performance of operation (procedure) on patient

not scheduled for surgery)

E876.7 (Performance of correct operation (procedure) on

wrong side/body part)

A complete list of all of the E-codes that will be implemented on

October 1, 2009, can be found on the CMS Web site home page at: http://

www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/07\_

summarytables.asp#TopOfPage in the download titled ``New, Deleted, and

Invalid Diagnosis and Procedure Codes.''

Currently, an E-code used as a principal diagnosis will receive the

MCE Edit ``E-code as principal diagnosis''. This edit will remain in

effect. However, we are proposing a change to the MCE so that E-codes

E876.5 through E876.7, whether they are in the principal or secondary

diagnosis position, will trigger the ``Wrong Surgery'' edit. Any claim

with this edit will be denied and returned to the provider.

f. Procedures Allowed for Females Only Edit

It has come to our attention that code 75.37 (Amnioinfusion) and

code 75.38 (Fetal pulse oximetry) were inadvertently omitted from the

MCE edit ``Procedures Allowed for Females Only.'' In order to correct

this omission, we are proposing to add codes 75.37 and 75.38 and to the

edit for procedures allowed for females only.

4. Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one

of which, occurring by itself, could result in assignment of the case

to a different MS-DRG within the MDC to which the principal diagnosis

is assigned. Therefore, it is necessary to have a decision rule within

the GROUPER by which these cases are assigned to a single MS-DRG. The

surgical hierarchy, an ordering of surgical classes from most resource-

intensive to least resource-intensive, performs that function.

Application of this hierarchy ensures that cases involving multiple

surgical procedures are assigned to the MS-DRG associated with the most

resource-intensive surgical class.

Because the relative resource intensity of surgical classes can

shift as a function of MS-DRG reclassification and recalibrations, we

reviewed the surgical hierarchy of each MDC, as we have for previous

reclassifications and recalibrations, to determine if the ordering of

classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more MS-DRGs. For

example, in MDC 11, the surgical class ``kidney transplant'' consists

of a single MS-DRG (MS-DRG 652) and the class ``major bladder

procedures'' consists of three MS-DRGs (MS-DRGs 653, 654, and 655).

Consequently, in many cases, the surgical hierarchy has an impact on

more than one MS-DRG. The methodology for determining the most

resource-intensive surgical class involves weighting the average

resources for each MS-DRG by frequency to determine the weighted

average resources for each surgical class. For example, assume surgical

class A includes MS-DRGs 1 and 2 and surgical class B includes MS-DRGs

3, 4, and 5. Assume also that the average costs of MS-DRG 1 is higher

than that of MS-DRG 3, but the average costs of MS-DRGs 4 and 5 are

higher than the average costs of MS-DRG 2. To determine whether

surgical class A should be higher or lower than surgical class B in the

surgical hierarchy, we would weight the average costs of each MS-DRG in

the class by frequency (that is, by the number of cases in the MS-DRG)

to determine average resource consumption for the surgical class. The

surgical classes would then be ordered from the class with the highest

average resource utilization to that with the lowest, with the

exception of ``other O.R. procedures'' as discussed below.

This methodology may occasionally result in assignment of a case

involving multiple procedures to the lower-weighted MS-DRG (in the

highest, most resource-intensive surgical class) of the available

alternatives. However, given that the logic underlying the surgical

hierarchy provides that the GROUPER search for the procedure in the

most resource-intensive surgical class, in cases involving multiple

procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a

few instances when a surgical class with a lower average cost is

ordered above a surgical class with a higher average cost. For example,

the ``other O.R. procedures'' surgical class is uniformly ordered last

in the surgical hierarchy of each MDC in which it occurs, regardless of

the fact that the average costs for the MS-DRG or MS-DRGs in that

surgical class may be higher than those for other surgical classes in

the MDC. The ``other O.R. procedures'' class is a group of procedures

that are only infrequently related to the diagnoses in the MDC, but are

still occasionally performed on patients in the MDC with these

diagnoses. Therefore, assignment to these surgical classes should only

occur if no other surgical class more closely related to the diagnoses

in the MDC is appropriate.

A second example occurs when the difference between the average

costs for two surgical classes is very small. We have found that small

differences

[[Page 24111]]

generally do not warrant reordering of the hierarchy because, as a

result of reassigning cases on the basis of the hierarchy change, the

average costs are likely to shift such that the higher-ordered surgical

class has a lower average costs than the class ordered below it.

For FY 2010, we are not proposing any revisions to the surgical

hierarchy.

5. Complications or Comorbidity (CC) Exclusions List

a. Background

As indicated earlier in the preamble of this proposed rule, under

the IPPS DRG classification system, we have developed a standard list

of diagnoses that are considered CCs. Historically, we developed this

list using physician panels that classified each diagnosis code based

on whether the diagnosis, when present as a secondary condition, would

be considered a substantial complication or comorbidity. A substantial

complication or comorbidity was defined as a condition that, because of

its presence with a specific principal diagnosis, would cause an

increase in the length of stay by at least 1 day in at least 75 percent

of the patients. We refer readers to section II.D.2. and 3. of the

preamble of the FY 2008 IPPS final rule with comment period for a

discussion of the refinement of CCs in relation to the MS-DRGs we

adopted for FY 2008 (72 FR 47121 through 47152).

b. CC Exclusions List for FY 2010

In the September 1, 1987 final notice (52 FR 33143) concerning

changes to the DRG classification system, we modified the GROUPER logic

so that certain diagnoses included on the standard list of CCs would

not be considered valid CCs in combination with a particular principal

diagnosis. We created the CC Exclusions List for the following reasons:

(1) To preclude coding of CCs for closely related conditions; (2) to

preclude duplicative or inconsistent coding from being treated as CCs;

and (3) to ensure that cases are appropriately classified between the

complicated and uncomplicated DRGs in a pair. As we indicated above, we

developed a list of diagnoses, using physician panels, to include those

diagnoses that, when present as a secondary condition, would be

considered a substantial complication or comorbidity. In previous

years, we have made changes to the list of CCs, either by adding new

CCs or deleting CCs already on the list.

In the May 19, 1987 proposed notice (52 FR 18877) and the September

1, 1987 final notice (52 FR 33154), we explained that the excluded

secondary diagnoses were established using the following five

principles:

Chronic and acute manifestations of the same condition

should not be considered CCs for one another.

Specific and nonspecific (that is, not otherwise specified

(NOS)) diagnosis codes for the same condition should not be considered

CCs for one another.

Codes for the same condition that cannot coexist, such as

partial/total, unilateral/bilateral, obstructed/unobstructed, and

benign/malignant, should not be considered CCs for one another.

Codes for the same condition in anatomically proximal

sites should not be considered CCs for one another.

Closely related conditions should not be considered CCs

for one another.

The creation of the CC Exclusions List was a major project

involving hundreds of codes. We have continued to review the remaining

CCs to identify additional exclusions and to remove diagnoses from the

master list that have been shown not to meet the definition of a CC.\2\

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\2\ See the FY 1989 final rule (53 FR 38485, September 30,

1988), for the revision made for the discharges occurring in FY

1989; the FY 1990 final rule (54 FR 36552, September 1, 1989), for

the FY 1990 revision; the FY 1991 final rule (55 FR 36126, September

4, 1990), for the FY 1991 revision; the FY 1992 final rule (56 FR

43209, August 30, 1991) for the FY 1992 revision; the FY 1993 final

rule (57 FR 39753, September 1, 1992), for the FY 1993 revision; the

FY 1994 final rule (58 FR 46278, September 1, 1993), for the FY 1994

revisions; the FY 1995 final rule (59 FR 45334, September 1, 1994),

for the FY 1995 revisions; the FY 1996 final rule (60 FR 45782,

September 1, 1995), for the FY 1996 revisions; the FY 1997 final

rule (61 FR 46171, August 30, 1996), for the FY 1997 revisions; the

FY 1998 final rule (62 FR 45966, August 29, 1997) for the FY 1998

revisions; the FY 1999 final rule (63 FR 40954, July 31, 1998), for

the FY 1999 revisions; the FY 2001 final rule (65 FR 47064, August

1, 2000), for the FY 2001 revisions; the FY 2002 final rule (66 FR

39851, August 1, 2001), for the FY 2002 revisions; the FY 2003 final

rule (67 FR 49998, August 1, 2002), for the FY 2003 revisions; the

FY 2004 final rule (68 FR 45364, August 1, 2003), for the FY 2004

revisions; the FY 2005 final rule (69 FR 49848, August 11, 2004),

for the FY 2005 revisions; the FY 2006 final rule (70 FR 47640,

August 12, 2005), for the FY 2006 revisions; the FY 2007 final rule

(71 FR 47870) for the FY 2007 revisions; the FY 2008 final rule (72

FR 47130) for the FY 2008 revisions, and the FY 2009 final rule (73

FR 48510). In the FY 2000 final rule (64 FR 41490, July 30, 1999, we

did not modify the CC Exclusions List because we did not make any

changes to the ICD-9-CM codes for FY 2000.

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For FY 2010, we are proposing to make limited revisions to the CC

Exclusions List to take into account the changes that will be made in

the ICD-9-CM diagnosis coding system effective October 1, 2009. (See

section II.G.7. of the preamble of this proposed rule for a discussion

of ICD-9-CM changes.) We are proposing to make these changes in

accordance with the principles established when we created the CC

Exclusions List in 1987.

Tables 6G and 6H, Additions to and Deletions from the CC Exclusion

List, respectively, which would be effective for discharges occurring

on or after October 1, 2009, are not being published in this proposed

rule because of the length of the two tables. Instead, we are making

them available through the Internet on the CMS Web site at: http://

www.cms.hhs.gov/AcuteInpatientPPS. Each of these principal diagnoses

for which there is a CC exclusion is shown in Tables 6G and 6H with an

asterisk, and the conditions that will not count as a CC, are provided

in an indented column immediately following the affected principal

diagnosis.

A complete updated MCC, CC, and Non-CC Exclusions List is also

available through the Internet on the CMS Web site at: http://

www.cms.hhs.gov/AcuteInpatientPPS. Beginning with discharges on or

after October 1, 2009, the indented diagnoses will not be recognized by

the GROUPER as valid CCs for the asterisked principal diagnosis.

To assist readers in the review of changes to the MCC and CC lists

that occurred as a result of updates to the ICD-9-CM codes, as

described in Tables 6A, 6C, and 6E of the Addendum to this proposed

rule, we are providing the following summaries of those MCC and CC

changes.

Summary of Additions to the MS-DRG MCC List--Table 6I.1

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Code Description

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277.88............................ Tumor lysis syndrome.

670.22............................ Puerperal sepsis, delivered, with

mention of postpartum complication.

670.24............................ Puerperal sepsis, postpartum

condition or complication.

670.32............................ Puerperal septic thrombophlebitis,

delivered, with mention of

postpartum complication.

670.34............................ Puerperal septic thrombophlebitis,

postpartum condition or

complication.

670.80............................ Other major puerperal infection,

unspecified as to episode of care

or not applicable.

670.82............................ Other major puerperal infection,

delivered, with mention of

postpartum complication.

670.84............................ Other major puerperal infection,

postpartum condition or

complication.

756.72............................ Omphalocele.

756.73............................ Gastroschisis.

768.73............................ Severe hypoxic-ischemic

encephalopathy.

779.32............................ Bilious vomiting in newborn.

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[[Page 24112]]

Summary of Deletions From the MS-DRG MCC List--Table 6I.2

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Code Description

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768.7............................. Hypoxic-ischemic encephalopathy

(HIE).

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Summary of Additions to the MS-DRG CC List--Table 6J.1

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Code Description

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209.71............................ Secondary neuroendocrine tumor of

distant lymph nodes.

209.72............................ Secondary neuroendocrine tumor of

liver.

209.73............................ Secondary neuroendocrine tumor of

bone.

209.74............................ Secondary neuroendocrine tumor of

peritoneum.

209.79............................ Secondary neuroendocrine tumor of

other sites.

416.2............................. Chronic pulmonary embolism.

453.50............................ Chronic venous embolism and

thrombosis of unspecified deep

vessels of lower extremity.

453.51............................ Chronic venous embolism and

thrombosis of deep vessels of

proximal lower extremity.

453.52............................ Chronic venous embolism and

thrombosis of deep vessels of

distal lower extremity.

453.6............................. Venous embolism and thrombosis of

superficial vessels of lower

extremity.

453.71............................ Chronic venous embolism and

thrombosis of superficial veins of

upper extremity.

453.72............................ Chronic venous embolism and

thrombosis of deep veins of upper

extremity.

453.73............................ Chronic venous embolism and

thrombosis of upper extremity,

unspecified.

453.74............................ Chronic venous embolism and

thrombosis axillary veins.

453.75............................ Chronic venous embolism and

thrombosis of subclavian veins.

453.76............................ Chronic venous embolism and

thrombosis of internal jugular

veins.

453.77............................ Chronic venous embolism and

thrombosis of other thoracic veins.

453.79............................ Chronic venous embolism and

thrombosis of other specified

veins.

453.81............................ Acute venous embolism and thrombosis

of superficial veins of upper

extremity.

453.82............................ Acute venous embolism and thrombosis

of deep veins of upper extremity.

453.83............................ Acute venous embolism and thrombosis

of upper extremity, unspecified.

453.84............................ Acute venous embolism and thrombosis

of axillary veins.

453.85............................ Acute venous embolism and thrombosis

of subclavian veins.

453.86............................ Acute venous embolism and thrombosis

of internal jugular veins.

453.87............................ Acute venous embolism and thrombosis

of other thoracic veins.

453.89............................ Acute venous embolism and thrombosis

of other specified veins.

569.71............................ Pouchitis.

569.79............................ Other complications of intestinal

pouch.

670.10............................ Puerperal endometritis, unspecified

as to episode of care or not

applicable.

670.12............................ Puerperal endometritis, delivered,

with mention of postpartum

complication.

670.14............................ Puerperal endometritis, postpartum

condition or complication.

670.20............................ Puerperal sepsis, unspecified as to

episode of care or not applicable.

670.30............................ Puerperal septic thrombophlebitis,

unspecified as to episode of care

or not applicable.

768.70............................ Hypoxic-ischemic encephalopathy,

unspecified.

768.71............................ Mild hypoxic-ischemic

encephalopathy.

768.72............................ Moderate hypoxic-ischemic

encephalopathy.

813.46............................ Torus fracture of ulna (alone).

813.47............................ Torus fracture of radius and ulna.

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Summary of Deletions From the MS-DRG CC List--Table 6J.2

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Code Description

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453.8............................. Other venous embolism and thrombosis

of other specified veins.

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Alternatively, the complete documentation of the GROUPER logic,

including the current CC Exclusions List, is available from 3M/Health

Information Systems (HIS), which, under contract with CMS, is

responsible for updating and maintaining the GROUPER program. The

current MS-DRG Definitions Manual, Version 26.0, is available for

$250.00, which includes shipping and handling. Version 26.0 of the

manual is also available on a CD for $200.00; a combination hard copy

and CD is available for $400.00. Version 27.0 of this manual, which

will include the final FY 2010 MS-DRG changes, will be available in CD

only for $225.00. These manuals may be obtained by writing 3M/HIS at

the following address: 100 Barnes Road, Wallingford, CT 06492; or by

calling (203) 949-0303, or by obtaining an order form at the Web site:

http://www.3MHIS.com. Please specify the revision or revisions

requested.

6. Review of Procedure Codes in MS DRGs 981 through 983; 984 through

986; and 987 through 989

Each year, we review cases assigned to former CMS DRG 468

(Extensive O.R. Procedure Unrelated to Principal Diagnosis), CMS DRG

476 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis), and

CMS DRG 477 (Nonextensive O.R. Procedure Unrelated to Principal

Diagnosis) to determine whether it would be appropriate to change the

procedures assigned among these CMS DRGs. Under the MS-DRGs that we

adopted for FY 2008, CMS DRG 468 was split three ways and became MS-

DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal

Diagnosis with MCC, with CC, and without CC/MCC). CMS DRG 476 became

MS-DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to

Principal Diagnosis with MCC, with CC, and without CC/MCC). CMS DRG 477

became MS-DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated

to Principal Diagnosis with MCC, with CC, and without CC/MCC).

MS-DRGs 981 through 983, 984 through 986, and 987 through 989

(formerly CMS DRGs 468, 476, and 477, respectively) are reserved for

those cases in which none of the O.R. procedures performed are related

to the principal diagnosis. These DRGs are intended to capture atypical

cases, that is, those cases not occurring with sufficient frequency to

represent a distinct, recognizable clinical group. MS-DRGs 984 through

986 (previously CMS DRG 476) are assigned to those discharges in which

one or more of the following prostatic procedures are performed and are

unrelated to the principal diagnosis:

60.0, Incision of prostate

60.12, Open biopsy of prostate

60.15, Biopsy of periprostatic tissue

60.18, Other diagnostic procedures on prostate and

periprostatic tissue

60.21, Transurethral prostatectomy

60.29, Other transurethral prostatectomy

60.61, Local excision of lesion of prostate

60.69, Prostatectomy, not elsewhere classified

60.81, Incision of periprostatic tissue

60.82, Excision of periprostatic tissue

60.93, Repair of prostate

60.94, Control of (postoperative) hemorrhage of prostate

[[Page 24113]]

60.95, Transurethral balloon dilation of the prostatic

urethra

60.96, Transurethral destruction of prostate tissue by

microwave thermotherapy

60.97, Other transurethral destruction of prostate tissue

by other thermotherapy

60.99, Other operations on prostate

All remaining O.R. procedures are assigned to MS-DRGs 981 through

983 and 987 through 989, with MS-DRGs 987 through 989 assigned to those

discharges in which the only procedures performed are nonextensive

procedures that are unrelated to the principal diagnosis.\3\

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\3\ The original list of the ICD-9-CM procedure codes for the

procedures we consider nonextensive procedures, if performed with an

unrelated principal diagnosis, was published in Table 6C in section

IV. of the Addendum to the FY 1989 final rule (53 FR 38591). As part

of the FY 1991 final rule (55 FR 36135), the FY 1992 final rule (56

FR 43212), the FY 1993 final rule (57 FR 23625), the FY 1994 final

rule (58 FR 46279), the FY 1995 final rule (59 FR 45336), the FY

1996 final rule (60 FR 45783), the FY 1997 final rule (61 FR 46173),

and the FY 1998 final rule (62 FR 45981), we moved several other

procedures from DRG 468 to DRG 477, and some procedures from DRG 477

to DRG 468. No procedures were moved in FY 1999, as noted in the

final rule (63 FR 40962); in FY 2000 (64 FR 41496); in FY 2001 (65

FR 47064); or in FY 2002 (66 FR 39852). In the FY 2003 final rule

(67 FR 49999) we did not move any procedures from DRG 477. However,

we did move procedure codes from DRG 468 and placed them in more

clinically coherent DRGs. In the FY 2004 final rule (68 FR 45365),

we moved several procedures from DRG 468 to DRGs 476 and 477 because

the procedures are nonextensive. In the FY 2005 final rule (69 FR

48950), we moved one procedure from DRG 468 to 477. In addition, we

added several existing procedures to DRGs 476 and 477. In the FY

2006 (70 FR 47317), we moved one procedure from DRG 468 and assigned

it to DRG 477. In FY 2007, we moved one procedure from DRG 468 and

assigned it to DRGs 479, 553, and 554. In FYs 2008 and 2009, no

procedures were moved, as noted in the FY 2008 final rule with

comment period (72 FR 46241), and in the FY 2009 final rule (73 FR

48513).

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For FY 2010, we are not proposing to change the procedures assigned

among these MS-DRGs.

a. Moving Procedure Codes from MS-DRGs 981 Through 983 or MS-DRGs 987

Through 989 to MDCs

We annually conduct a review of procedures producing assignment to

MS-DRGs 981 through 983 (formerly CMS DRG 468) or MS-DRGs 987 through

989 (formerly CMS DRG 477) on the basis of volume, by procedure, to see

if it would be appropriate to move procedure codes out of these MS-DRGs

into one of the surgical MS-DRGs for the MDC into which the principal

diagnosis falls. The data are arrayed in two ways for comparison

purposes. We look at a frequency count of each major operative

procedure code. We also compare procedures across MDCs by volume of

procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain

principal diagnoses with sufficient frequency to justify adding them to

one of the surgical DRGs for the MDC in which the diagnosis falls. For

FY 2010, we are not proposing to remove any procedures from MS-DRGs 981

through 983 or MS-DRGs 987 through 989.

b. Reassignment of Procedures among MS-DRGs 981 through 983, 984

through 986, and 987 through 989)

We also annually review the list of ICD-9-CM procedures that, when

in combination with their principal diagnosis code, result in

assignment to MS-DRGs 981 through 983, 984 through 986, and 987 through

989 (formerly, CMS DRGs 468, 476, and 477, respectively), to ascertain

whether any of those procedures should be reassigned from one of these

three MS-DRGs to another of the three MS-DRGs based on average charges

and the length of stay. We look at the data for trends such as shifts

in treatment practice or reporting practice that would make the

resulting MS-DRG assignment illogical. If we find these shifts, we

would propose to move cases to keep the MS-DRGs clinically similar or

to provide payment for the cases in a similar manner. Generally, we

move only those procedures for which we have an adequate number of

discharges to analyze the data.

For FY 2010, we are not proposing to move any procedure codes among

these MS-DRGs.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on our review this year, we are not proposing to add any

diagnosis codes to MDCs for FY 2010.

7. Changes to the ICD-9-CM Coding System

As described in section II.B.1. of the preamble of this proposed

rule, the ICD-9-CM is a coding system used for the reporting of

diagnoses and procedures performed on a patient. In September 1985, the

ICD-9-CM Coordination and Maintenance Committee was formed. This is a

Federal interdepartmental committee, co-chaired by the National Center

for Health Statistics (NCHS), the Centers for Disease Control and

Prevention, and CMS, charged with maintaining and updating the ICD-9-CM

system. The Committee is jointly responsible for approving coding

changes, and developing errata, addenda, and other modifications to the

ICD-9-CM to reflect newly developed procedures and technologies and

newly identified diseases. The Committee is also responsible for

promoting the use of Federal and non-Federal educational programs and

other communication techniques with a view toward standardizing coding

applications and upgrading the quality of the classification system.

The Official Version of the ICD-9-CM contains the list of valid

diagnosis and procedure codes. (The Official Version of the ICD-9-CM is

available from the Government Printing Office on CD-ROM for $19.00 by

calling (202) 512-1800.) Complete information on ordering the CD-ROM is

also available at: http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/

05\_CDROM.asp#TopOfPage. The Official Version of the ICD-9-CM is no

longer available in printed manual form from the Federal Government; it

is only available on CD-ROM. Users who need a paper version are

referred to one of the many products available from publishing houses.

The NCHS has lead responsibility for the ICD-9-CM diagnosis codes

included in the Tabular List and Alphabetic Index for Diseases, while

CMS has lead responsibility for the ICD-9-CM procedure codes included

in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the above process by

health-related organizations. In this regard, the Committee holds

public meetings for discussion of educational issues and proposed

coding changes. These meetings provide an opportunity for

representatives of recognized organizations in the coding field, such

as the American Health Information Management Association (AHIMA), the

American Hospital Association (AHA), and various physician specialty

groups, as well as individual physicians, health information management

professionals, and other members of the public, to contribute ideas on

coding matters. After considering the opinions expressed at the public

meetings and in writing, the Committee formulates recommendations,

which then must be approved by the agencies.

The Committee presented proposals for coding changes for

implementation in FY 2010 at a public meeting held on September 24-25,

2008 and finalized the coding changes after consideration of comments

received at the meetings and in writing by December 5, 2008. Those

coding changes are announced in Tables 6A through 6F in the Addendum to

this proposed rule. The Committee held its 2009 meeting on March 11-12,

2009. New codes for which there was a

[[Page 24114]]

consensus of public support and for which complete tabular and indexing

changes are made by May 2009 will be included in the October 1, 2009

update to ICD-9-CM. Code revisions that were discussed at the March 11-

12, 2009 Committee meeting but that could not be finalized in time to

include them in the Addendum to this proposed rule are not included in

Tables 6A through 6F. These additional codes will be included in Tables

6A through 6F of the final rule and will be marked with an asterisk

(\*).

Copies of the minutes of the procedure codes discussions at the

Committee's September 24-25, 2008 meeting and March 11-12, 2009 meeting

can be obtained from the CMS Web site at: http://cms.hhs.gov/

ICD9ProviderDiagnosticCodes/03\_meetings.asp. The minutes of the

diagnosis codes discussions at the September 24-25, 2008 meeting and

March 11-12, 2009 meeting are found at: http://www.cdc.gov/nchs/

icd9.htm. Paper copies of these minutes are no longer available and the

mailing list has been discontinued. These Web sites also provide

detailed information about the Committee, including information on

requesting a new code, attending a Committee meeting, and timeline

requirements and meeting dates.

We encourage commenters to address suggestions on coding issues

involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD-9-CM

Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo

Road, Hyattsville, MD 20782. Comments may be sent by e-mail to:

dfp4@cdc.gov.

Questions and comments concerning the procedure codes should be

addressed to: Patricia E. Brooks, Co-Chairperson, ICD-9-CM Coordination

and Maintenance Committee, CMS, Center for Medicare Management,

Hospital and Ambulatory Policy Group, Division of Acute Care, C4-08-06,

7500 Security Boulevard, Baltimore, MD 21244-1850. Comments may be sent

by e-mail to: patricia.brooks2@cms.hhs.gov.

The ICD-9-CM code changes that have been approved will become

effective October 1, 2009. The new ICD-9-CM codes are listed, along

with their DRG classifications, in Tables 6A and 6B (New Diagnosis

Codes and New Procedure Codes, respectively) in the Addendum to this

proposed rule. As we stated above, the code numbers and their titles

were presented for public comment at the ICD-9-CM Coordination and

Maintenance Committee meetings. Both oral and written comments were

considered before the codes were approved. In this FY 2010 IPPS

proposed rule, we are only soliciting comments on the proposed

classification of these new codes.

For codes that have been replaced by new or expanded codes, the

corresponding new or expanded diagnosis codes are included in Table 6A

in the Addendum to this proposed rule. New procedure codes are shown in

Table 6B in the Addendum to this proposed rule. Diagnosis codes that

have been replaced by expanded codes or other codes or have been

deleted are in Table 6C (Invalid Diagnosis Codes) in the Addendum to

this proposed rule. These invalid diagnosis codes will not be

recognized by the GROUPER beginning with discharges occurring on or

after October 1, 2009. Table 6D in the Addendum to this proposed rule

contains invalid procedure codes. These invalid procedure codes will

not be recognized by the GROUPER beginning with discharges occurring on

or after October 1, 2009. Revisions to diagnosis code titles are in

Table 6E (Revised Diagnosis Code Titles) in the Addendum to this

proposed rule, which also includes the MS-DRG assignments for these

revised codes. Table 6F in the Addendum to this proposed rule includes

revised procedure code titles for FY 2010.

In the September 7, 2001 final rule implementing the IPPS new

technology add-on payments (66 FR 46906), we indicated we would attempt

to include proposals for procedure codes that would describe new

technology discussed and approved at the Spring meeting as part of the

code revisions effective the following October. As stated previously,

ICD-9-CM codes discussed at the March 11-12, 2009 Committee meeting

that receive consensus and that were finalized by May 2009 will be

included in Tables 6A through 6F in the Addendum to the final rule.

Section 503(a) of Public Law 108-173 included a requirement for

updating ICD-9-CM codes twice a year instead of a single update on

October 1 of each year. This requirement was included as part of the

amendments to the Act relating to recognition of new technology under

the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by

adding a clause (vii) which states that the ``Secretary shall provide

for the addition of new diagnosis and procedure codes on April 1 of

each year, but the addition of such codes shall not require the

Secretary to adjust the payment (or diagnosis-related group

classification) \* \* \* until the fiscal year that begins after such

date.'' This requirement improves the recognition of new technologies

under the IPPS system by providing information on these new

technologies at an earlier date. Data will be available 6 months

earlier than would be possible with updates occurring only once a year

on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the

addition of new diagnosis and procedure codes on April 1 of each year

shall not require the Secretary to adjust the payment, or DRG

classification, under section 1886(d) of the Act until the fiscal year

that begins after such date, we have to update the DRG software and

other systems in order to recognize and accept the new codes. We also

publicize the code changes and the need for a mid-year systems update

by providers to identify the new codes. Hospitals also have to obtain

the new code books and encoder updates, and make other system changes

in order to identify and report the new codes.

The ICD-9-CM Coordination and Maintenance Committee holds its

meetings in the spring and fall in order to update the codes and the

applicable payment and reporting systems by October 1 of each year.

Items are placed on the agenda for the ICD-9-CM Coordination and

Maintenance Committee meeting if the request is received at least 2

months prior to the meeting. This requirement allows time for staff to

review and research the coding issues and prepare material for

discussion at the meeting. It also allows time for the topic to be

publicized in meeting announcements in the Federal Register as well as

on the CMS Web site. The public decides whether or not to attend the

meeting based on the topics listed on the agenda. Final decisions on

code title revisions are currently made by March 1 so that these titles

can be included in the IPPS proposed rule. A complete addendum

describing details of all changes to ICD-9-CM, both tabular and index,

is published on the CMS and NCHS Web sites in May of each year.

Publishers of coding books and software use this information to modify

their products that are used by health care providers. This 5-month

time period has proved to be necessary for hospitals and other

providers to update their systems.

A discussion of this timeline and the need for changes are included

in the December 4-5, 2005 ICD-9-CM Coordination and Maintenance

Committee minutes. The public agreed that there was a need to hold the

fall meetings earlier, in September or October, in order to meet the

new implementation dates. The public provided comment that additional

time would be needed to update hospital

[[Page 24115]]

systems and obtain new code books and coding software. There was

considerable concern expressed about the impact this new April update

would have on providers.

In the FY 2005 IPPS final rule, we implemented section

1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law

108-173, by developing a mechanism for approving, in time for the April

update, diagnosis and procedure code revisions needed to describe new

technologies and medical services for purposes of the new technology

add-on payment process. We also established the following process for

making these determinations. Topics considered during the Fall ICD-9-CM

Coordination and Maintenance Committee meeting are considered for an

April 1 update if a strong and convincing case is made by the requester

at the Committee's public meeting. The request must identify the reason

why a new code is needed in April for purposes of the new technology

process. The participants at the meeting and those reviewing the

Committee meeting summary report are provided the opportunity to

comment on this expedited request. All other topics are considered for

the October 1 update. Participants at the Committee meeting are

encouraged to comment on all such requests. There were no requests

approved for an expedited April 1, 2009 implementation of an ICD-9-CM

code at the September 24-25, 2008 Committee meeting. Therefore, there

were no new ICD-9-CM codes implemented on April 1, 2009.

Current addendum and code title information is published on the CMS

Web site at: http://www.cms.hhs.gov/icd9ProviderDiagnosticCodes/01\_

overview.aspTopofPage. Information on ICD-9-CM diagnosis

codes, along with the Official ICD-9-CM Coding Guidelines, can be found

on the Web site at: http://www.cdc.gov/nchs/icd9.htm. Information on

new, revised, and deleted ICD-9-CM codes is also provided to the AHA

for publication in the Coding Clinic for ICD-9-CM. AHA also distributes

information to publishers and software vendors.

CMS also sends copies of all ICD-9-CM coding changes to its

Medicare contractors for use in updating their systems and providing

education to providers.

These same means of disseminating information on new, revised, and

deleted ICD-9-CM codes will be used to notify providers, publishers,

software vendors, contractors, and others of any changes to the ICD-9-

CM codes that are implemented in April. The code titles are adopted as

part of the ICD-9-CM Coordination and Maintenance Committee process.

Thus, although we publish the code titles in the IPPS proposed and

final rules, they are not subject to comment in the proposed or final

rules. We will continue to publish the October code updates in this

manner within the IPPS proposed and final rules. For codes that are

implemented in April, we will assign the new procedure code to the same

DRG in which its predecessor code was assigned so there will be no DRG

impact as far as DRG assignment. Any midyear coding updates will be

available through the Web sites indicated above and through the Coding

Clinic for ICD-9-CM. Publishers and software vendors currently obtain

code changes through these sources in order to update their code books

and software systems. We will strive to have the April 1 updates

available through these Web sites 5 months prior to implementation

(that is, early November of the previous year), as is the case for the

October 1 updates.

H. Recalibration of MS-DRG Weights

In section II.E. of the preamble of this proposed rule, we state

that we fully implemented the cost-based DRG relative weights for FY

2009, which was the third year in the 3-year transition period to

calculate the relative weights at 100 percent based on costs. In the FY

2008 IPPS final rule with comment period (72 FR 47267), as recommended

by RTI, for FY 2008, we added two new CCRs for a total of 15 CCRs: One

for ``Emergency Room'' and one for ``Blood and Blood Products,'' both

of which can be derived directly from the Medicare cost report.

In developing the FY 2010 proposed system of weights, we used two

data sources: Claims data and cost report data. As in previous years,

the claims data source is the MedPAR file. This file is based on fully

coded diagnostic and procedure data for all Medicare inpatient hospital

bills. The FY 2008 MedPAR data used in this proposed rule include

discharges occurring on October 1, 2007, through September 30, 2008,

based on bills received by CMS through December 31, 2008, from all

hospitals subject to the IPPS and short-term, acute care hospitals in

Maryland (which are under a waiver from the IPPS under section

1814(b)(3) of the Act). The FY 2008 MedPAR file used in calculating the

relative weights includes data for approximately 11,648,471 Medicare

discharges from IPPS providers. Discharges for Medicare beneficiaries

enrolled in a Medicare Advantage managed care plan are excluded from

this analysis. The data exclude CAHs, including hospitals that

subsequently became CAHs after the period from which the data were

taken. The second data source used in the cost-based relative weighting

methodology is the FY 2007 Medicare cost report data files from HCRIS

(that is, cost reports beginning on or after October 1, 2006, and

before October 1, 2007), which represents the most recent full set of

cost report data available. We used the December 31, 2008 update of the

HCRIS cost report files for FY 2007 in setting the relative cost-based

weights.

The methodology we used to calculate the DRG cost-based relative

weights from the FY 2008 MedPAR claims data and FY 2007 Medicare cost

report data is as follows:

To the extent possible, all the claims were regrouped

using the proposed FY 2010 MS-DRG classifications discussed in sections

II.B. and G. of the preamble of this proposed rule.

The transplant cases that were used to establish the

relative weights for heart and heart-lung, liver and/or intestinal, and

lung transplants (MS-DRGs 001, 002, 005, 006, and 007, respectively)

were limited to those Medicare-approved transplant centers that have

cases in the FY 2008 MedPAR file. (Medicare coverage for heart, heart-

lung, liver and/or intestinal, and lung transplants is limited to those

facilities that have received approval from CMS as transplant centers.)

Organ acquisition costs for kidney, heart, heart-lung,

liver, lung, pancreas, and intestinal (or multivisceral organs)

transplants continue to be paid on a reasonable cost basis. Because

these acquisition costs are paid separately from the prospective

payment rate, it is necessary to subtract the acquisition charges from

the total charges on each transplant bill that showed acquisition

charges before computing the average cost for each MS-DRG and before

eliminating statistical outliers.

Claims with total charges or total length of stay less

than or equal to zero were deleted. Claims that had an amount in the

total charge field that differed by more than $10.00 from the sum of

the routine day charges, intensive care charges, pharmacy charges,

special equipment charges, therapy services charges, operating room

charges, cardiology charges, laboratory charges, radiology charges,

other service charges, labor and delivery charges, inhalation therapy

charges, emergency room charges, blood charges, and anesthesia charges

were also deleted.

At least 95.9 percent of the providers in the MedPAR file

had

[[Page 24116]]

charges for 10 of the 15 cost centers. Claims for providers that did

not have charges greater than zero for at least 10 of the 15 cost

centers were deleted.

Statistical outliers were eliminated by removing all cases

that were beyond 3.0 standard deviations from the mean of the log

distribution of both the total charges per case and the total charges

per day for each MS-DRG.

Effective October 1, 2008, because hospital inpatient

claims include a POA indicator field for each diagnosis present on the

claim, the POA indicator field was reset to ``Y'' for ``Yes'' just for

relative weight-setting purposes for all claims that otherwise have an

``N'' (No) or a ``U'' (documentation insufficient to determine if the

condition was present at the time of inpatient admission) in the POA

field.

Under current payment policy, the presence of specific HAC codes,

as indicated by the POA field values, can generate a lower payment for

the claim. Specifically, if the particular condition is present on

admission (that is, a ``Y'' indicator is associated with the diagnosis

on the claim), then it is not a ``HAC,'' and the hospital is paid with

the higher severity (and, therefore, higher weighted MS-DRG). If the

particular condition is not present on admission (that is, an ``N''

indicator is associated with the diagnosis on the claim) and there are

no other complicating conditions, the DRG GROUPER assigns the claim to

a lower severity (and, therefore, lower weighted) MS-DRG as a penalty

for allowing a Medicare inpatient to contract a ``HAC.'' While this

meets policy goals of encouraging quality care and generates program

savings, it presents an issue for the relative weight-setting process.

Because cases identified as HACs are likely to be more complex than

similar cases that are not identified as HACs, the charges associated

with HACs are likely to be higher as well. Thus, if the higher charges

of these HAC claims are grouped into lower severity MS-DRGs prior to

the relative weight-setting process, the relative weights of these

particular MS-DRGs would become artificially inflated, potentially

skewing the relative weights. In addition, we want to protect the

integrity of the budget neutrality process by ensuring that, in

estimating payments, no increase to the standardized amount occurs as a

result of lower overall payments in a previous year that stem from

using weights and case-mix that are based on lower severity MS-DRG

assignments. If this would occur, the anticipated cost savings from the

HAC policy would be lost. To avoid these problems, we are proposing to

reset the POA indicator field to ``Y'' just for relative weight-setting

purposes for all claims that otherwise have an ``N'' or a ``U'' in the

POA field. This ``forces'' the more costly HAC claims into the higher

severity MS-DRGs as appropriate, and the relative weights calculated

for each MS-DRG more closely reflect the true costs of those cases.

Once the MedPAR data were trimmed and the statistical outliers were

removed, the charges for each of the 15 cost groups for each claim were

standardized to remove the effects of differences in area wage levels,

IME and DSH payments, and for hospitals in Alaska and Hawaii, the

applicable cost-of-living adjustment. Because hospital charges include

charges for both operating and capital costs, we standardized total

charges to remove the effects of differences in geographic adjustment

factors, cost-of-living adjustments, and DSH payments under the capital

IPPS as well. Charges were then summed by MS-DRG for each of the 15

cost groups so that each MS-DRG had 15 standardized charge totals.

These charges were then adjusted to cost by applying the national

average CCRs developed from the FY 2007 cost report data.

The 15 cost centers that we used in the relative weight calculation

are shown in the following table. The table shows the lines on the cost

report and the corresponding revenue codes that we used to create the

15 national cost center CCRs.

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[[Page 24117]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.004

[[Page 24118]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.005

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[GRAPHIC] [TIFF OMITTED] TP22MY09.006

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[GRAPHIC] [TIFF OMITTED] TP22MY09.007

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[GRAPHIC] [TIFF OMITTED] TP22MY09.008

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[GRAPHIC] [TIFF OMITTED] TP22MY09.009

[[Page 24123]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.010

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We developed the national average CCRs as follows:

Taking the FY 2007 cost report data, we removed CAHs, Indian Health

Service hospitals, all-inclusive rate hospitals, and cost reports that

represented time periods of less than 1 year (365 days). We included

hospitals located in Maryland as we are including their charges in our

claims database. We then created CCRs for each provider for each cost

center (see prior table for line items used in the calculations) and

removed any CCRs that were greater than 10 or less than 0.01. We

normalized the departmental CCRs by dividing the CCR for each

department by the total CCR for the hospital for the purpose of

trimming the data. We then took the logs of the normalized cost center

CCRs and removed any cost center CCRs where the log of the cost center

CCR was greater or less than the mean log plus/minus 3 times the

standard deviation for the log of that cost center CCR. Once the cost

report data were trimmed, we calculated a Medicare-specific CCR. The

Medicare-specific CCR was determined by taking the Medicare charges for

each line item from Worksheet D-4 and deriving the Medicare-specific

costs by applying the hospital-specific departmental CCRs to the

Medicare-specific charges for each line item from Worksheet D-4. Once

each hospital's Medicare-specific costs were established, we summed the

total Medicare-specific costs and divided by the sum of the total

Medicare-specific charges to produce national average, charge-weighted

CCRs.

After we multiplied the total charges for each MS-DRG in each of

the 15 cost centers by the corresponding national average CCR, we

summed the 15 ``costs'' across each MS-DRG to produce a total

standardized cost for the MS-DRG. The average standardized cost for

each MS-DRG was then computed as the total standardized cost for the

MS-DRG divided by the transfer-adjusted case count for the MS-DRG. The

average cost for each MS-DRG was then divided by the national average

standardized cost per case to determine the relative weight.

The new cost-based relative weights were then normalized by an

adjustment factor of 1.54005 so that the average case weight after

recalibration was equal to the average case weight before

recalibration. The normalization adjustment is intended to ensure that

recalibration by itself neither increases nor decreases total payments

under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The 15 proposed national average CCRs for FY 2010 are as follows:

------------------------------------------------------------------------

Group CCR

------------------------------------------------------------------------

Routine Days............................................... 0.534

Intensive Days............................................. 0.469

Drugs...................................................... 0.199

Supplies & Equipment....................................... 0.344

Therapy Services........................................... 0.408

Laboratory................................................. 0.160

Operating Room............................................. 0.281

Cardiology................................................. 0.178

Radiology.................................................. 0.161

Emergency Room............................................. 0.276

Blood and Blood Products................................... 0.426

Other Services............................................. 0.418

Labor & Delivery........................................... 0.460

Inhalation Therapy......................................... 0.199

Anesthesia................................................. 0.134

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As we explained in section II.E. of the preamble of this proposed

rule, we have completed our 2-year transition to the MS-DRGs. For FY

2008, the first year of the transition, 50 percent of the relative

weight for an MS-DRG was based on the two-thirds cost-based weight/one-

third charge-based weight calculated using FY 2006 MedPAR data grouped

to the Version 24.0 (FY 2007) DRGs. The remaining 50 percent of the FY

2008 relative weight for an MS-DRG was based on the two-thirds cost-

based weight/one-third charge-based weight calculated using FY 2006

MedPAR grouped to the Version 25.0 (FY 2008) MS-DRGs. In FY 2009, the

relative weights were based on 100 percent cost weights computed using

the Version 26.0 (FY 2009) MS-DRGs.

When we recalibrated the DRG weights for previous years, we set a

threshold of 10 cases as the minimum number of cases required to

compute a reasonable weight. We are proposing to use that same case

threshold in recalibrating the MS-DRG weights for FY 2010. Using the FY

2008 MedPAR data set, there are 8 MS-DRGs that contain fewer than 10

cases. Under the MS-DRGs, we have fewer low-volume DRGs than under the

CMS DRGs because we no longer have separate DRGs for patients age 0 to

17 years. With the exception of newborns, we previously separated some

DRGs based on whether the patient was age 0 to 17 years or age 17 years

and older. Other than the age split, cases grouping to these DRGs are

identical. The DRGs for patients age 0 to 17 years generally have very

low volumes because children are typically ineligible for Medicare. In

the past, we have found that the low volume of cases for the pediatric

DRGs could lead to significant year-to-year instability in their

relative weights. Although we have always encouraged non-Medicare

payers to develop weights applicable to their own patient populations,

we have heard frequent complaints from providers about the use of the

Medicare relative weights in the pediatric population. We believe that

eliminating this age split in the MS-DRGs will provide more stable

payment for pediatric cases by determining their payment using adult

cases that are much higher in total volume. Newborns are unique and

require separate MS-DRGs that are not mirrored in the adult population.

Therefore, it remains necessary to retain separate MS-DRGs for

newborns. All of the low-volume MS-DRGs listed below are for newborns.

In FY 2010, because we do not have sufficient MedPAR data to set

accurate and stable cost weights for these low-volume MS-DRGs, we are

proposing to compute weights for the low-volume MS-DRGs by adjusting

their FY 2009 weights by the percentage change in the average weight of

the

[[Page 24124]]

cases in other MS-DRGs. The crosswalk table is shown below:

------------------------------------------------------------------------

Low-volume MS-DRG MS-DRG title Crosswalk to MS-DRG

------------------------------------------------------------------------

768..................... Vaginal Delivery with FY 2009 FR weight

O.R. Procedure Except (adjusted by percent

Sterilization and/or change in average

D&C. weight of the cases

in other MS-DRGs).

789..................... Neonates, Died or FY 2009 FR weight

Transferred to (adjusted by percent

Another Acute Care change in average

Facility. weight of the cases

in other MS-DRGs).

790..................... Extreme Immaturity or FY 2009 FR weight

Respiratory Distress (adjusted by percent

Syndrome, Neonate. change in average

weight of the cases

in other MS-DRGs).

791..................... Prematurity with Major FY 2009 FR weight

Problems. (adjusted by percent

change in average

weight of the cases

in other MS-DRGs).

792..................... Prematurity without FY 2009 FR weight

Major Problems. (adjusted by percent

change in average

weight of the cases

in other MS-DRGs).

793..................... Full-Term Neonate with FY 2009 FR weight

Major Problems. (adjusted by percent

change in average

weight of the cases

in other MS-DRGs).

794..................... Neonate with Other FY 2009 FR weight

Significant Problems. (adjusted by percent

change in average

weight of the cases

in other MS-DRGs).

795..................... Normal Newborn........ FY 2009 FR weight

(adjusted by percent

change in average

weight of the cases

in other MS-DRGs).

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I. Proposed Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of

identifying and ensuring adequate payment for new medical services and

technologies (sometimes collectively referred to in this section as

``new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the

Act specifies that a medical service or technology will be considered

new if it meets criteria established by the Secretary after notice and

opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act

specifies that the process must apply to a new medical service or

technology if, ``based on the estimated costs incurred with respect to

discharges involving such service or technology, the DRG prospective

payment rate otherwise applicable to such discharges under this

subsection is inadequate.'' We note that beginning with FY 2008, CMS

transitioned from CMS-DRGs to MS-DRGs.

The regulations implementing these provisions specify three

criteria for a new medical service or technology to receive an

additional payment: (1) The medical service or technology must be new;

(2) the medical service or technology must be costly such that the DRG

rate otherwise applicable to discharges involving the medical service

or technology is determined to be inadequate; and (3) the service or

technology must demonstrate a substantial clinical improvement over

existing services or technologies. These three criteria are explained

below in the ensuing paragraphs in further detail.

Under the first criterion, as reflected in 42 CFR 412.87(b)(2), a

specific medical service or technology will be considered ``new'' for

purposes of new medical service or technology add-on payments until

such time as Medicare data are available to fully reflect the cost of

the technology in the MS-DRG weights through recalibration. Typically,

there is a lag of 2 to 3 years from the point a new medical service or

technology is first introduced on the market (generally on the date

that the technology receives FDA approval/clearance) and when data

reflecting the use of the medical service or technology are used to

calculate the MS-DRG weights. For example, data from discharges

occurring during FY 2008 are used to calculate the FY 2010 MS-DRG

weights in this proposed rule. Section 412.87(b)(2) of the regulations

therefore provides that ``a medical service or technology may be

considered new within 2 or 3 years after the point at which data begin

to become available reflecting the ICD-9-CM code assigned to the new

medical service or technology (depending on when a new code is assigned

and data on the new medical service or technology become available for

DRG recalibration). After CMS has recalibrated the DRGs, based on

available data to reflect the costs of an otherwise new medical service

or technology, the medical service or technology will no longer be

considered `new' under the criterion for this section.''

The 2-year to 3-year period during which a medical service or

technology can be considered new would ordinarily begin on the date on

which the medical service or technology received FDA approval or

clearance. (We note that, for purposes of this section of the proposed

rule, we generally refer to both FDA approval and FDA clearance as FDA

``approval.'') However, in some cases, initially there may be no

Medicare data available for the new service or technology following FDA

approval. For example, the newness period could extend beyond the 2-

year to 3-year period after FDA approval is received in cases where the

product initially was generally unavailable to Medicare patients

following FDA approval, such as in cases of a national noncoverage

determination or a documented delay in bringing the product onto the

market after that approval (for instance, component production or drug

production has been postponed following FDA approval due to shelf life

concerns or manufacturing issues). After the MS-DRGs have been

recalibrated to reflect the costs of an otherwise new medical service

or technology, the medical service or technology is no longer eligible

for special add-on payment for new medical services or technologies (as

specified under Sec. 412.87(b)(2)). For example, an approved new

technology that received FDA approval in October 2008 and entered the

market at that time may be eligible to receive add-on payments as a new

technology for discharges occurring before October 1, 2011 (the start

of FY 2012). Because the FY 2012 MS-DRG weights would be calculated

using FY 2010 MedPAR data, the costs of such a new technology would be

fully reflected in the FY 2012 MS-DRG weights. Therefore, the new

technology would no longer be eligible to receive add-on payments as a

new technology for discharges occurring in FY 2012 and thereafter.

Under the second criterion, Sec. 412.87(b)(3) further provides

that, to be eligible for the add-on payment for new medical services or

technologies,

[[Page 24125]]

the MS-DRG prospective payment rate otherwise applicable to the

discharge involving the new medical services or technologies must be

assessed for adequacy. Under the cost criterion, to assess the adequacy

of payment for a new technology paid under the applicable MS-DRG

prospective payment rate, we evaluate whether the charges for cases

involving the new technology exceed certain threshold amounts. In the

FY 2004 IPPS final rule (68 FR 45385), we established the threshold at

the geometric mean standardized charge for all cases in the MS-DRG plus

75 percent of 1 standard deviation above the geometric mean

standardized charge (based on the logarithmic values of the charges and

converted back to charges) for all cases in the MS-DRG to which the new

medical service or technology is assigned (or the case-weighted average

of all relevant MS-DRGs, if the new medical service or technology

occurs in more than one MS-DRG).

However, section 503(b)(1) of Public Law 108-173 amended section

1886(d)(5)(K)(ii)(I) of the Act to provide that, beginning in FY 2005,

CMS will apply ``a threshold \* \* \* that is the lesser of 75 percent of

the standardized amount (increased to reflect the difference between

cost and charges) or 75 percent of one standard deviation for the

diagnosis-related group involved.'' (We refer readers to section IV.D.

of the preamble to the FY 2005 IPPS final rule (69 FR 49084) for a

discussion of the revision of the regulations to incorporate the change

made by section 503(b)(1) of Public Law 108-173.) Table 10 that was

included in the notice published in the Federal Register on October 3,

2008, contains the final thresholds that are being used to evaluate

applications for new technology add-on payments for FY 2010 (73 FR

57888).

We note that section 124 of Public Law 110-275 extended, through FY

2009, wage index reclassifications under section 508 of Public Law 108-

173 (the MMA) and special exceptions contained in the final rule

promulgated in the Federal Register on August 11, 2004 (69 FR 49105 and

49107) and extended under section 117 of Public Law 110-173 (the

MMSEA). The wage data affects the standardized amounts (as well as the

outlier offset and budget neutrality factors that are applied to the

standardized amounts), which we use to compute the cost criterion

thresholds. Therefore, the thresholds reflected in Table 10 in the

Addendum to the FY 2009 IPPS final rule were tentative. As noted

earlier, on October 3, 2008, we published a Federal Register notice (73

FR 57888) that contained a new Table 10 with revised thresholds that

reflect the wage index rates for FY 2009 as a result of implementation

of section 124 of Public Law 110-275. The revised thresholds also were

published on the CMS Web site. The revised thresholds published in

Table 10 in the October 3, 2008 Federal Register notice are being used

to determine if an applicant for new technology add-on payments

discussed in this FY 2010 proposed rule meets the cost criterion

threshold for new technology add-on payments for FY 2010.

In the September 7, 2001 final rule that established the new

technology add-on payment regulations (66 FR 46917), we discussed the

issue of whether the HIPAA Privacy Rule at 45 CFR Parts 160 and 164

applies to claims information that providers submit with applications

for new technology add-on payments. Specifically, we explained that

health plans, including Medicare, and providers that conduct certain

transactions electronically, including the hospitals that would be

receiving payment under the FY 2001 IPPS final rule, are required to

comply with the HIPAA Privacy Rule. We further explained how such

entities could meet the applicable HIPAA requirements by discussing how

the HIPAA Privacy Rule permitted providers to share with health plans

information needed to ensure correct payment, if they had obtained

consent from the patient to use that patient's data for treatment,

payment, or health care operations. We also explained that, because the

information to be provided within applications for new technology add-

on payment would be needed to ensure correct payment, no additional

consent would be required. The HHS Office of Civil Rights has since

amended the HIPAA Privacy Rule, but the results remain. The HIPAA

Privacy Rule no longer requires covered entities to obtain consent from

patients to use or disclose protected health information for treatment,

payment, or health care operations, and expressly permits such entities

to use or to disclose protected health information for any of these

purposes. (We refer readers to 45 CFR 164.502(a)(1)(ii), and

164.506(c)(1) and (c)(3), and the Standards for Privacy of Individually

Identifiable Health Information published in the Federal Register on

August 14, 2002, for a full discussion of changes in consent

requirements.)

Under the third criterion, Sec. 412.87(b)(1) of our existing

regulations provides that a new technology is an appropriate candidate

for an additional payment when it represents ``an advance that

substantially improves, relative to technologies previously available,

the diagnosis or treatment of Medicare beneficiaries.'' For example, a

new technology represents a substantial clinical improvement when it

reduces mortality, decreases the number of hospitalizations or

physician visits, or reduces recovery time compared to the technologies

previously available. (We refer readers to the September 7, 2001 final

rule for a complete discussion of this criterion (66 FR 46902).)

The new medical service or technology add-on payment policy under

the IPPS provides additional payments for cases with relatively high

costs involving eligible new medical services or technologies while

preserving some of the incentives inherent under an average-based

prospective payment system. The payment mechanism is based on the cost

to hospitals for the new medical service or technology. Under Sec.

412.88, if the costs of the discharge (determined by applying cost to

charge ratios (``CCRs'') as described in Sec. 412.84(h)) exceed the

full DRG payment (including payments for IME and DSH, but excluding

outlier payments), Medicare will make an add-on payment equal to the

lesser of: (1) 50 percent of the estimated costs of the new technology

(if the estimated costs for the case including the new technology

exceed Medicare's payment); or (2) 50 percent of the difference between

the full DRG payment and the hospital's estimated cost for the case.

Unless the discharge qualifies for an outlier payment, Medicare payment

is limited to the full MS-DRG payment plus 50 percent of the estimated

costs of the new technology.

Section 1886(d)(4)(C)(iii) of the Act requires that the adjustments

to annual MS-DRG classifications and relative weights must be made in a

manner that ensures that aggregate payments to hospitals are not

affected. Therefore, in the past, we accounted for projected payments

under the new medical service and technology provision during the

upcoming fiscal year, while at the same time estimating the payment

effect of changes to the MS-DRG classifications and recalibration. The

impact of additional payments under this provision was then included in

the budget neutrality factor, which was applied to the standardized

amounts and the hospital-specific amounts. However, section 503(d)(2)

of Public Law 108-173 provides that there shall be no reduction or

adjustment in aggregate payments under the IPPS due to add-on payments

for new medical services and technologies. Therefore, following section

503(d)(2) of Public

[[Page 24126]]

Law 108-173, add-on payments for new medical services or technologies

for FY 2005 and later years have not been subjected to budget

neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we

modified our regulations at Sec. 412.87 to codify our current practice

of how CMS evaluates the eligibility criteria for new medical service

or technology add-on payment applications. We also amended Sec.

412.87(c) to specify that all applicants for new technology add-on

payments must have FDA approval for their new medical service or

technology by July 1 of each year prior to the beginning of the fiscal

year that the application is being considered.

Applicants for add-on payments for new medical services or

technologies for FY 2011 must submit a formal request, including a full

description of the clinical applications of the medical service or

technology and the results of any clinical evaluations demonstrating

that the new medical service or technology represents a substantial

clinical improvement, along with a significant sample of data to

demonstrate the medical service or technology meets the high-cost

threshold. Complete application information, along with final deadlines

for submitting a full application, will be posted as it becomes

available on our Web site at: http://www.cms.hhs.gov/AcuteInpatientPPS/

08\_newtech.asp. To allow interested parties to identify the new

medical services or technologies under review before the publication of

the proposed rule for FY 2011, the Web site also will list the tracking

forms completed by each applicant.

The Council on Technology and Innovation (CTI) at CMS oversees the

agency's cross-cutting priority on coordinating coverage, coding and

payment processes for Medicare with respect to new technologies and

procedures, including new drug therapies, as well as promoting the

exchange of information on new technologies between CMS and other

entities. The CTI, composed of senior CMS staff and clinicians, was

established under section 942(a) of Public Law 108-173. The Council is

co-chaired by the Director of the Office of Clinical Standards and

Quality (OCSQ) and the Director of the Center for Medicare Management

(CMM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are

implemented by CMM, OCSQ, and the local claims-payment contractors (in

the case of local coverage and payment decisions). The CTI supplements,

rather than replaces, these processes by working to assure that all of

these activities reflect the agency-wide priority to promote high-

quality, innovative care. At the same time, the CTI also works to

streamline, accelerate, and improve coordination of these processes to

ensure that they remain up to date as new issues arise. To achieve its

goals, the CTI works to streamline and create a more transparent coding

and payment process, improve the quality of medical decisions, and

speed patient access to effective new treatments. It is also dedicated

to supporting better decisions by patients and doctors in using

Medicare-covered services through the promotion of better evidence

development, which is critical for improving the quality of care for

Medicare beneficiaries.

CMS plans to continue its Open Door forums with stakeholders who

are interested in CTI's initiatives. In addition, to improve the

understanding of CMS' processes for coverage, coding, and payment and

how to access them, the CTI has developed an ``innovator's guide'' to

these processes. The intent is to consolidate this information, much of

which is already available in a variety of CMS documents and in various

places on the CMS Web site, in a user-friendly format. This guide was

published in August 2008 and is available on the CMS Web site at:

http://www.cms.hhs.gov/CouncilonTechInnov/Downloads/InnovatorsGuide8\_

25\_08.pdf.

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we

invite any product developers or manufacturers of new medical

technologies to contact the agency early in the process of product

development if they have questions or concerns about the evidence that

would be needed later in the development process for the agency's

coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and

initiatives to stakeholders, including Medicare beneficiaries,

advocates, medical product manufacturers, providers, and health policy

experts. Stakeholders with further questions about Medicare's coverage,

coding, and payment processes, or who want further guidance about how

they can navigate these processes, can contact the CTI at

CTI@cms.hhs.gov or from the ``Contact Us'' section of the CTI home page

(http://www.cms.hhs.gov/CouncilonTechInnov/).

2. Public Input Before Publication of a Notice of Proposed Rulemaking

on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section

503(b)(2) of Public Law 108-173, provides for a mechanism for public

input before publication of a notice of proposed rulemaking regarding

whether a medical service or technology represents a substantial

clinical improvement or advancement. The process for evaluating new

medical service and technology applications requires the Secretary to--

Provide, before publication of a proposed rule, for public

input regarding whether a new service or technology represents an

advance in medical technology that substantially improves the diagnosis

or treatment of Medicare beneficiaries;

Make public and periodically update a list of the services

and technologies for which applications for add-on payments are

pending;

Accept comments, recommendations, and data from the public

regarding whether a service or technology represents a substantial

clinical improvement; and

Provide, before publication of a proposed rule, for a

meeting at which organizations representing hospitals, physicians,

manufacturers, and any other interested party may present comments,

recommendations, and data regarding whether a new medical service or

technology represents a substantial clinical improvement to the

clinical staff of CMS.

In order to provide an opportunity for public input regarding add-

on payments for new medical services and technologies for FY 2010 prior

to publication of this proposed rule, we published a notice in the

Federal Register on November 28, 2008 (73 FR 72490), and held a town

hall meeting at the CMS Headquarters Office in Baltimore, MD, on

February 17, 2009. In the announcement notice for the meeting, we

stated that the opinions and alternatives provided during the meeting

would assist us in our evaluations of applications by allowing public

discussion of the substantial clinical improvement criterion for each

of the FY 2010 new medical service and technology add-on payment

applications before the publication of the FY 2010 IPPS proposed rule.

Approximately 90 individuals registered to attend the town hall

meeting in person, while additional individuals listened over an open

telephone line. Each of the five FY 2010 applicants presented

information on its

[[Page 24127]]

technology, including a discussion of data reflecting the substantial

clinical improvement aspect of the technology. We considered each

applicant's presentation made at the town hall meeting, as well as

written comments submitted on each applicant's application, in our

evaluation of the new technology add-on applications for FY 2010 in

this proposed rule.

In response to the published notice and the new technology town

hall meeting, we received two written comments regarding applications

for FY 2010 new technology add-on payments. We have summarized these

comments or, if applicable, indicated that there were no comments

received, at the end of each discussion of the individual applications.

We did not receive any general comments about the application of the

substantial clinical improvement criterion.

A further discussion of our evaluation of the applications and the

documentation for new technology add-on payments submitted for FY 2010

approval is provided under the specified areas under this section.

3. FY 2010 Status of Technologies Approved for FY 2009 Add-On Payments

We approved one application for new technology add-on payments for

FY 2009: CardioWestTM Temporary Total Artificial Heart

System (CardioWestTM TAH-t).

SynCardia Systems, Inc. submitted an application for approval of

the CardioWest TM temporary Total Artificial Heart system

(TAH-t). The TAH-t is a technology that is used as a bridge to heart

transplant device for heart transplant-eligible patients with end-stage

biventricular failure. The TAH-t pumps up to 9.5 liters of blood per

minute. This high level of perfusion helps improve hemodynamic function

in patients, thus making them better heart transplant candidates.

The TAH-t was approved by the FDA on October 15, 2004, for use as a

bridge to transplant device in cardiac transplant-eligible candidates

at risk of imminent death from biventricular failure. The TAH-t is

intended to be used in hospital inpatients. One of the FDA's post-

approval requirements is that the manufacturer agrees to provide a

post-approval study demonstrating success of the device at one center

can be reproduced at other centers. The study was to include at least

50 patients who would be followed up to 1 year, including (but not

limited to) the following endpoints: Survival to transplant; adverse

events; and device malfunction.

In the past, Medicare did not cover artificial heart devices,

including the TAH-t. However, on May 1, 2008, CMS issued a final

national coverage determination (NCD) expanding Medicare coverage of

artificial hearts when they are implanted as part of a study that is

approved by the FDA and is determined by CMS to meet CMS's Coverage

with Evidence Development (CED) clinical research criteria. (The final

NCD is available on the CMS Web site at: http://www.cms.hhs.gov/mcd/

viewdecisionmemo.asp?id=211.)

We indicated in the FY 2009 IPPS final rule (73 FR 48555) that,

because Medicare's previous coverage policy with respect to this device

had precluded payment from Medicare, we did not expect the costs

associated with this technology to be currently reflected in the data

used to determine the relative weights of MS-DRGs. As we have indicated

in the past, and as we discussed in the FY 2009 IPPS final rule,

although we generally believe that the newness period would begin on

the date that FDA approval was granted, in cases where the applicant

can demonstrate a documented delay in market availability subsequent to

FDA approval, we would consider delaying the start of the newness

period. This technology's situation represented such a case. We also

noted that section 1886(d)(5)(K)(ii)(II) of the Act requires that we

provide for the collection of cost data for a new medical service or

technology for a period of at least 2 years and no more than 3 years

``beginning on the date on which an inpatient hospital code is issued

with respect to the service or technology.'' Furthermore, the statute

specifies that the term ``inpatient hospital code'' means any code that

is used with respect to inpatient hospital services for which payment

may be made under the IPPS and includes ICD-9-CM codes and any

subsequent revisions. Although the TAH-t has been described by the ICD-

9-CM code(s) since the time of its FDA approval, because the TAH-t had

not been covered under the Medicare program (and, therefore, no

Medicare payment had been made for this technology), this code could

not be ``used with respect to inpatient hospital services for which

payment'' is made under the IPPS, and thus we assumed that none of the

costs associated with this technology would be reflected in the

Medicare claims data used to recalibrate the MS-DRG relative weights

for FY 2009. For this reason, as discussed in the FY 2009 IPPS final

rule, despite the FDA approval date of the technology, we determined

that TAH-t would still be eligible to be considered ``new'' for

purposes of the new technology add-on payment because the TAH-t met the

newness criterion on the date that Medicare coverage began, consistent

with issuance of the final NCD, effective on May 1, 2008.

After evaluation of the newness, costs, and substantial clinical

improvement criteria for new technology add-on payments for the TAH-t

and consideration of the public comments we received on the FY 2009

IPPS proposed rule, we approved the TAH-t for new technology add-on

payments for FY 2009 (73 FR 48557). We indicated that we believed the

TAH-t offered a new treatment option that previously did not exist for

patients with end-stage biventricular failure. However, we indicated

that we recognized that Medicare coverage of the TAH-t is limited to

approved clinical trial settings. The new technology add-on payment

status does not negate the restrictions under the NCD nor does it

obviate the need for continued monitoring of clinical evidence for the

TAH-t. We remain interested in seeing whether the clinical evidence

demonstrates that the TAH-t continues to be effective. If evidence is

found that the TAH-t may no longer offer a substantial clinical

improvement, we reserve the right to discontinue new technology add-on

payments, even within the 2 to 3 year period that the device may still

be considered to be new.

The new technology add-on payment for the TAH-t for FY 2009 is

triggered by the presence of ICD-9-CM procedure code 37.52

(Implantation of total heart replacement system), condition code 30,

and the diagnosis code reflecting clinical trial--V70.7 (Examination of

participant in clinical trial). For FY 2009 we finalized a maximum add-

on payment of $53,000 (that is 50 percent of the estimated operating

costs of the device of $106,000) for cases that involve this

technology. As noted above, the TAH-t is still eligible to be

considered ``new'' for purposes of the new technology add-on payment

because the TAH-t met the newness criterion on the date that Medicare

coverage began, consistent with issuance of the final NCD, effective on

May 1, 2008. Therefore, for FY 2010, we are proposing to continue new

technology add-on payments for cases involving the TAH-t in FY 2010

with a maximum add-on payment of $53,000.

[[Page 24128]]

4. FY 2010 Applications for New Technology Add-On Payments

We received six applications to be considered for new technology

add-on payment for FY 2010. However, one applicant withdrew its

application. Emphasys Medical submitted an application for new

technology add-on payments for FY 2010 for the Emphasys Medical

Zephyr[supreg] Endobronchial Valve (Zephyr[supreg] EBV). However,

Emphasys Medical withdrew its application from further review in

December 2008. Since the Zephyr[supreg] EBV application was withdrawn

prior to the town hall meeting and publication of the FY 2010 IPPS

proposed rule, we are not discussing the application in this proposed

rule.

A discussion of the remaining five applications is presented below.

At the time this proposed rule was developed, some of the technologies

had not yet received FDA approval. Consequently, our discussion below

of these cases may be limited.

a. The AutoLITT TM System

Monteris Medical submitted an application for new technology add-on

payments for FY 2010 for the AutoLITT TM. AutoLITT

TM is a minimally invasive, MRI-guided catheter tipped laser

designed to destroy malignant brain tumors with interstitial thermal

energy and is designed to cause immediate coagulation and necrosis of

diseased tissue. The applicant asserts that the AutoLITT TM

delivers laser energy to the lesion with a proprietary 3mm diameter

probe that directs the energy radially (that is, at right angle to the

axis of the probe) toward the targeted tumor tissue in a narrow beam

profile and at the same time, a proprietary probe cooling system

removes heat from tissue not directly in the path of the laser beam,

ostensibly protecting it from thermal damage and enabling the physician

to selectively coagulate only targeted tissue. The applicant expects

that AutoLITT TM will receive a 510K FDA clearance in early

2009, and the FDA approval will be for use in patients with

glioblastoma multiforme brain tumors. Because the technology is not yet

approved by the FDA, we will limit our discussion of this technology to

data and information that the applicant submitted, rather than make

specific proposals with respect to whether the device would meet the

new technology add-on payment criteria.

With regard to the newness criterion, we are concerned that the

AutoLITT TM may be substantially similar to the device that

it listed as its predicate device in its application to the FDA for

approval. The applicant identified Visual-ase as its predicate device,

which is also used to treat tumors of the brain. Visual-ase was

approved by the FDA in 2006. The applicant maintains that AutoLITT

TM can be distinguished from the Visual-ase by its mechanism

of action (that is, side-firing laser versus elliptical firing).

A new ICD-9-CM procedure code, 17.61 (Laser interstitial thermal

therapy [LITT] of lesion or tissue of brain under guidance), was

recommended for approval at the September 2008 ICD-9-CM Coordination

and Maintenance Committee meeting. If approved, the new code would

become effective on October 1, 2009. We welcome comments from the

public regarding whether or not the AutoLITT TM is

substantially similar to the Visual-ase.

In an effort to demonstrate that AutoLITT TM meets the

cost criterion, the applicant used 2006 Medicare data from the

Healthcare Cost and Utilization Project (HCUP). We first note that the

applicant believes that cases eligible for the AutoLITT TM

will map to MS-DRGs 25 (Craniotomy and Endovascular Intracranial

Procedures with MCC), 26 (Craniotomy and Endovascular Intracranial

Procedures with CC), and 27 (Craniotomy and Endovascular Intracranial

Procedures without CC or MCC). The applicant searched HCUP hospital

data for cases potentially eligible for the AutoLITT TM that

was assigned one of the following ICD-9-CM diagnosis codes: a diagnosis

code that begins with a prefix of 191 (Malignant neoplasm of brain);

diagnosis code 225.0 (Benign neoplasm of brain and other parts of

nervous system); or diagnosis code 239.6 (Neoplasm of the brain of

unspecified nature). The applicant found 39,295 cases and weighted the

standardized charge per case based on the amount of cases found within

each of the diagnosis codes listed above rather than the percentage of

cases that would group to different MS-DRGs. Based on this analysis,

the average standardized charge per case was $46,754. While the

applicant's analysis established a case-weighted average charge per

case, it did not determine a case-weighted average standardized charge

per case by MS-DRG (as required by the application). Therefore, in

order to determine a case-weighted average standardized charge per case

by MS-DRG, the applicant used data from a Rand health report \4\ to

first determine the percentage of cases that would map to MS-DRGs 25,

26, and 27 and combined this analysis with the analysis above to

determine a case-weighted average standardized charge per case by MS-

DRG. According to its report, Rand used 2006 MedPAR claims data and

found 63,876 cases in CMS-DRG 1 (Craniotomy Age Greater Than 17 with

CC) and 39,878 cases in CMS-DRG 2 (Craniotomy Age Greater Than 17

without CC) for a total of 103,754 cases. Based on ICD-9-CM procedure

and diagnosis codes, Rand converted these cases from CMS-DRGs 1 and 2

to MS-DRGs 25, 26, and 27. Rand determined that, of the 63,876 cases in

CMS-DRG 1, 24,116 of these cases would map to MS-DRG 25 (or 23.2

percent of all cases) and 39,760 cases would map to MS-DRG 26 (or 38.4

percent of all cases). All 39,878 cases from CMS-DRG 2 would map to MS-

DRG 27 (or 38.4 percent of all cases in CMS-DRGs 1 and 2). Using the

percentages from Rand's analysis, the case-weighted average

standardized charge per case by MS-DRG was $46,754. We note that,

combining the Rand analysis with the HCUP analysis did not change the

case-weighted average standardized charge per case from the results

from the HCUP analysis (both analyses produced a case-weighted average

standardized charge per case of $46,754). The applicant did identify

the average standardized charge per case in the aggregate but has yet

to identify cases within the MS-DRGs themselves and, therefore, the

applicant has not determined the case-weighted average standardized

charge per case by MS-DRG.

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\4\ Rand Corporation: Rand Health--Understanding Medicare

Severity-DRGs. A presentation given by Barbara Wynn at the Florida

Hospital Association Meeting on November 1, 2007.

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The applicant also noted that the case-weighted average

standardized charge per case of $46,754 did not include charges related

to the AutoLITT TM. Therefore, it is necessary to add the

charges related to the device to the case-weighted average standardized

charge per case in evaluating the cost threshold criterion. Although

the applicant submitted data related to the estimated cost of the

AutoLITT TM per case, the applicant stated that the cost of

the device was proprietary information. Based on a study of charge

compression data by RTI \5\ and charge master data from Stanford

University and University of California, San Francisco, the applicant

estimates $24,389 in charges related to the AutoLITT TM (we

note that some of the data used a markup of 294 percent of the costs).

Adding the estimated charges related to the device to the case-weighted

average standardized charge

[[Continued on page 24129]]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

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[[pp. 24129-24178]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24128]]

[[Page 24129]]

per case resulted in a case-weighted average standardized charge per

case of $71,143 ($46,754 plus $24,389). Using the FY 2010 thresholds

published in Table 10 (73 FR 58008), the case-weighted threshold for

MS-DRGs 25, 26, and 27 was $58,069 (all calculations above were

performed using unrounded numbers). Because the case-weighted average

standardized charge per case for the applicable MS-DRGs exceeds the

case-weighted threshold amount, the applicant maintains that the

AutoLITT TM would meet the cost criterion.

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\5\ RTI International, A Study of Charge Compression in

Calculating DRG Relative Weights, RTI Project No. 0207964.012.008;

January 2007.

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We invite public comment on whether or not the AutoLITT

TM meets the cost criterion for a new technology add-on

payment, particularly in light of the fact that the applicant did not

determine a case-weighted average standardized charge per case by MS-

DRG (as discussed above).

With respect to the substantial clinical improvement criterion, the

applicant maintains that it meets this criterion in its application.

Specifically, the applicant stated that several non-AutoLITT \TM\

clinical trials have demonstrated that nonfocused LITT (and more

recently, the use of LITT plus MRI) improved survival, quality of life,

and recovery in patients with advanced glioblastoma multiforme tumors

and advanced metastatic brain tumors that cannot be effectively treated

with surgery, radiosurgery, radiation, chemotherapy, or any currently

available clinical procedure. In a number of these patients, nonfocused

LITT was the treatment of last resort, due to either the

unresponsiveness or inability of these therapies to treat the brain

tumor (due to tumor location, type, or size, among others). The

applicant also maintains that improved clinical outcomes using

nonfocused LITT have included reduced recovery time and a reduced rate

of complications (that is, infection, brain edema). The applicant

stated that these factors, as discussed in the FY 2001 final rule (66

FR 46914 through 46915) demonstrate that the AutoLITT \TM\ meets the

new technology criterion for substantial clinical improvement.

The applicant further asserts that AutoLITT \TM\ would represent a

substantial clinical improvement over existing standards of care for a

number of reasons and should build upon less sophisticated, nonfocused

LITT therapies. These clinical improvements cited by the applicant

include: a less invasive method of tumor ablation, potentially leading

to lower complication rates post procedure (infection, edema); an

ability to employ multiple interventions over shorter periods of time

and an ability to be used as a treatment of last resort (radiosurgery

is limited due to radiation dosing and craniotomy is limited to 1 to 2

procedures); an ability to be used in hard-to-reach brain tumors (the

AutoLITT \TM\ may be used as a treatment of last resort); and a shorter

recovery time (the possibility for same day surgery, which has been

demonstrated above with non-focused LITT).

We appreciate the applicant's summary of why this technology

represents a substantial clinical improvement. While we recognize the

future potential of this interesting therapy, we have concerns that,

besides lacking FDA approval at this time, to date the AutoLITT \TM\

has been used for the treatment of only a few patients as part of a

safety evaluation with no comparative efficacy data and, therefore,

there may not be sufficient objective clinical evidence to determine if

the AutoLITT \TM\ meets the substantial clinical improvement criteria.

We invite public comment on whether or not the AutoLITT \TM\ meets the

substantial clinical improvement criterion.

We did not receive any written public comments regarding this

application for new technology add-on payments concerning the new

technology town hall meeting.

b. CLOLAR [supreg] (clofarabine) Injection

Genzyme Oncology submitted an application for new technology add-on

payments for FY 2010 for CLOLAR [supreg] (clofarabine) injection.

CLOLAR [supreg] is a chemotherapeutic agent that is administered

intravenously and is currently being evaluated for the treatment of

patients with acute myeloid leukemia (AML). CLOLAR [supreg] was first

granted FDA approval in December 2004 for the treatment of pediatric

patients (ages 1-21 years), a population not typically eligible for

Medicare, with acute lymphoblastic leukemia (ALL) who did not respond

to at least two prior treatment attempts. Genzyme Oncology submitted a

supplement to its pediatric application (sNDA) to the FDA in November

2008, in which it requested approval for CLOLAR[supreg] use in

previously untreated adult patients with AML with at least one

unfavorable baseline prognostic factor. Unfavorable prognostic factors

include: Age greater than or equal to 70 years; antecedent hematologic

disorder (AHD); Easter Cooperative Oncology Group (ECOG) performance

status (PS) of 2; or intermediate/unfavorable risk karyotype. CLOLAR

[supreg] is expecting to receive sNDA approval from the FDA by May

2009. Because the technology is not yet approved by the FDA, we are

limiting our discussion of this technology to data that the applicant

submitted, rather than making specific proposals with respect to

whether the device would meet the new technology add-on payment

criteria.

With regard to the newness criterion, we note that, although the

applicant has submitted an application to the FDA for an sNDA for the

treatment of patients with AML, the FDA approval for the new indication

alone does not necessarily demonstrate that CLOLAR [supreg] would meet

the newness criterion for purposes of new technology add-on payments.

The newness criterion is intended to apply to technologies that have

been available to Medicare beneficiaries for no more than 2 to 3 years.

Therefore, a technology that applies for a supplemental FDA approval

must demonstrate that the new approval is not substantially similar to

the prior approval.

As discussed above, the new technology add-on payment is available

to new medical services or technologies that satisfy the three criteria

set forth in our regulations at Sec. 412.87(b) (that is, newness,

high-costs, and substantial clinical improvement). Typically, we begin

our analysis with an evaluation of whether an applicant's technology

meets what we refer to as the ``newness criterion'' under Sec.

412.87(b)(2) (that is, whether Medicare data are available to fully

reflect the cost of the technology in the MS-DRG weights through

recalibration). Generally, we believe that the costs of a technology

begin to be reflected in the hospital charge data used to recalibrate

the MS-DRG relative weights when the technology becomes available on

the market, usually on or soon after the date on which it receives FDA

approval. Unlike the typical applicant for the new technology add-on

payment, however, CLOLAR [supreg] is not new to the market but has been

available since it was first granted FDA approval in December 2004 for

the treatment of pediatric patients with acute lymphoblastic leukemia

(ALL). Therefore, we first must determine whether CLOLAR [supreg]

nevertheless should be considered a new technology if approved by the

FDA for a new indication, specifically for use in adult patients age 70

and above with AML.

Congress provided for the new technology add-on payment in order to

ensure that Medicare beneficiaries have access to new technologies. As

discussed previously, there often is a lag time of 2 to 3 years before

the costs of new technologies are reflected in the recalibration of the

relevant MS-DRGs. Because a new technology often has higher costs than

existing technologies,

[[Page 24130]]

during this lag time the current MS-DRG payment may not adequately

reflect the costs of the new technology. The new technology add-on

payment addresses this concern by ensuring that hospitals receive an

add-on payment under the IPPS for costly new technologies that

represent a substantial clinical improvement over existing technologies

until such time when the cost of the technology is reflected within the

MS-DRG relative weights. When an existing technology receives FDA

approval for a new indication, similar concerns may arise. If, prior to

the FDA approval for the new indication, the technology has not been

used to treat Medicare patients for purposes consistent with the new

indication, the relevant MS-DRGs may not reflect the cost of the

technology. Consequently, Medicare beneficiaries may not have adequate

access to the technology when used for purposes consistent with the new

indication. Allowing the new technology add-on payment for the

technology when used for the new indication would address this concern.

For these reasons, we believe that treating an existing technology as

``new'' when approved by the FDA for a new indication may be warranted

under certain circumstances.

In the September 7, 2001 final Rule (66 FR 46915), we stated that a

new use of an existing technology may be eligible for the new

technology add-on payment under certain conditions. We believe it is

appropriate to consider an existing technology for the new technology

add-on payments when its new use is not substantially similar to

existing uses of the technology. In the FY 2006 IPPS final rule (70 FR

47351), we explained our policy regarding substantial similarity in

detail and its relevance for assessing if the hospital charge data used

in the development of the relative weights for the relevant DRGs

reflect the costs of the technology. In that final rule, we stated

that, for determining substantial similiarity, we consider (1) Whether

a product uses the same or a similar mechanism of action to achieve a

therapeutic outcome, and (2) whether a product is assigned to the same

or a different DRG are relevant for determining substantial similarity.

We indicated that both of the above criteria should be met in order for

a technology to be considered ``substantially similar'' to an existing

technology. However, in that same final rule, we also noted that, due

to the complexity of issues regarding the substantial similarity

component of the newness criterion, it may be necessary to exercise

flexibility when considering whether technologies are substantially

similar to one another. Specifically, we stated that we may consider

additional criteria or factors in some contexts, but not others.

We believe that in determining whether a new use of an existing

technology is substantially similar to existing uses of the technology,

it may be relevant to consider not only the two criteria discussed in

the FY 2006 IPPS final rule, but also certain additional factors.

Specifically, we believe it may also be appropriate to analyze whether,

as compared to existing uses of the technology, the new use involves

the treatment of the same or similar type of disease and the same or

similar patient population. Accordingly, we would determine that the

new use of an existing technology is substantially similar to one or

more existing uses of the technology if (1) the new and existing uses

of the technology use the same or a similar mechanism of action to

achieve a therapeutic outcome, (2) the new use of the product is

assigned to the same MS-DRG(s) as the existing uses, and (3) the new

use of the technology involves the treatment of the same or similar

type of disease and the same or similar patient population. If all

three criteria are met and the new use is deemed substantially similar

to one or more of the existing uses of the technology (that is beyond

the newness period), we would conclude that the technology is not new

and, therefore is not eligible for the new technology add-on payment.

We note that we considered, but rejected, the inclusion of the third

factor in the FY 2006 IPPS final rule on the grounds that we believed

that it was more relevant to analyze whether the costs of the

technology were already reflected in the relative weights of the MS-

DRGs. However, upon further consideration, we believe that both the

type of disease and patient population for which a technology is used

are also relevant in determining whether one indication of a technology

is ``substantially similar'' to another.

We note that the discussion of substantial similarity in the FY

2006 IPPS final rule related to comparing two separate technologies

made by different manufacturers. Nevertheless, we believe the criteria

discussed in the FY 2006 IPPS final rule also are relevant when

comparing the similarity between a new use and existing uses of the

same technology (or a very similar technology manufactured by the same

manufacturer). In other words, it is necessary to establish that the

new indication for which the technology has received FDA approval is

not substantially similar to that of the prior indication. Such a

distinction is necessary to determine the appropriate start date of the

newness period in evaluating whether the technology would qualify for

add-on payments (that is, the date of the ``new'' FDA approval or that

of the prior approval), or whether the technology could qualify for

separate new technology add-on payments under each indication. We

welcome comments on our proposed modification to analyzing whether a

technology is substantially similar to another.

With respect to CLOLAR[supreg], it is relevant to consider whether

there is a clear distinction between the types of disease that

CLOLAR[supreg] is intended to treat and the patient populations

described in the indications in assessing whether the indication for

which a supplemental FDA approval is pending is substantially similar

to the indication related to the existing FDA approval for CLOLAR.

Accordingly, we have analyzed both the current and pending FDA

approvals and indications in order to determine whether or not

CLOLAR[supreg] for the treatment of ALL in patients ages 1-21 should be

deemed substantially similar to CLOLAR[supreg] when used for the

treatment of AML in patients ages 70 and above. In this case, we

compared the two indications against the substantial similarity factors

that we outlined in the FY 2006 IPPS final rule (referenced above). We

determined that CLOLAR[supreg] meets both factors of the substantial

similarity criteria that we outlined in the FY 2006 IPPS final rule

(that is, the use of CLOLAR[supreg] for either indication utilizes the

same or a similar mechanism of effect to achieve a therapeutic outcome,

and both indications map to the same MS-DRGs). We also analyzed both

the current and pending FDA approvals and indications against the two

additional factors we described above (that is, whether the new

indication as compared to the old indication would involve the use of

CLOLAR to treat the same or similar disease and the same or similar

patient population). In the course of our analysis, we determined that,

although ALL and AML are both types of leukemia, they are separate and

distinct hematologic malignancies that typically affect different

patient populations. Furthermore, patients ages 1-21 with ALL differ

significantly from older patients ages 70 and above with AMI in terms

of clinical factors, such as the presence of comorbid conditions, and

expected prognosis. Accordingly, because the two indications do not

meet the additional factors we included under substantial similarity,

we do not

[[Page 24131]]

believe that CLOLAR[supreg] for the indication of treatment of ALL in

patients ages 1-21 should be considered substantially similar to

CLOLAR[supreg] for the indication of treatment of AML in older

patients.

With respect to application of the newness criterion under Sec.

412.87(b)(2), our evaluation also considers whether the data for the

relevant MS-DRGs reflect use of the new technology for one or more

purposes outside the previously approved indication(s). To the extent

that the data suggest that the technology has been used outside the

previously approved indication for more than 2 or 3 years (for example,

the technology has been used for a purpose that is the basis of the

newly approved indication), we believe that the costs of the technology

for the new use are reflected in the weights assigned to the relevant

MS-DRGs. In this case, we will conclude that the technology does not

meet the newness criterion under Sec. 412.87(b)(2) because its costs

are already reflected within the relevant MS-DRGs. Therefore, even if

we determine that the new use of CLOLAR[supreg] is not substantially

similar to the existing use of CLOLAR[supreg], we believe it is

relevant to assess whether the likelihood that the costs of this drug

are included in the data that goes into determining the MS-DRG relative

weights because CLOLAR[supreg] has not been FDA approved to treat the

types of patients that are commonly found in the Medicare population.

Regarding this point, the applicant maintains that because of the age

group for which CLOLAR[supreg] is currently used to treat patients with

ALL (that is, pediatric patients who are ages 1-21 years), ``it is

statistically improbable that claims paid under the relevant MS-DRGs

include CLOLAR[supreg] costs.'' Currently, ICD-9-CM procedure code

99.25 (Injection or infusion of cancer chemotherapeutic substance)

would be used to identify the administration of CLOLAR[supreg] for the

treatment of both ALL and AML. We note that the applicant submitted an

application for a unique ICD-9-CM procedure code that was discussed at

the March 11, 2009 ICD-9-CM Coordination and Maintenance Committee

meeting. In addition, cases involving the use of CLOLAR[supreg] for

either indication would be expected to routinely map to MS-DRGs 837,

838, and 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis

or High Dose Chemotherapy Agent with MCC, Chemotherapy with Acute

Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy

Agent, and Chemotherapy with Acute Leukemia as Secondary Diagnosis

without CC/MCC, respectively). Although we generally agree with the

applicant's statement that it is statistically improbable that any

Medicare patients received CLOLAR[supreg] under the currently approved

indication for younger patients with ALL, the applicant has not, to

date, demonstrated that none of the inpatients who received

CLOLAR[supreg] for the treatment of patients with ALL were Medicare

patients. The applicant maintains that no data are available to

identify the exact number of Medicare beneficiaries who are age 21

years or less (that is, those patients whose age identically matches

that of the group for whom CLOLAR[supreg] is an approved treatment).

However, the applicant conducted an analysis of the FY 2007 MedPAR

claims data for the MS-DRGs associated with chemotherapy treatment for

ALL (CMS-DRG 492 and MS-DRGs 837, 838, and 839) and found that less

than 1 percent of all claims that map to those DRGs were for patients

who are age 25 years or less. Therefore, the applicant asserts that,

given the small number of patients eligible to receive CLOLAR[supreg]

for its FDA approved indication, it is statistically improbable that

claims paid under the relevant DRGs include or adequately reflect the

costs of CLOLAR[supreg].

We welcome comments from the public on whether the costs of

CLOLAR[supreg] are already included in the data used to determine the

relative weights for the MS-DRGs to which cases involving

CLOLAR[supreg] map and on whether the current FDA-approved indication

of CLOLAR[supreg] is substantially similar to that of the pending one.

In an effort to demonstrate that CLOLAR[supreg] meets the cost

criterion, the applicant searched the FY 2007 MedPAR file for cases

potentially eligible for CLOLAR[supreg] that were assigned a

combination of the following codes: any principal diagnosis code with a

prefix of V58.1 (Encounter for antineoplastic chemotherapy and

immunotherapy), or a principal diagnosis code of V67.2 (Chemotherapy

follow up examination), or any diagnosis code that begins with a prefix

of 205 (Acute promyelocytic leukemia). The applicant found 874 cases

(or 30.3 percent of all cases) in MS-DRG 837 (Chemotherapy with Acute

Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent

with MCC), 863 cases (or 29.9 percent of all cases) in MS-DRG 838

(Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or

with High Dose Chemotherapy Agent), and 1,148 cases (or 39.8 percent of

all cases) in MS-DRG 839 (Chemotherapy with Acute Leukemia as Secondary

Diagnosis without CC/MCC). The average standardized charge per case was

$133,428 for MS-DRG 837, $66,997 for MS-DRG 838, and $28,453 for MS-DRG

839, which result in a case-weighted average standardized charge per

case of $71,785.

The average standardized charge per case does not include charges

related to CLOLAR[supreg]; therefore, it is necessary to add the

charges related to CLOLAR[supreg] to the average standardized charge

per case in evaluating the cost threshold criterion. Although the

applicant submitted data related to the estimated cost of

CLOLAR[supreg] per case, the applicant noted that the cost of the drug

was proprietary information. The applicant estimates $63,364 in charges

related to CLOLAR[supreg] (based on a 100-percent charge markup of the

cost of the drug). Adding the charges related to the drug to the

average standardized charge per case (based on the case distribution

from the applicant's FY 2007 MedPAR claims data analysis) resulted in a

case-weighted average standardized charge per case of $135,149 ($71,785

plus $63,364). Using the FY 2010 thresholds published in Table 10 (73

FR 58008), the case-weighted threshold for MS-DRGs 837, 838, and 839

was $55,802 (all calculations above were performed using unrounded

numbers). Because the case-weighted average standardized charge per

case for the applicable MS-DRGs exceeds the case-weighted threshold

amount, the applicant maintains that CLOLAR[supreg] would meet the cost

criterion. We invite public comment on whether or not CLOLAR[supreg]

meets the cost criterion.

With regard to the substantial clinical improvement criterion, the

applicant asserts that despite significant advances that have been made

in the management of AML in younger adults (that is, persons under the

age of 60 years), including the benefit of intensive remission

induction therapy [often comprised of an anthracycline combined with

intermediate or highdose cytarabine (``7 + 3'')] to either achieve or

maintain a complete remission (CR) or CR with incomplete platelet

recovery (CRp) that has been progressively demonstrated over the past

several years, such success has not been achieved in persons over the

age of 60 years. The applicant stated that for the older patient

population, conventional induction therapy with ``7 + 3'' is poorly

tolerated and often does not benefit older patients with unfavorable

baseline prognostic factors. In addition, the applicant stated that

older adult patients are also at high risk for early induction

mortality. According to the applicant, depending on comorbidity

factors, the rate of

[[Page 24132]]

induction mortality can be as high as 65 percent within 8 weeks

following conventional intensive chemotherapy.

The applicant also presented an analysis of some recent data that

has emerged in connection with CLOLAR[supreg] use in older patients

with AML. A Phase II study comparing single agent CLOLAR[supreg] to

CLOLAR[supreg] combined with low-dose cytarabine (LDAC) in patients age

60 years and older, found that 42 percent of the patients treated with

CLOLAR[supreg] alone achieved a CR or CR with incomplete peripheral

blood count recovery, and found that 59 percent of the patients treated

with the combination therapy achieved a CR or CR with incomplete

peripheral blood count recovery. Both treatment regimens were tolerated

in this patient population without a distinction in terms of toxicity.

The safety and efficacy of CLOLAR[supreg] was recently reported in

another Phase II study of 66 older adult patients (over age 65 years)

with untreated AML. All patients were considered unfit for conventional

induction therapy due to the presence of one or more unfavorable

prognostic factors. In the group of patients with adverse cytogenetic

profiles, the overall response rate was 53 percent with a CR rate of 42

percent. In addition, this group had a significantly prolonged median

survival (more than 6 months) when compared to a similar group that had

received LDAC.

The applicant conducted a pivotal, multicenter clinical trial which

serves as the basis for an sNDA to the FDA for approval of

CLOLAR[supreg] as a treatment for adult AML. According to the

applicant, the primary objective of this study was to assess the

efficacy of CLOLAR[supreg] in previously untreated adults who were at

least 60 years old with AML for whom standard induction chemotherapy

was unlikely to be of benefit due to at least one unfavorable baseline

prognostic factor. The results of this pivotal trial indicate that

single agent CLOLAR[supreg] is active and well-tolerated when

administered to previously untreated adults with AML and at least one

adverse prognostic factor. The overall remission rate (CR + CRp = 45

percent) with CLOLAR[supreg] compared favorably to historical studies

with ``7 + 3'' regimens. Responses in patients receiving CLOLAR[supreg]

were consistent regardless of the number or the type of unfavorable

prognostic factor including a CR of 43 percent in patients with

unfavorable cytogenetics, 50 percent in patients with AHD, 40 percent

in patients more than the age of 70, and 38 percent in patients with an

Eastern Cooperative Oncology Group (ECOG) PS of 2. In addition, it did

not appear that response rates were affected by the presence of

multiple adverse prognostic factors (50 percent, 48 percent, and 42

percent in patients with one, two and three risk factors,

respectively). The overall response rate was even higher in patients

who were less than age 70 years (56 percent), and in patients with an

ECOG PS of 0 (64 percent). Thirty-day mortality (for all causes) was

9.6 percent. Drug-related adverse events were consistent with prior

reports with single agent CLOLAR[supreg], and were manageable in the

patient population studied. Five patients (4 percent) had to

discontinue treatment due to toxicity, but many patients were able to

receive subsequent consolidation CLOLAR[supreg] treatments. The

applicant maintains that there is no standard treatment in older adult

patients with comorbid conditions or adverse disease characteristics

for whom conventional induction therapy is not considered an

appropriate option. The applicant further asserts that the absence of

treatment options, especially in a disease with onset at a median age

of 67, clearly represents a significant unmet medical need.

We are concerned that this drug may offer little to no increased

survival benefit in a patient population whose overall prognosis is

exceedingly poor. Therefore, it is not clear that the drug represents a

substantial clinical improvement over existing therapies, such as

increased benefit survival or reduced need for hospitalization or

physician visits. (We refer readers to 66 FR 46941 for a more detailed

discussion relating to the substantial clinical improvement criterion.)

We welcome public comment about whether or not CLOLAR[supreg]

represents a substantial clinical improvement.

We did not receive any written public comments regarding this

application for new technology add-on payments concerning the new

technology town hall meeting.

c. LipiScanTM Coronary Imaging System

InfraReDx, Inc. submitted an application for new technology add-on

payments for FY 2010 for the LipiScanTM Coronary Imaging

System (LipiScanTM). The LipiScanTM device is a

diagnostic tool that uses Intravascular Near Infrared Spectroscopy

(INIRS) during an invasive coronary catheterization to scan the artery

wall in order to determine coronary plaque composition. The purpose of

the device is to identify lipid-rich areas in the artery because such

areas have been shown to be more prone to rupture. The procedure does

not require flushing or occlusion of the artery. INIRS identifies the

chemical content of plaque by focusing near infrared light at the

vessel wall and measuring reflected light at different wavelengths

(that is, spectroscopy). The LipiScanTM system collects

approximately 1,000 measurements per 12.5 mm of pullback, with each

measurement interrogating an area of 1 to 2 mm\2\ of lumen surface

perpendicular to the longitudinal axis of the catheter. When the

catheter is in position, the physician activates the pullback and

rotation device and the scan is initiated providing 360 degree images

of the length of the artery. The rapid acquisition speed for the image

freezes the motion of the heart and permits scanning of the artery in

less than 2 minutes. When the catheter pullback is completed, the

console displays the scan results, which is referred to as a

``chemogram'' image. The chemogram image requires reading by a trained

user, but, according to the applicant was designed to be simple to

interpret.

With regard to the newness criterion, the LipiScanTM

received a 510K FDA clearance for a new indication on April 25, 2008,

and was available on the market immediately thereafter. On June 23,

2006, InfraReDx, Inc. was granted a 510K FDA clearance for the

``InfraReDx Near Infrared (NIR) Imaging System.'' Both devices are

under the common name of ``Near Infrared Imaging System'' according to

the 510K summary document from the FDA. However, the InfraReDx NIR

Imaging System device that was approved by the FDA in 2006 was approved

``for the near infrared imaging of the coronary arteries,'' whereas the

LipiscanTM device cleared by the FDA in 2008 is for a

modified indication. The modified indication specified that

LipiscanTM is ``intended for the near-infrared examination

of coronary arteries \* \* \*, the detection of lipid-core-containing

plaques of interest \* \* \* [and] for the assessment of coronary artery

lipid core burden.''

We have concerns regarding whether LipiscanTM is

substantially similar to its predicate device that was approved by FDA

in 2006. Specifically, it appears that the two devices, which are

manufactured by the same company, do not differ in either design or

functionality, according to the approval order documents from the FDA.

In the 2008 approval order, the FDA stated, ``The LipiScan Coronary

Imaging System utilizes the same basic catheter design as the

predicate, the InfraReDx NIR Imaging System (June 23, 2006). These

devices have a similar intended use, use the same operating principal,

incorporate the same basic catheter design, have the same shelf life,

and are

[[Page 24133]]

packaged using the same materials and processes. The modifications from

the lnfraReDx NIR Imaging System to the LipiScan Coronary Imaging

System are the improved catheter design, improved user interface

(including PBR and console), and the additional testing required to

support an expanded indication for use.'' Therefore, it appears that

the only difference between the two approvals may be a modification of

the intended use.

As mentioned earlier in our discussion of the CLOLAR[supreg]

application in section II.I.4.b. of this proposed rule, our policy

regarding substantial similarity discussed in the FY 2006 final rule

(70 FR 47351 through 47532) outlined two criteria as it relates to two

separate technologies that are made by different manufacturers that

were used to guide our determination of whether two technologies were

substantially similar to one another. Although the LipicanTM

is a diagnostic device and not a therapeutic device we believe that the

substantial similarity component of the newness criterion still

applies.

Both the prior and the new FDA indications for

LipiScanTM use the same or a similar mechanism of action to

achieve a desired therapeutic outcome, and both treat patients that

would generally be assigned to the same MS-DRG. Similarly, both

indications of LipiScanTM are intended to treat the same

disease in the same patient population. Consequently, we have concerns

as to whether or not the two intended uses are substantially similar,

especially considering that the technologies appear essentially

identical. We welcome public comment on whether or not the latest 510K

FDA clearance should be considered ``substantially similar'' to its

predicate technology approved by the FDA in 2006.

We note that the LipiscanTM technology is identified by

ICD-9-CM procedure code 38.23 (Intravascular spectroscopy), which

became effective October 1, 2008, and cases involving the use of this

device generally map to MS-DRG 246 (Percutaneous Cardiovascular

Procedures with Drug-Eluting Stent(s) with MCC or 4+ Vessels/Stents);

MS-DRG 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting

Stent(s) without MCC); MS-DRG 248 (Percutaneous Cardiovascular

Procedures with Non-Drug-Eluting Stent(s) with MCC or 4+ Vessels/

Stents); MS-DRG 249 (Percutaneous Cardiovascular Procedures with Non-

Drug-Eluting Stent(s) without MCC); MS-DRG 250 (Percutaneous

Cardiovascular Procedures without Coronary Artery Stent with MCC); and

MS-DRG 251 (Percutaneous Cardiovascular Procedures without Coronary

Artery Stent without MCC).

In an effort to demonstrate that the technology meets the cost

criterion, the applicant used the FY 2009 After Outliers Removed (AOR)

file (posted on the CMS Web site) for cases potentially eligible for

LipiscanTM. The applicant believes that every case within

DRGs 246, 247, 248, 249, 250, and 251 are eligible for

LipiscanTM. In addition, the applicant believes that

LipiscanTM will be evenly distributed across patients in

each of the six MS-DRGs (16.6 percent within each MS-DRG). Using data

from the AOR file, the applicant found the average standardized charge

per case for MS-DRGs 246, 247, 248, 249, 250, and 251 was $65,364,

$42,162, $58,754, $37,048, $61,016, and $35,878 respectively, equating

to an average standardized charge per case of $50,037. The applicant

indicated that the average standardized charge per case does not

include charges related to LipiscanTM; therefore, it is

necessary to add the charges related to the device to the average

standardized charge per case in evaluating the cost threshold

criterion. Although the applicant submitted data related to the

estimated cost of LipiscanTM per case, the applicant noted

that the cost of the device was proprietary information. Based on a

sampling of two hospitals that have used the device, the applicant used

a markup of 120 percent of the costs and estimates $5,280 in charges

related to LipiscanTM. Because the applicant lacked a

significant sample of cases to determine the charges associated with

the device, we have concerns as to whether or not the estimate of

$5,280 in charges related to the device is a valid estimate. Adding the

estimated charges related to the drug to the average standardized

charge per case (based on the case distribution from the applicant's

2009 AOR analysis) results in a case-weighted average standardized

charge per case of $55,317 ($50,037 plus $5,280). Using the FY 2010

thresholds published in Table 10 (73 FR 58008), the case-weighted

threshold for MS-DRGs 246, 247, 248, 249, 250, and 251 was $53,847 (all

calculations above were performed using unrounded numbers). Because the

case-weighted average standardized charge per case for the applicable

MS-DRGs exceeds the case-weighted threshold amount, the applicant

maintains that LipiscanTM would meet the cost criterion. We

invite public comment on whether or not LipiscanTM meets the

cost criterion.

With regard to substantial clinical improvement, the applicant

maintains that the device meets this criterion for the following

reasons. The applicant noted that the September 1, 2001 final rule

states that one facet of the criterion for substantial clinical

improvement is ``the device offers the ability to diagnose a medical

condition in a patient population where the medical condition is

currently undetectable or offers the ability to diagnose a medical

condition earlier in a patient population than allowed by currently

available methods. There must also be evidence that use of the device

to make a diagnosis affects the management of the patient'' (66 FR

46914). The applicant believes that LipiscanTM meets all

facets of this criterion. The applicant asserted that the device is

able to detect a condition that is not currently detectable. The

applicant explained that LipiScanTM is the first device of

its kind to be able to detect lipid-core-containing plaques of interest

and to assess of coronary artery lipid core burden. The applicant

further noted that FDA, in its approval documentation, has indicated

that ``This is the first device that can help assess the chemical

makeup of coronary artery plaques and help doctors identify those of

particular concern.''

In addition, the applicant stated that the LipiScanTM

chemogram permits a clinician to detect lipid-core-containing plaques

in the coronary arteries compared to other currently available devices

that do not have this ability. The applicant explained that the

angiogram, the conventional test for coronary atherosclerosis, shows

only minimal coronary narrowing. However, the applicant indicated that

the LipiScanTM chemogram has the ability to reveal when an

artery contains extensive lipid-core-containing plaque at an earlier

stage.

The applicant also noted that the device has the ability to make a

diagnosis that better affects the management of the patient.

Specifically, the applicant explained that the chemogram results are

available to the interventional cardiologist during the PCI procedure,

and have been found to be useful in decision-making. Physicians have

reported changes in therapy based on LipiScanTM findings in

20 to 50 percent of patients. The most common use of

LipiScanTM results has been for selection of the length of

artery to be stented. In some cases a longer stent has been used when

there is a lipid-core-containing plaque adjacent to the area that is

being stented because a flow-limiting stenosis is present. Therefore,

the applicant contends that the use of LipiScanTM by

clinicians to select the length of artery to be stented and as an aid

in selection of intensity of lipid-altering therapy, demonstrates that

[[Page 24134]]

LipiScanTM affects the management of patients.

While we recognize that the identification of lipid-rich plaques in

the coronary vasculature holds promise in the management of coronary

artery disease, we are concerned that statements in the FDA approval

documents, as well as statements made by investigators in the

literature, suggest that the clinical implications of identifying these

lipid-rich plaques are not yet certain and that further studies need to

be done to understand the clinical implications of obtaining this

information. We are also concerned that there are no outcome data

regarding the use of the LipiScanTM technology.

The applicant also submitted commentary from Interventional

Cardiologists (a group of clinicians who currently utilize the

LipiScanTM device) explaining the clinical benefits of the

device. The applicant further noted that the device may have other

potential uses that would be of clinical benefit, and studies are

currently being conducted to investigate these other potential uses.

The applicant explained that LipiScanTM offers promise as a

means to enhance progress against the two leading problems in coronary

disease management: (1) The unacceptably high rate of second events

that occur even after catheterization, revascularization, and the

institution of optimal medical therapy; and (2) the failure to diagnose

coronary disease early, which results in sudden death or myocardial

infarction being the first sign of the disease in most patients. The

applicant further stated that the identification of coronary lipid-

core-containing plaques, which can most readily be done in those

already undergoing catheterization, is likely to be of benefit in the

prevention of second events. In the longer term, the applicant stated

that the identification of lipid-core-containing plaques by

LipiScanTM may contribute to the important goal of primary

prevention of coronary events, which, in the absence of adequate

diagnostic methods, continue to cause extensive morbidity, mortality

and health care expenditures in Medicare beneficiaries and the general

population.

We welcome public comment regarding whether or not the

LipiScanTM technology represents a substantial clinical

improvement in the Medicare population.

Below we summarize the written comments we received in response to

the town hall meeting.

Comment: The manufacturer of LipiScanTM stated that,

prior to the availability of LipiScanTM, current methods of

diagnosis could not detect that a patient has a lipid-core plaque prior

to the occurrence of a myocardial infarction. In April 2008, the FDA

approved the LipiScanTM Coronary Imaging System for

identification of these lipid-core plaques in patients undergoing

coronary angiography, thereby allowing the detection of this condition

in patients prior to the occurrence of a myocardial infarction.

The manufacturer stated that, since its FDA approval,

LipiScanTM has been used in over 110 patients and has

identified lipid-core plaques that were previously undetectable,

thereby revealing earlier stages of the disease. The manufacturer noted

that physicians have used this diagnostic information to provide

clinical benefits to their patients, including improved identification

of the length of the artery to be stented and selection of the

appropriate intensity of pharmacologic therapy designed to alter plasma

lipids.

In addition to these early diagnostic uses, the manufacturer

believes that LipiScanTM opens the possibility of eventual

detection and treatment of lipid-core plaques before they cause a

stenosis and/or a clinical event. The manufacturer added that the use

of this technology could lead to prevention of myocardial infarction,

which in turn would reduce the occurrence of heart failure and

arrhythmias--two conditions responsible for severe morbidity and

massive health care expenditures.

In addition, the manufacturer reiterated its assertion that

LipiScanTM meets the newness criterion. The manufacturer

explained that FDA, in its approval documentation, has indicated that

``This is the first device that can help assess the chemical makeup of

coronary artery plaques and help doctors identify those of particular

concern.'' The manufacturer further noted that, while

LipiScanTM is equivalent to the predicate intravascular

ultrasound (IVUS) device, the features of the LipiScanTM

system produce different information because it permits the physician

to detect lipid-core plaques of interest and the lipid burden index.

The manufacturer also noted that the case-weighted average

standardized charge per case exceeds the case-weighted threshold (as

discussed above) and, therefore, the manufacturer believes that the

technology meets the cost criterion. In addition, the manufacturer

reasserted that it meets the substantial clinical improvement criterion

by the arguments it put forth in its application regarding substantial

clinical improvement (which are presented above in this section of the

preamble).

Finally, in its comment, the manufacturer concluded that

LipiScanTM is a novel diagnostic method that meets the three

criteria for a new technology add-on payment and that more frequent

utilization of LipiScanTM would occur with additional

reimbursement resulting in possible improved outcomes for patients

undergoing stenting. The manufacturer stated that LipiScanTM

has the added potential of contributing to the prevention of acute

coronary syndromes.

Response: We thank the manufacturer for its comments that were

submitted concerning the town hall meeting. We have considered these

comments in our evaluation of the technology in this proposed rule. As

stated above, we invite additional public comment relating to objective

data regarding the assertions presented by the manufacturer.

d. Spiration[supreg] IBV[supreg] Valve System

Spiration, Inc. submitted an application for new technology add-on

payments for FY 2010 for the Spiration[supreg] IBV[supreg] Valve System

(Spiration[supreg] IBV[supreg]). The Spiration[supreg] IBV[supreg] is a

device that is used to place, via bronchoscopy, small, one-way valves

into selected small airways in the lung in order to limit airflow into

selected portions of lung tissue that have prolonged air leaks

following surgery while still allowing mucus, fluids, and air to exit,

thereby reducing the amount of air that enters the pleural space. The

device is intended to control prolonged air leaks following three

specific surgical procedures: lobectomy; segmentectomy; or lung volume

reduction surgery. According to the applicant, an air leak that is

present on postoperative day 7 is considered ``prolonged'' unless

present only during forced exhalation or cough. In order to help

prevent valve migration, there are five anchors with tips that secure

the valve to the airway. The implanted valves are intended to be

removed no later than 6 weeks after implantation.

With regard to the newness criterion, the Spiration[supreg]

IBV[supreg] received a Humanitarian Device Exemption (HDE) approval

from the FDA on October 24, 2008. We are unaware of any previously FDA-

approved predicate devices, or otherwise similar devices, that could be

considered substantially similar to the Spiration[supreg] IBV[supreg].

However, the applicant asserted that the FDA has precluded the device

from being used in the treatment of any patients until Institutional

Review Board (IRB)

[[Page 24135]]

approvals regarding its study sites. Therefore, it would appear that

the Spiration[supreg] IBV[supreg] would meet the newness criterion once

it has obtained at least one IRB approval because the device would then

be available on the market to treat Medicare beneficiaries. We welcome

public comments about the date on which the newness period should begin

for this technology should it meet the other criteria to be approved

for new technology add-on payments. We note that the Spiration[supreg]

IBV[supreg] is currently described by ICD-9-CM procedure code 33.71

(Endoscopic insertion or replacement of bronchial valve(s)). At the

September 2008 ICD-9-CM Coordination and Maintenance Committee meeting,

we discussed a proposal to revise the existing code and create a new

code for endoscopic bronchial valve insertion in single and multiple

lobes.

In an effort to demonstrate that the technology meets the cost

criterion, the applicant searched the FY 2007 MedPAR file for cases

potentially eligible for use of the Spiration[supreg] IBV[supreg].

Specifically, the applicant searched for cases with one of the

following procedure codes: 32.4 (Lobectomy of lung); 32.3 (Segmental

resection of lung); or 32.22 (Long volume reduction surgery). The

applicant found 4,225 cases (or 21.6 percent of all cases) in MS-DRG

163 (Major Chest Procedure with MCC), 8,960 cases (or 45.8 percent of

all cases) in MS-DRG 164 (Major Chest Procedure with CC), and 6,358

cases (or 32.5 percent of all cases) in MS-DRG 165 (Major Chest

Procedure without CC/MCC). The average standardized charge per case was

$88,326 for MS-DRG 163, $48,494 for MS-DRG 164, and $38,463 for MS-DRG

165, equating to a case-weighted average standardized charge per case

of $53,842.

The average standardized charge per case does not include charges

related to the Spiration[supreg] IBV[supreg]; therefore, it is

necessary to add the charges related to the device to the average

standardized charge per case in evaluating the cost threshold

criterion. Although the applicant submitted data related to the

estimated cost of the Spiration[supreg] IBV[supreg] per case, the

applicant noted that the cost of the device was proprietary

information. The applicant estimates $21,450 in charges related to the

Spiration[supreg] IBV[supreg] (based on a 100-percent charge markup of

the cost of the device). The applicant based this amount on seven

actual cases that received the device. Because the applicant lacked a

significant sample of cases to determine the charges associated with

the device, we have concerns as to whether or not the $21,450 in

charges related to the device is a valid estimate. In addition, based

on the seven cases, the applicant made an estimate of the number of

valves used per case (the applicant noted that the number of valves

used per case is proprietary). We also have concerns that the applicant

lacked a significant sample of cases to determine a valid estimate of

the number of valves per case. Adding the estimated charges related to

the device to the average standardized charge per case (based on the

case distribution from the applicant's FY 2007 MedPAR claims data

analysis) resulted in a case-weighted average standardized charge per

case of $75,292 ($53,842 plus $21,450). Using the FY 2010 thresholds

published in Table 10 (73 FR 58008), the case-weighted threshold for

MS-DRGs 163, 164, and 165 was $54,715 (all calculations above were

performed using unrounded numbers). Because the case-weighted average

standardized charge per case for the applicable MS-DRGs exceeds the

case-weighted threshold amount, the applicant maintains that the

Spiration[supreg] IBV[supreg] would meet the cost criterion. We invite

public comment on whether or not the Spiration[supreg] IBV[supreg]

meets the cost criterion.

With respect to how the device would meet the substantial clinical

improvement criterion, the applicant submitted information that was

based on the Summary of Safety and Probable Benefit (SSPB) from the

FDA's HDE approval order for the device. The clinical results indicate

the Spiration[supreg] IBV[supreg] can be deployed in the intended

airway reasonably safely with a minimally invasive bronchoscopy

procedure. There have been a limited number of device complications and

no occurrences of device erosion or migration. The Spiration[supreg]

IBV[supreg] can be removed using a bronchoscope. Laboratory results

indicate that the Spiration[supreg] IBV[supreg] significantly reduces

airflow to the lung tissue beyond the treated airway. A significant

reduction in distal airflow is anticipated to augment the resolution of

air leaks of the lung. Therefore, the applicant asserts, it is

reasonable to conclude that the probable benefit to health associated

with using the device for the target population outweighs the risk of

illness or injuries, taking into account the probable risks and

benefits of currently available devices or alternative forms of

treatment when used as indicated in accordance with the directions for

use.

We recognize that prolonged air leaks after these types of lung

surgery can be a significant problem, and that Spiration[supreg]

IBV[supreg] therapy may represent a new alternative in treating

properly selected patients. However, we have concerns that the outcome

data presented is from a sample set of only seven patients, and the FDA

HDE did not require demonstration of either safety or effectiveness.

Therefore, we welcome public comment as to whether or not the

Spiration[supreg] IBV[supreg] represents a substantial clinical

improvement for Medicare beneficiaries.

We did not receive any written public comments regarding this

application for new technology add-on payments concerning the new

technology town hall meeting.

e. TherOx Downstream[supreg] System

TherOx, Inc. submitted an application for new technology add-on

payments for FY 2010 for the TherOx Downstream[supreg] System. The

TherOx Downstream[supreg] System uses SuperSaturatedOxygen Therapy

(SSO2) that is designed to limit myocardial necrosis by minimizing

microvascular damage in acute myocardial infarction (AMI) patients

following intervention with percutaneous transluminal coronary

angioplasty (PTCA), and coronary stent placement by perfusing the

affected myocardium with blood that has been supersaturated with

oxygen. SSO2 therapy refers to the delivery of superoxygenated arterial

blood directly to areas of myocardial tissue that have been reperfused

using PTCA and stent placement, but which may still be at risk. The

desired effect of SSO2 therapy is to reduce infarct size and, thus,

preserve heart muscle and function. The TherOx DownStream[supreg]

System is the console portion of a disposable cartridge-based system

that withdraws a small amount of the patient's arterial blood, mixes it

with a small amount of saline, and supersaturates it with oxygen to

create highly oxygen-enriched blood. The superoxygenated blood is

delivered directly to the infarct-related artery via the TherOx

infusion catheter. SSO2 therapy is a catheter laboratory-based

procedure. Additional time in the catheter laboratory area averages 100

minutes. The applicant claimed that the SSO2 therapy duration lasts 90

minutes and requires an additional 10 minutes post-procedure

preparation for transfer time. We note that the TherOx

DownStream[supreg] System is currently identified by ICD-9-CM procedure

code 00.49 (Supersaturated oxygen therapy). TherOx, Inc. submitted an

application for new technology add-on payments for FY 2009 for this

technology. However, although FDA approval was expected in the second

quarter of 2008, it had not received FDA approval at the time the

proposed rule for FY 2009 was published. Because the technology was

[[Page 24136]]

not approved by the FDA during the development of the proposed rule, we

limited our discussion of this technology to data that the applicant

submitted, rather than make specific proposals with respect to whether

the device would meet the new technology add-on payment criteria.

For its FY 2010 new technology add on payment application, the

applicant has indicated to CMS that it expects to receive FDA approval

in the second quarter of 2009. However, because the technology has not

yet received approval by the FDA, we are limiting our discussion of

this technology to data that the applicant submitted rather than making

specific proposals with respect to whether the device would meet the

new technology add-on payment criteria in this proposed rule.

In an effort to demonstrate that TherOx Downstream[supreg] System

would meet the cost criterion, the applicant submitted two analyses.

The applicant stated that it believed that the cases that would be

eligible for the TherOx Downstream[supreg] System would most frequently

group to MS-DRGs 246 (Percutaneous Cardiovascular Procedure with Drug-

Eluting Stent with MCC or 4+ Vessels/Stents), 247 (Percutaneous

Cardiovascular Procedure with Drug-Eluting Stent without MCC), 248

(Percutaneous Cardiovascular Procedure with Non-Drug-Eluting Stent with

MCC or 4+ Vessels/Stents), and 249 (Percutaneous Cardiovascular

Procedure with Non-Drug-Eluting Stent without MCC). The first analysis

used data based on 83 clinical trial patients from 10 clinical sites.

Of the 83 cases, 78 were assigned to MS-DRGs 246, 247, 248, or 249.

(The remaining five cases grouped to MS-DRGs that the technology would

not frequently group to and, therefore, are not included in this

analysis.) The data showed that 32 of these patients were 65 years old

or older. There were 12 cases (or 15.4 percent of the 78 cases) in MS-

DRG 246, 56 cases (or 71.8 percent of the 78 cases) in MS-DRG 247, 2

cases (or 2.6 percent of the 78 cases) in MS-DRG 248, and 8 cases (or

10.3 percent of the 78 cases) in MS-DRG 249. The average standardized

charge per case for MS-DRGs 246, 247, 248, and 249 was $71,955,

$60,790, $55,238, and $42,723, respectively, equating to a case-

weighted average standardized charge per case of $60,512. The average

standardized charge per case does not include charges related to the

TherOx Downstream[supreg] System. Therefore, it is necessary to add the

charges related to the device to the average standardized charge per

case in evaluating the cost threshold criterion. Although the applicant

submitted data related to the estimated cost of the TherOx

Downstream[supreg] System per case, the applicant noted that the cost

of the device was proprietary information. The applicant estimates

$22,739.40 in charges related to the TherOx Downstream[supreg] System

(based on a 100-percent charge markup of the cost of the drug). Adding

the charges related to the device to the average standardized charge

per case resulted in a case-weighted average standardized charge per

case of $83,251 ($60,512 plus $22,739). Based on the FY 2010 threshold

from Table 10 (73 FR 58008), the case-weighted threshold for the four

MS-DRGs listed above was $51,564 (all calculations above were performed

using unrounded numbers).

The applicant also searched the FY 2007 MedPAR file to identify

cases that would be eligible for the TherOx Downstream[supreg] System.

The applicant specifically searched for cases with primary ICD-9-CM

diagnosis code 410.00 (Acute myocardial infarction of anterolateral

wall with episode of care unspecified), 410.01 (Acute myocardial

infarction of anterolateral wall with initial episode of care), 410.10

(Acute myocardial infarction of other anterior wall with episode of

care unspecified), or 410.11 (Acute myocardial infarction of other

anterior wall with initial episode of care) in combination with ICD-9-

CM procedure code 36.06 (Insertion of non-drug-eluting coronary artery

stent(s)) or 36.07 (Insertion of drug-eluting coronary artery

stent(s)). The applicant's search found 12,345 cases within MS-DRGs

246, 247, 248, and 249 distributed as follows: 1,591 cases (or 12.9

percent of cases) in MS-DRG 246; 6,203 cases (or 50.2 percent of cases)

in MS-DRG 247; 1,132 cases (or 9.2 percent of cases) in MS-DRG 248; and

3,419 cases (or 27.7 percent of cases) in MS-DRG 249. Not including the

charges associated with the technology, the average standardized charge

per case for MS-DRGs 246, 247, 248, and 249 was $65,967, $46,828,

$56,807 and $40,107, respectively, equating to a case-weighted average

standardized charge per case of $48,348. The applicant estimated that

it was necessary to add an additional $22,739 in charges to the total

case-weighted average standardized charge per case (as described

above). In the additional charge amount, the applicant included charges

for supplies and tests related to the technology, charges for 100

minutes of additional procedure time in the catheter laboratory, and

charges for the technology itself. The inclusion of these charges would

result in a total case-weighted average standardized charge per case of

$71,087. The case-weighted threshold for MS-DRGs 246, 247, 248, and 249

(from Table 10 (73 FR 58008)) was $51,073 (all calculations above were

performed using unrounded numbers). Because the total case-weighted

average standardized charge per case from the first analysis of

clinical trial patients and the case-weighted standardized charge per

case from the second analysis of the FY 2006 MedPAR claims data exceeds

the applicable case-weighted thresholds, the applicant maintained the

TherOx Downstream[supreg] System would meet the cost criterion.

We invite public comment on whether or not the TherOx

Downstream[supreg] System meets the cost criterion.

With respect to the substantial clinical improvement criterion, the

applicant asserts that their technology represents a substantial

clinical improvement in the treatment of acute anterior myocardial

infarction in conjunction with percutaneous coronary intervention (PCI)

with stent placement within 6 hours of onset of symptoms compared to

PCI and stent placement alone. Specifically, the applicant asserts that

there is a 6.5 percent absolute reduction in infarct size using the

TherOx Downstream[supreg] System as assessed using Tc-99m Sestamibi

SPECT nuclear imaging in the Acute Myocardial Infarction Hyperbaric

Oxygen Treatment (AMIHOT) II clinical trial, and such a reduction has

been correlated with both short-term (less than 30 day) and long-term

(greater than 30 day) mortality reductions.

Although the TherOx Downstream[supreg] System remains

investigational and has not yet received approval from the FDA at this

time, we do recognize that a clear reduction of infarct size in acute

anterior myocardial infarction may represent a substantial clinical

improvement. However, we have concerns that the data presented by the

applicant in the application are derived from a Bayesian methodology,

which includes data from a subgroup of an earlier trial (AMIHOT I),

that showed no overall benefit of using the technology, and that the

AMIHOT II trial has yet to be published in any peer reviewed

literature. We also are concerned that there were a higher number of

adverse bleeding events in patients who had been treated in the group

of AMIHOT II clinical trial, and the study did not demonstrate any

specific improved clinical outcomes.

We invite public comment on whether or not the TherOx

Downstream[supreg] System meets the

[[Page 24137]]

substantial clinical improvement criterion.

Below we summarize the written comments we received concerning the

town hall meeting.

Comment: The physician who presented information at the town hall

meeting on behalf of the applicant also submitted additional written

comments in response to questions raised during the town hall meeting.

Specifically, the physician addressed questions relating to the study

of additional functional endpoints, such as ejection fraction a year

after a patient received therapy using the TherOx Downstream[supreg]

System or New York Heart Association (NYHA) functional class, and why

the AMIHOT I study design included patients who presented up to 24

hours after infarction (instead of up to 6 hours). With regard to

studying ejection fraction out to one year, the physician acknowledged

that such an endpoint was considered during the design of the AMIHOT II

trial, but that it was ultimately rejected because it was not required

by the FDA.

The physician further acknowledged that the AMIHOT I trial failed

to meet its overall primary efficacy endpoint, but asserted that when

analyzing the subset of 105 patients from the trial who had an anterior

myocardial infarction and were reperfused within 6 hours, ``substantial

clinical benefit'' was observed. The physician noted that, although

some people may have considered the subset of the anterior myocardial

infarction patients a ``post hoc'' analysis, the subset was actually a

``pre-specified data set.'' In addition, the physician maintained that

the analysis of the subset of data was the basis for the second

randomized trial (AMIHOT II), and that the FDA ``was unambiguous in its

contention that infarct size by single photon emission computed

tomography (SPECT) imaging had been thoroughly validated as a surrogate

endpoint\* \* \*.''

Finally, the physician emphasized information regarding the

technology's efficacy that was presented in its application. First, the

physician stated that patients with an ejection fraction of less than

40 percent who received supersaturated oxygen therapy had an absolute

difference in infarct size of 12.5 percent when compared to the control

arm. The physician further asserted that such outcomes support that

``among the sickest acute MI patients\* \* \* supersaturated oxygen is of

the greatest benefit.'' Secondly, the physician noted that the pooled,

adjusted data for AMIHOT II and the anterior MI patients from AMIHOT I

show that there were nearly twice as many supersaturated oxygen

patients with an imperceptible infarct compared to controls (18.2

percent versus 10.3 percent, respectively). The physician described an

``imperceptible'' infarct as that which is nearly undetectable upon

SPECT imaging after an acute myocardial infarction patient undergoes

primary coronary intervention at the hospital.

Response: In response to the physician's statements regarding the

FDA rejecting the use of ejection fraction as a primary endpoint for

the AMIHOT II trial, we note that the standards used in the

determination of whether a new technology is ``safe and effective''

(FDA standards for approval) are not necessarily equivalent to the

standards that are used to determine whether a new technology

represents a substantial clinical improvement to the Medicare

beneficiary patient population over existing technologies. While we

welcome insight and data obtained during the FDA approval process, we

are charged with going beyond the ``safe and effective'' standards of

FDA for purposes of deeming that a new technology represents a

substantial clinical improvement to the Medicare beneficiary patient

population.

We have considered the comments concerning the town hall meeting

and in response to questions raised at the town hall meeting in our

evaluation of this technology in this proposed rule. As stated above,

we invite additional public comment on objective data regarding the

assertions presented by the physician.

5. Technical Correction to the Regulations

In the FY 2009 IPPS final rule, when we revised the regulations at

Sec. 412.87 to incorporate changes relating to the announcement of

determinations and deadline for consideration of new medical service or

technology applications, we made a change to paragraph (b)(1) (73 FR

48755). In paragraph (b)(1), we inadvertently used the incorrect word

``relating'' in the provision that read ``A new medical service or

technology represents an advance that substantially improves, relating

to technologies previously available, the diagnosis or treatment of

Medicare beneficiaries'' (emphasis added). The correct word should have

been ``relative''. We are proposing to make this technical change to

Sec. 412.87(b)(1).

III. Proposed Changes to the Hospital Wage Index for Acute Care

Hospitals

A. Background

Section 1886(d)(3)(E) of the Act requires that, as part of the

methodology for determining prospective payments to hospitals, the

Secretary must adjust the standardized amounts ``for area differences

in hospital wage levels by a factor (established by the Secretary)

reflecting the relative hospital wage level in the geographic area of

the hospital compared to the national average hospital wage level.'' In

accordance with the broad discretion conferred under the Act, we

currently define hospital labor market areas based on the definitions

of statistical areas established by the Office of Management and Budget

(OMB). A discussion of the proposed FY 2010 hospital wage index based

on the statistical areas, including OMB's revised definitions of

Metropolitan Areas, appears under section III.C. of this preamble.

Beginning October 1, 1993, section 1886(d)(3)(E) of the Act

requires that we update the wage index annually. Furthermore, this

section provides that the Secretary base the update on a survey of

wages and wage-related costs of short-term, acute care hospitals. The

survey must exclude the wages and wage-related costs incurred in

furnishing skilled nursing services. This provision also requires us to

make any updates or adjustments to the wage index in a manner that

ensures that aggregate payments to hospitals are not affected by the

change in the wage index. The proposed adjustment for FY 2010 is

discussed in section II.B. of the Addendum to this proposed rule.

As discussed below in section III.I. of this preamble, we also take

into account the geographic reclassification of hospitals in accordance

with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating

IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the

Secretary is required to adjust the standardized amounts so as to

ensure that aggregate payments under the IPPS after implementation of

the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the

Act are equal to the aggregate prospective payments that would have

been made absent these provisions. The proposed budget neutrality

adjustment for FY 2010 is discussed in section II.A.4.b. of the

Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection

of data every 3 years on the occupational mix of employees for short-

term, acute care hospitals participating in the Medicare program, in

order to construct an occupational mix adjustment to the wage index. A

discussion of the occupational mix adjustment that we are proposing to

apply beginning October 1, 2009 (the FY 2010 wage

[[Page 24138]]

index) appears under section III.D. of this preamble.

B. Requirements of Section 106 of the MIEA-TRHCA

1. Wage Index Study Required under the MIEA-TRHCA

a. Legislative Requirement

Section 106(b)(1) of the MIEA-TRHCA (Pub. L. 109-432) required

MedPAC to submit to Congress, not later than June 30, 2007, a report on

the Medicare wage index classification system applied under the

Medicare IPPS. Section 106(b) of MIEA-TRHCA required the report to

include any alternatives that MedPAC recommends to the method to

compute the wage index under section 1886(d)(3)(E) of the Act.

In addition, section 106(b)(2) of the MIEA-TRHCA instructed the

Secretary of Health and Human Services, taking into account MedPAC's

recommendations on the Medicare wage index classification system, to

include in the FY 2009 IPPS proposed rule one or more proposals to

revise the wage index adjustment applied under section 1886(d)(3)(E) of

the Act for purposes of the IPPS. The Secretary was also to consider

each of the following:

Problems associated with the definition of labor markets

for the wage index adjustment.

The modification or elimination of geographic

reclassifications and other adjustments.

The use of Bureau of Labor of Statistics (BLS) data or

other data or methodologies to calculate relative wages for each

geographic area.

Minimizing variations in wage index adjustments between

and within MSAs and statewide rural areas.

The feasibility of applying all components of CMS'

proposal to other settings.

Methods to minimize the volatility of wage index

adjustments while maintaining the principle of budget neutrality.

The effect that the implementation of the proposal would

have on health care providers on each region of the country.

Methods for implementing the proposal(s), including

methods to phase in such implementations.

Issues relating to occupational mix such as staffing

practices and any evidence on quality of care and patient safety

including any recommendation for alternative calculations to the

occupational mix.

In the FY 2009 IPPS final rule (73 FR 48563 through 48567), we

discussed the MedPAC's study and recommendations, the CMS contract with

Acumen, L.L.C. for assistance with impact analysis and study of wage

index reform, and public comments we received on the MedPAC

recommendations and the CMS/Acumen study and analysis.

b. Interim and Final Reports on Results of Acumen's Study

(1) Interim Report on Impact Analysis of Using MedPAC's Recommended

Wage Index

In the FY 2009 IPPS final rule (73 FR 48566 through 48567), we

discussed the analysis conducted by Acumen comparing use of the MedPAC

recommended wage indices to the current CMS wage index. We refer

readers to section III.B.1.e. of that final rule for a full discussion

of the impact analysis as well as to Acumen's interim report available

on the Web site: http://www.acumenllc.com/reports/cms.

(2) Acumen's Final Report on Analysis of the Wage Index Data and

Methodology

Acumen's final report addressing the issues in section 106(b)(2) of

the MIEA-TRHCA is divided into two parts. The first part analyzes the

strengths and weaknesses of the data sources used to construct the

MedPAC and CMS indexes. This part of Acumen's study is complete and

will be published immediately after the publication of this proposed

rule. The second part, which is expected to be released after the

publication of the FY 2010 IPPS final rule, will focus on the

methodology of wage index construction and covers issues related to the

definition of wage areas and methods of adjusting for differences among

neighboring wage areas, as well as reasons for differential impacts of

shifting to a new index. Both reports, when available, will be

accessible at the Web site: http://www.acumenllc.com/reports/cms.

The following is a description of the analyses for both parts of

Acumen's final report.

Part I: Wage Data Analysis

Differences between the BLS data and the CMS wage data--

Acumen assessed the strengths and weaknesses of the data used to

construct the CMS wage index and the MedPAC compensation index by

examining the differences between the BLS and the CMS wage data. Acumen

also evaluated the importance of accounting for self-employed workers,

part-time workers, and industry wage differences.

Employee benefit (wage-related) cost--Acumen considered

whether benefit costs need to be included in the hospital wage index

and discussed the differences between Worksheet A benefits data

(proposed by MedPAC to use with BLS wage data) and Worksheet S-3

benefit data. Acumen also analyzed the possibility of using BLS'

Employer Costs for Employee Compensation (ECEC) series as an

alternative to Worksheet A or Worksheet S-3 benefits data that would

pose less of a data collection burden for providers.

Impact of the fixed national occupational weights--Acumen

assessed MedPAC's and CMS' methods for adjusting for occupational mix

differences. While the proposed MedPAC compensation index uses fixed

weights for occupations representative of the hospital industry

nationally, the CMS wage index incorporates an occupational mix

adjustment (OMA) from a separate data collection.

Year-to-year volatility in the CMS and BLS wage data--

Acumen calculated the extent of volatility in the CMS and BLS wage

indexes using several measures of volatility. Acumen also explored

potential causes of volatility, such as the number of hospitals and the

annual change in the number of hospitals in a wage area. Finally,

Acumen evaluated the impact on annual volatility of using a 2-year

rolling average of CMS wage index values.

Part II: Wage Index Construction

Alternative wage area definitions--Acumen will explore the

conceptual basis for defining wage areas and investigate alternative

wage area definitions that have been considered in prior literature to

reduce differences between areas.

Differences between and within contiguous wage areas--

Acumen will estimate different methods for smoothing wage index values

between geographically proximate areas and examine the justification

for and sensitivity to assumptions used by MedPAC in its smoothing

method.

Reasons for differential impacts of shifting to a new

index--Acumen will analyze the impact on hospitals if CMS were to adopt

MedPAC's proposed compensation index, with a focus on hospitals that

would no longer qualify for exceptions such as geographic

reclassification and the rural floor. Acumen will also determine if

there are identifiable reasons for the different impacts.

As of the publication date of this proposed rule, Acumen has not

completed its analysis for the second part of its final report.

We indicated in the FY 2009 IPPS final rule that, in developing any

proposal(s) for additional wage index reform that may be included in

the FY

[[Page 24139]]

2010 IPPS proposed rule, we would consider all of the public comments

on the MedPAC recommendations that we had received in that proposed

rulemaking cycle, along with the interim and final reports to be

submitted to us by Acumen. As Acumen's study is not yet complete, we

are not proposing any additional changes to the hospital wage index for

acute care hospitals in this proposed rule.

2. FY 2009 Policy Changes in Response to Requirements Under Section

106(b) of the MIEA-TRHCA

To implement the requirements of section 106(b) of the MIEA-TRHCA

and respond to MedPAC's recommendations in its June 2007 report to

Congress, in the FY 2009 IPPS final rule (73 FR 48567 through 48574),

we made the following policy changes relating to the hospital wage

index. (We refer readers to the FY 2009 IPPS final rule for a full

discussion of the basis for the proposals, the public comments

received, and the FY 2009 final policy.)

a. Reclassification Average Hourly Wage Comparison Criteria

In the FY 2009 IPPS final rule, we adopted the policy to adjust the

reclassification average hourly wage standard, comparing a

reclassifying hospital's (or county hospital group's) average hourly

wage relative to the average hourly wage of the area to which it seeks

reclassification. We provided for a phase-in of the adjustment over 2

years. For applications for reclassification for the first transitional

year, FY 2010, the average hourly wage standards were set at 86 percent

for urban hospitals and group reclassifications and 84 percent for

rural hospitals. For applications for reclassification for FY 2011 (for

which the application deadline is September 1, 2009) and for subsequent

fiscal years, the average hourly wage standards will be 88 percent for

urban and group reclassifications and 86 percent for rural hospitals

(Sec. Sec. 412.230, 412.232, and 412.234 of the regulations). As

stated above, these policies were adopted in the FY 2009 IPPS final

rule.

b. Within-State Budget Neutrality Adjustment for the Rural and Imputed

Floors

In the FY 2009 IPPS final rule, we adopted State level budget

neutrality (rather than the national budget neutrality adjustment) for

the rural and imputed floors, to be effective beginning with the FY

2009 wage index. The transition from the national budget neutrality

adjustment to the State level budget neutrality adjustment is being

phased in over a 3-year period. In FY 2009, hospitals received a

blended wage index that was 20 percent of a wage index with the State

level rural and imputed floor budget neutrality adjustment and 80

percent of a wage index with the national budget neutrality adjustment.

In FY 2010, the blended wage index will reflect 50 percent of the State

level adjustment and 50 percent of the national adjustment. In FY 2011,

the adjustment will be completely transitioned to the State level

methodology.

In the FY 2009 IPPS final rule, we incorporated this policy in our

regulation at Sec. 412.64(e)(4). Specifically, we provided that CMS

makes an adjustment to the wage index to ensure that aggregate payments

after implementation of the rural floor under section 4410 of the

Balanced Budget Act of 1997 (Pub. L. 105-33) and the imputed rural

floor under Sec. 412.64(h)(4) are made in a manner that ensures that

aggregate payments to hospitals are not affected and that, beginning

October 1, 2008, CMS would transition from a nationwide adjustment to a

statewide adjustment, with a statewide adjustment fully in place by

October 1, 2010. We note that the imputed floor expires on September

30, 2011 (as discussed in section III.H. of this preamble).

C. Core-Based Statistical Areas for the Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis

of the labor market area in which the hospital is located. In

accordance with the broad discretion under section 1886(d)(3)(E) of the

Act, beginning with FY 2005, we define hospital labor market areas

based on the Core-Based Statistical Areas (CBSAs) established by OMB

and announced in December 2003 (69 FR 49027). For a discussion of OMB's

revised definitions of CBSAs and our implementation of the CBSA

definitions, we refer readers to the preamble of the FY 2005 IPPS final

rule (69 FR 49026 through 49032).

As with the FY 2009 final rule, for FY 2010, we are proposing to

provide that hospitals receive 100 percent of their wage index based

upon the CBSA configurations. Specifically, for each hospital, we are

proposing to determine a wage index for FY 2010 employing wage index

data from hospital cost reports for cost reporting periods beginning

during FY 2006 and using the CBSA labor market definitions. We consider

CBSAs that are MSAs to be urban, and CBSAs that are Micropolitan

Statistical Areas as well as areas outside of CBSAs to be rural. In

addition, it has been our longstanding policy that where an MSA has

been divided into Metropolitan Divisions, we consider the Metropolitan

Division to comprise the labor market areas for purposes of calculating

the wage index (69 FR 49029) (regulations at Sec.

412.64(b)(1)(ii)(A)).

On November 20, 2008, OMB announced three Micropolitan Statistical

Areas that now qualify as MSAs (OMB Bulletin No. 09-01). The new urban

CBSAs are as follows:

Cape Girardeau-Jackson, Missouri-Illinois (CBSA 16020).

This CBSA is comprised of the principal cities of Cape Girardeau and

Jackson, Missouri in Alexander County, Illinois; Bollinger County,

Missouri, and Cape Girardeau County, Missouri.

Manhattan, Kansas (CBSA 31740). This CBSA is comprised of

the principal city of Manhattan, Kansas in Geary County, Pottawatomie

County, and Riley County.

Mankato-North Mankato, Minnesota (CBSA 31860). This CBSA

is comprised of the principal cities of Mankato and North Mankato,

Minnesota in Blue Earth County and Nicollet County.

OMB also changed the principal cities and titles of a number of

CBSAs and a Metropolitan Division, as follows:

Broomfield, Colorado qualifies as a new principal city of

the Denver-Aurora, Colorado CBSA. The new title is Denver-Aurora-

Broomfield, Colorado CBSA.

Chapel Hill, North Carolina qualifies as a new principal

city of the Durham, North Carolina CBSA. The new title is Durham-Chapel

Hill, North Carolina CBSA.

Chowchilla, California qualifies as a new principal city

of the Madera, California CBSA. The new title is Madera-Chowchilla,

California CBSA.

Panama City Beach, Florida qualifies as a new principal

city of the Panama City-Lynn Haven, Florida CBSA. The new title is

Panama City-Lynn Haven-Panama City Beach, Florida CBSA.

East Wenatchee, Washington qualifies as a new principal

city of the Wenatchee, Washington CBSA. The new title is Wenatchee-East

Wenatchee, Washington CBSA.

Rockville, Maryland replaces Gaithersburg, Maryland as the

third most populous city of the Bethesda-Frederick-Gaithersburg,

Maryland Metropolitan Division. The new title is Bethesda-Frederick-

Rockville, Maryland Metropolitan Division.

The OMB bulletin is available on the OMB Web site at http://

www.whitehouse.gov/OMB\_go to ``Bulletins'' or ``Statistical Programs

and

[[Page 24140]]

Standards.'' CMS will apply these changes to the IPPS beginning October

1, 2009.

D. Proposed Occupational Mix Adjustment to the Proposed FY 2010 Wage

Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for

the collection of data every 3 years on the occupational mix of

employees for each short-term, acute care hospital participating in the

Medicare program, in order to construct an occupational mix adjustment

to the wage index, for application beginning October 1, 2004 (the FY

2005 wage index). The purpose of the occupational mix adjustment is to

control for the effect of hospitals' employment choices on the wage

index. For example, hospitals may choose to employ different

combinations of registered nurses, licensed practical nurses, nursing

aides, and medical assistants for the purpose of providing nursing care

to their patients. The varying labor costs associated with these

choices reflect hospital management decisions rather than geographic

differences in the costs of labor.

1. Development of Data for the Proposed FY 2010 Occupational Mix

Adjustment Based on the 2007-2008 Occupational Mix Survey

As provided for under section 1886(d)(3)(E) of the Act, we collect

data every 3 years on the occupational mix of employees for each short-

term, acute care hospital participating in the Medicare program. For

the FY 2009 hospital wage index, we used data from the 2006 Medicare

Wage Index Occupational Mix Survey (the 2006 survey) to calculate the

occupational mix adjustment. In the 2006 survey, we included several

modifications to the original occupational mix survey, the 2003 survey,

including (1) allowing hospitals to report their own average hourly

wage rather than using BLS data; (2) extending the prospective survey

period; and (3) reducing the number of occupational categories but

refining the subcategories for registered nurses.

The 2006 survey provided for the collection of hospital-specific

wages and hours data, a 6-month prospective reporting period (that is,

January 1, 2006, through June 30, 2006), the transfer of each general

service category that comprised less than 4 percent of total hospital

employees in the 2003 survey to the ``all other occupations'' category

(the revised survey focused only on the mix of nursing occupations),

additional clarification of the definitions for the occupational

categories, an expansion of the registered nurse category to include

functional subcategories, and the exclusion of average hourly rate data

associated with advance practice nurses. The 2006 survey included only

two general occupational categories: Nursing and ``all other

occupations.'' The nursing category had four subcategories: Registered

nurses, licensed practical nurses, aides, orderlies, attendants, and

medical assistants. The registered nurse subcategory included two

functional subcategories: Management personnel and staff nurses or

clinicians. As indicated above, the 2006 survey provided for a 6-month

data collection period, from January 1, 2006 through June 30, 2006. To

allow flexibility for the reporting period beginning and ending dates

to accommodate some hospitals' biweekly payroll and reporting systems,

we modified the 6-month data collection period for the 2006 survey from

January 1, 2006 through June 30, 2006, to a 6-month reporting period

that began on or after December 25, 2005, and end before July 9, 2006.

OMB approved the revised 2006 occupational mix survey (Form CMS-10079

(2006)) on April 25, 2006. The original timelines for the collection,

review, and correction of the 2006 occupational mix data were discussed

in detail in the FY 2007 IPPS final rule (71 FR 48008).

For the proposed FY 2010 hospital wage index, we are using

occupational mix data collected on a revised 2007-2008 Medicare Wage

Index Occupational Mix Survey (the 2007-2008 survey) to compute the

proposed occupational mix adjustment for FY 2010. In the FY 2008 IPPS

final rule with comment period (72 FR 47315), we discussed how we

modified the 2006 occupational mix survey. The revised 2007-2008

occupational mix survey provided for the collection of hospital-

specific wages and hours data for the 1-year period of July 1, 2007,

through June 30, 2008, additional clarifications to the survey

instructions, the elimination of the registered nurse subcategories,

some refinements to the definitions of the occupational categories, and

the inclusion of additional cost centers that typically provide nursing

services.

On February 2, 2007, we published in the Federal Register a notice

soliciting comments on the proposed revisions to the 2006 occupational

mix survey (72 FR 5055). The comment period for the notice ended on

April 3, 2007. After considering the comments we received, we made a

few minor editorial changes and published the final 2007-2008

occupational mix survey on September 14, 2007 (72 FR 52568). OMB

approved the survey without change on February 1, 2008 (OMB Control

Number 0938 0907). The 2007-2008 Medicare occupational mix survey (Form

CMS-10079 (2008)) is available on the CMS Web site at: http://

www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage, and through

the fiscal intermediaries/MACs. Hospitals were required to submit their

completed surveys to their fiscal intermediaries/MACs by September 2,

2008. The preliminary, unaudited 2007-2008 occupational mix survey data

was released in early October 2008, along with the FY 2006 Worksheet S-

3 wage data, for the FY 2010 wage index review and correction process.

2. Calculation of the Proposed Occupational Mix Adjustment for FY 2010

For FY 2010 (as we did for FY 2009), we are proposing to calculate

the occupational mix adjustment factor using the following steps:

Step 1--For each hospital, determine the percentage of the total

nursing category attributable to a nursing subcategory by dividing the

nursing subcategory hours by the total nursing category's hours. Repeat

this computation for each of the four nursing subcategories: Registered

nurses; licensed practical nurses; nursing aides, orderlies, and

attendants; and medical assistants.

Step 2--Determine a national average hourly rate for each nursing

subcategory by dividing a subcategory's total salaries for all

hospitals in the occupational mix survey database by the subcategory's

total hours for all hospitals in the occupational mix survey database.

Step 3--For each hospital, determine an adjusted average hourly

rate for each nursing subcategory by multiplying the percentage of the

total nursing category (from Step 1) by the national average hourly

rate for that nursing subcategory (from Step 2). Repeat this

calculation for each of the four nursing subcategories.

Step 4--For each hospital, determine the adjusted average hourly

rate for the total nursing category by summing the adjusted average

hourly rate (from Step 3) for each of the nursing subcategories.

Step 5--Determine the national average hourly rate for the total

nursing category by dividing total nursing category salaries for all

hospitals in the occupational mix survey database by total nursing

category hours for all hospitals in the occupational mix survey

database.

Step 6--For each hospital, compute the occupational mix adjustment

factor for the total nursing category by dividing the national average

hourly rate for the total nursing category (from

[[Page 24141]]

Step 5) by the hospital's adjusted average hourly rate for the total

nursing category (from Step 4).

If the hospital's adjusted average hourly rate is less than the

national average hourly rate (indicating the hospital employs a less

costly mix of nursing employees), the occupational mix adjustment

factor is greater than 1.0000. If the hospital's adjusted average

hourly rate is greater than the national average hourly rate, the

occupational mix adjustment factor is less than 1.0000.

Step 7--For each hospital, calculate the occupational mix adjusted

salaries and wage-related costs for the total nursing category by

multiplying the hospital's total salaries and wage-related costs (from

Step 5 of the unadjusted wage index calculation in section III.G. of

this preamble) by the percentage of the hospital's total workers

attributable to the total nursing category (using the occupational mix

survey data, this percentage is determined by dividing the hospital's

total nursing category salaries by the hospital's total salaries for

``nursing and all other'') and by the total nursing category's

occupational mix adjustment factor (from Step 6 above).

The remaining portion of the hospital's total salaries and wage-

related costs that is attributable to all other employees of the

hospital is not adjusted by the occupational mix. A hospital's all

other portion is determined by subtracting the hospital's nursing

category percentage from 100 percent.

Step 8--For each hospital, calculate the total occupational mix

adjusted salaries and wage-related costs for a hospital by summing the

occupational mix adjusted salaries and wage-related costs for the total

nursing category (from Step 7) and the portion of the hospital's

salaries and wage-related costs for all other employees (from Step 7).

To compute a hospital's occupational mix adjusted average hourly

wage, divide the hospital's total occupational mix adjusted salaries

and wage-related costs by the hospital's total hours (from Step 4 of

the unadjusted wage index calculation in section III.G. of this

preamble).

Step 9--To compute the occupational mix adjusted average hourly

wage for an urban or rural area, sum the total occupational mix

adjusted salaries and wage-related costs for all hospitals in the area,

then sum the total hours for all hospitals in the area. Next, divide

the area's occupational mix adjusted salaries and wage-related costs by

the area's hours.

Step 10--To compute the national occupational mix adjusted average

hourly wage, sum the total occupational mix adjusted salaries and wage-

related costs for all hospitals in the Nation, then sum the total hours

for all hospitals in the Nation. Next, divide the national occupational

mix adjusted salaries and wage-related costs by the national hours. The

proposed FY 2010 occupational mix adjusted national average hourly wage

is $33.4935.

Step 11--To compute the occupational mix adjusted wage index,

divide each area's occupational mix adjusted average hourly wage (Step

9) by the national occupational mix adjusted average hourly wage (Step

10).

Step 12--To compute the Puerto Rico specific occupational mix

adjusted wage index, follow Steps 1 through 11 above. The proposed FY

2010 occupational mix adjusted Puerto Rico specific average hourly wage

is $14.2555.

The table below is an illustrative example of the proposed

occupational mix adjustment.

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[[Page 24143]]

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[[Page 24144]]

Because the occupational mix adjustment is required by statute, all

hospitals that are subject to payments under the IPPS, or any hospital

that would be subject to the IPPS if not granted a waiver, must

complete the occupational mix survey, unless the hospital has no

associated cost report wage data that are included in the proposed FY

2010 wage index. For the FY 2007-2008 survey, the response rate was 89

percent.

In computing the proposed FY 2010 wage index, if a hospital did not

respond to the occupational mix survey, or if we determined that a

hospital's submitted data were too erroneous to include in the wage

index, we assigned the hospital the average occupational mix adjustment

for the labor market area. We believed this method had the least impact

on the wage index for other hospitals in the area. For areas where no

hospital submitted data for purposes of calculating the proposed

occupational mix adjustment, we applied the national occupational mix

factor of 1.0000 in calculating the area's proposed FY 2010

occupational mix adjusted wage index. (We indicated in the FY 2008 and

FY 2009 IPPS final rules that we reserve the right to apply a different

approach in future years, including potentially penalizing

nonresponsive hospitals (72 FR 47314).) In addition, if a hospital

submitted a survey, but that survey data cannot be used because we

determine it to be aberrant, we also are proposing to assign the

hospital the average occupational mix adjustment for its labor market

area. For example, if a hospital's individual nurse category average

hourly wages were out of range (that is, unusually high or low), and

the hospital did not provide sufficient documentation to explain the

aberrancy, or the hospital did not submit any registered nurse salaries

or hours data, we are proposing to assign the hospital the average

occupational mix adjustment for the labor market area in which it is

located.

In calculating the average occupational mix adjustment factor for a

labor market area, we replicated Steps 1 through 6 of the calculation

for the occupational mix adjustment. However, instead of performing

these steps at the hospital level, we aggregated the data at the labor

market area level. In following these steps, for example, for CBSAs

that contain providers that did not submit occupational mix survey

data, the occupational mix adjustment factor ranged from a low of

0.8452 (CBSA 17780, College Station-Bryan, TX), to a high of 1.0939

(CBSA 29700, Laredo, TX). Also, in computing a hospital's occupational

mix adjusted salaries and wage-related costs for nursing employees

(Step 7 of the calculation), in the absence of occupational mix survey

data, we multiplied the hospital's total salaries and wage-related

costs by the percentage of the area's total workers attributable to the

area's total nursing category. For FY 2010, there are 8 CBSAs (that

include 16 hospitals) for which we did not have occupational mix data

for any of its hospitals. The CBSAs are:

CBSA 16220--Casper, WY (one hospital)

CBSA 21940--Fajardo, PR (one hospital)

CBSA 22140--Farmington, NM (one hospital)

CBSA 25020--Guayama, PR (three hospitals)

CBSA 36140--Ocean City, NJ (one hospital)

CBSA 38660--Ponce, PR (six hospitals)

CBSA 41900--San German-Cabo Rojo, PR (two hospitals)

CBSA 49500--Yauco, PR (one hospital)

Since the FY 2007 IPPS final rule, we have periodically discussed

applying a hospital-specific penalty to hospitals that fail to submit

occupational mix survey data (71 FR 48013 through 48014; 72 FR 47314

through 47315; and 73 FR 48580). During the FY 2008 rulemaking cycle,

some commenters suggested a penalty equal to a 1- to 2-percent

reduction in the hospital's wage index value or a set percentage of the

standardized amount. During the FY 2009 rulemaking cycle, several

commenters reiterated their view that full participation in the

occupational mix survey is critical, and that CMS should develop a

methodology that encourages hospitals to report occupational mix survey

data but does not unfairly penalize neighboring hospitals. However, to

date, we have not adopted a penalty for hospitals that fail to submit

occupational mix data.

After review of the data for the proposed FY 2010 wage index, we

became concerned about the increasing number of hospitals that fail to

submit occupational mix data and the impact it may have on area wage

indices. The survey response rate has dropped significantly from 93.8

percent for the 2003 survey to 90.7 percent for the 2006 survey and 89

percent for the 2007-2008 survey. In 43 areas, the response rate was

only 66.7 percent or less. In addition, for 46 areas, including New

York-White Plains-Wayne, New York-New Jersey (35644), Oklahoma City,

Oklahoma (36420), Rural Georgia (11), and Rural Oklahoma (37), the area

response rate decreased 20 percent or more between the 2006 survey and

the 2007-2008 survey. In all of Puerto Rico, only 21.6 percent of

hospitals submitted 2007-2008 survey data. If we had proposed to apply

a penalty for nonresponsive hospitals for the FY 2010 wage index,

Puerto Rico hospitals would have been significantly adversely affected

in both the proposed national and Puerto Rico-specific wage indices.

While we are not proposing a penalty at this time, we will consider the

public comments we previously received, as well as any public comments

on this proposed rule, as we develop the proposed FY 2011 wage index.

One approach that we will explore is to assign any nonresponsive

hospital the occupational mix factor deriving from the survey that

would result in the greatest negative adjustment to the hospital's wage

index. We also will consider applying the same penalty to hospitals

that submit unusable occupational mix data. Although we would apply

this penalty factor in establishing the hospital's payment rate, we

would not use this factor in computing the area's wage index. Rather,

in computing the area wage index, we would apply the same methodology

as described above (that is, assign the nonresponsive hospital the

average occupational mix adjustment factor for the labor market area)

so that other hospitals in the area are minimally impacted by the

hospital's failure to submit occupational mix data. Again, we note that

we reserve the right to penalize nonresponsive hospitals in the future.

We welcome public comments on this matter and look forward to

addressing this issue in next year's IPPS proposed rule.

E. Worksheet S-3 Wage Data for the Proposed FY 2010 Wage Index

The proposed FY 2010 wage index values are based on the data

collected from the Medicare cost reports submitted by hospitals for

cost reporting periods beginning in FY 2006 (the FY 2009 wage index was

based on FY 2005 wage data).

1. Included Categories of Costs

The proposed FY 2010 wage index includes the following categories

of data associated with costs paid under the IPPS (as well as

outpatient costs):

Salaries and hours from short-term, acute care hospitals

(including paid lunch hours and hours associated with military leave

and jury duty)

Home office costs and hours

Certain contract labor costs and hours (which includes

direct patient care, certain top management, pharmacy, laboratory, and

nonteaching

[[Page 24145]]

physician Part A services, and certain contract indirect patient care

services (as discussed in the FY 2008 final rule with comment period

(72 FR 47315))

Wage-related costs, including pensions and other deferred

compensation costs. We note that, on March 28, 2008, CMS published a

technical clarification to the cost reporting instructions for pension

and deferred compensation costs (sections 2140 through 2142.7 of the

Provider Reimbursement Manual, Part I). These instructions are used for

developing pension and deferred compensation costs for purposes of the

wage index, as discussed in the instructions for Worksheet S-3, Part

II, Lines 13 through 20 and in the FY 2006 IPPS final rule (70 FR

47369).

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2009, the

proposed wage index for FY 2010 also excludes the direct and overhead

salaries and hours for services not subject to IPPS payment, such as

SNF services, home health services, costs related to GME (teaching

physicians and residents) and certified registered nurse anesthetists

(CRNAs), and other subprovider components that are not paid under the

IPPS. The proposed FY 2010 wage index also excludes the salaries,

hours, and wage-related costs of hospital-based rural health clinics

(RHCs), and Federally qualified health centers (FQHCs) because Medicare

pays for these costs outside of the IPPS (68 FR 45395). In addition,

salaries, hours, and wage-related costs of CAHs are excluded from the

wage index, for the reasons explained in the FY 2004 IPPS final rule

(68 FR 45397).

3. Use of Wage Index Data by Providers Other Than Acute Care Hospitals

under the IPPS

Data collected for the IPPS wage index are also currently used to

calculate wage indices applicable to other providers, such as SNFs,

home health agencies, and hospices. In addition, they are used for

prospective payments to IRFs, IPFs, and LTCHs, and for hospital

outpatient services. We note that, in the IPPS rules, we do not address

comments pertaining to the wage indices for non-IPPS providers, other

than for LTCHs. (Beginning with the FY 2010 IPPS rule, for the RY 2010,

we are including in the same document updates to the LTCH PPS.) Such

comments should be made in response to separate proposed rules for

those providers.

F. Verification of Worksheet S-3 Wage Data

The wage data for the proposed FY 2010 wage index were obtained

from Worksheet S-3, Parts II and III of the FY 2006 Medicare cost

reports. Instructions for completing Worksheet S-3, Parts II and III

are in the Provider Reimbursement Manual (PRM), Part II, sections

3605.2 and 3605.3. The data file used to construct the wage index

includes FY 2006 data submitted to us as of March 2, 2009. As in past

years, we performed an intensive review of the wage data, mostly

through the use of edits designed to identify aberrant data.

We asked our fiscal intermediaries/MACs to revise or verify data

elements that resulted in specific edit failures. For the proposed FY

2010 wage index, we identified and excluded 34 providers with data that

was too aberrant to include in the proposed wage index, although if

data elements for some of these providers are corrected, we intend to

include some of these providers in the FY 2010 final wage index. We

instructed fiscal intermediaries/MACs to complete their data

verification of questionable data elements and to transmit any changes

to the wage data no later than April 15, 2009. We believe all

unresolved data elements will be resolved by the date the final rule is

issued. The revised data will be reflected in the FY 2010 IPPS final

rule.

In constructing the proposed FY 2010 wage index, we included the

wage data for facilities that were IPPS hospitals in FY 2006, inclusive

of those facilities that have since terminated their participation in

the program as hospitals, as long as those data did not fail any of our

edits for reasonableness. We believe that including the wage data for

these hospitals is, in general, appropriate to reflect the economic

conditions in the various labor market areas during the relevant past

period and to ensure that the current wage index represents the labor

market area's current wages as compared to the national average of

wages. However, we excluded the wage data for CAHs as discussed in the

FY 2004 IPPS final rule (68 FR 45397). For this proposed rule, we

removed 11 hospitals that converted to CAH status between February 18,

2008, the cut-off date for CAH exclusion from the FY 2009 wage index,

and February 16, 2009, the cut-off date for CAH exclusion from the FY

2010 wage index. After removing hospitals with aberrant data and

hospitals that converted to CAH status, the proposed FY 2010 wage index

is calculated based on 3,521 hospitals.

In the FY 2008 final rule with comment period (72 FR 47317) and the

FY 2009 IPPS final rule (73 FR 48582), we discussed our policy for

allocating a multicampus hospital's wages and hours data, by full-time

equivalent (FTE) staff, among the different labor market areas where

its campuses are located. During the FY 2010 wage index desk review

process, we requested fiscal intermediaries/MACs to contact multicampus

hospitals that had campuses in different labor market areas to collect

the data for the allocation. The proposed FY 2010 wage index in this

proposed rule includes separate wage data for campuses of three

multicampus hospitals.

For FY 2010, we are again allowing hospitals to use FTE or

discharge data for the allocation of a multicampus hospital's wage data

among the different labor market areas where its campuses are located.

The Medicare cost report was updated in May 2008 to provide for the

reporting of FTE data by campus for multicampus hospitals. Because the

data from cost reporting periods that begin in FY 2008 will not be used

in calculating the wage index until FY 2012, a multicampus hospital

will still have the option, through the FY 2011 wage index, to use

either FTE or discharge data for allocating wage data among its

campuses by providing the information from the applicable cost

reporting period to CMS through its fiscal intermediary/MAC. Two of the

three multicampus hospitals chose to have their wage data allocated by

their Medicare discharge data for the FY 2010 wage index. One of the

hospitals provided FTE staff data for the allocation. The average

hourly wage associated with each geographical location of a multicampus

hospital is reflected in Table 2 of the Addendum to this proposed rule.

G. Method for Computing the Proposed FY 2010 Unadjusted Wage Index

The method used to compute the proposed FY 2009 wage index without

an occupational mix adjustment follows:

Step 1--As noted above, we are basing the proposed FY 2010 wage

index on wage data reported on the FY 2006 Medicare cost reports. We

gathered data from each of the non-Federal, short-term, acute care

hospitals for which data were reported on the Worksheet S-3, Parts II

and III of the Medicare cost report for the hospital's cost reporting

period beginning on or after October 1, 2005, and before October 1,

2006. In addition, we included data from some hospitals that had cost

reporting periods beginning

[[Page 24146]]

before October 2005 and reported a cost reporting period covering all

of FY 2005. These data are included because no other data from these

hospitals would be available for the cost reporting period described

above, and because particular labor market areas might be affected due

to the omission of these hospitals. However, we generally describe

these wage data as FY 2005 data. We note that, if a hospital had more

than one cost reporting period beginning during FY 2006 (for example, a

hospital had two short cost reporting periods beginning on or after

October 1, 2005, and before October 1, 2006), we included wage data

from only one of the cost reporting periods, the longer, in the wage

index calculation. If there was more than one cost reporting period and

the periods were equal in length, we included the wage data from the

later period in the wage index calculation.

Step 2--Salaries--The method used to compute a hospital's average

hourly wage excludes certain costs that are not paid under the IPPS.

(We note that, beginning with FY 2008 (72 FR 47315), we include Lines

22.01, 26.01, and 27.01 of Worksheet S-3, Part II for overhead services

in the wage index. However, we note that the wages and hours on these

lines are not incorporated into Line 101, Column 1 of Worksheet A,

which, through the electronic cost reporting software, flows directly

to Line 1 of Worksheet S-3, Part II. Therefore, the first step in the

wage index calculation for FY 2010 is to compute a ``revised'' Line 1,

by adding to the Line 1 on Worksheet S-3, Part II (for wages and hours

respectively) the amounts on Lines 22.01, 26.01, and 27.01.) In

calculating a hospital's average salaries plus wage-related costs, we

subtract from Line 1 (total salaries) the GME and CRNA costs reported

on Lines 2, 4.01, 6, and 6.01, the Part B salaries reported on Lines 3,

5 and 5.01, home office salaries reported on Line 7, and exclude

salaries reported on Lines 8 and 8.01 (that is, direct salaries

attributable to SNF services, home health services, and other

subprovider components not subject to the IPPS). We also subtract from

Line 1 the salaries for which no hours were reported. To determine

total salaries plus wage-related costs, we add to the net hospital

salaries the costs of contract labor for direct patient care, certain

top management, pharmacy, laboratory, and nonteaching physician Part A

services (Lines 9 and 10), home office salaries and wage-related costs

reported by the hospital on Lines 11 and 12, and nonexcluded area wage-

related costs (Lines 13, 14, and 18).

We note that contract labor and home office salaries for which no

corresponding hours are reported are not included. In addition, wage-

related costs for nonteaching physician Part A employees (Line 18) are

excluded if no corresponding salaries are reported for those employees

on Line 4.

Step 3--Hours--With the exception of wage-related costs, for which

there are no associated hours, we compute total hours using the same

methods as described for salaries in Step 2.

Step 4--For each hospital reporting both total overhead salaries

and total overhead hours greater than zero, we then allocate overhead

costs to areas of the hospital excluded from the wage index

calculation. First, we determine the ratio of excluded area hours (sum

of Lines 8 and 8.01 of Worksheet S-3, Part II) to revised total hours

(Line 1 minus the sum of Part II, Lines 2, 3, 4.01, 5, 5.01, 6, 6.01,

7, and Part III, Line 13 of Worksheet S-3). We then compute the amounts

of overhead salaries and hours to be allocated to excluded areas by

multiplying the above ratio by the total overhead salaries and hours

reported on Line 13 of Worksheet S-3, Part III. Next, we compute the

amounts of overhead wage-related costs to be allocated to excluded

areas using three steps: (1) We determine the ratio of overhead hours

(Part III, Line 13 minus the sum of lines 22.01, 26.01, and 27.01) to

revised hours excluding the sum of lines 22.01, 26.01, and 27.01 (Line

1 minus the sum of Lines 2, 3, 4.01, 5, 5.01, 6, 6.01, 7, 8, 8.01,

22.01, 26.01, and 27.01). (We note that for the FY 2008 and subsequent

wage index calculations, we are excluding the sum of lines 22.01,

26.01, and 27.01 from the determination of the ratio of overhead hours

to revised hours because hospitals typically do not provide fringe

benefits (wage-related costs) to contract personnel. Therefore, it is

not necessary for the wage index calculation to exclude overhead wage-

related costs for contract personnel. Further, if a hospital does

contribute to wage-related costs for contracted personnel, the

instructions for Lines 22.01, 26.01, and 27.01 require that associated

wage-related costs be combined with wages on the respective contract

labor lines.); (2) we compute overhead wage-related costs by

multiplying the overhead hours ratio by wage-related costs reported on

Part II, Lines 13, 14, and 18; and (3) we multiply the computed

overhead wage-related costs by the above excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related

costs, and hours associated with excluded areas from the total salaries

(plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5--For each hospital, we adjust the total salaries plus wage-

related costs to a common period to determine total adjusted salaries

plus wage-related costs. To make the wage adjustment, we estimate the

percentage change in the employment cost index (ECI) for compensation

for each 30-day increment from October 14, 2003, through April 15,

2005, for private industry hospital workers from the BLS' Compensation

and Working Conditions. We use the ECI because it reflects the price

increase associated with total compensation (salaries plus fringes)

rather than just the increase in salaries. In addition, the ECI

includes managers as well as other hospital workers. This methodology

to compute the monthly update factors uses actual quarterly ECI data

and assures that the update factors match the actual quarterly and

annual percent changes. We also note that, since April 2006 with the

publication of March 2006 data, the BLS' ECI uses a different

classification system, the North American Industrial Classification

System (NAICS), instead of the Standard Industrial Codes (SICs), which

no longer exist. We have consistently used the ECI as the data source

for our wages and salaries and other price proxies in the IPPS market

basket and do not propose to make any changes to the usage for FY 2010.

The factors used to adjust the hospital's data were based on the

midpoint of the cost reporting period, as indicated below.

Midpoint of Cost Reporting Period

------------------------------------------------------------------------

Adjustment

After Before factor

------------------------------------------------------------------------

10/14/2005.............................. 11/15/2005 1.04966

11/14/2005.............................. 12/15/2005 1.04632

12/14/2005.............................. 01/15/2006 1.04296

01/14/2006.............................. 02/15/2006 1.03955

02/14/2006.............................. 03/15/2006 1.03610

03/14/2006.............................. 04/15/2006 1.03269

04/14/2006.............................. 05/15/2006 1.02936

05/14/2006.............................. 06/15/2006 1.02613

06/14/2006.............................. 07/15/2006 1.02298

07/14/2006.............................. 08/15/2006 1.01990

08/14/2006.............................. 09/15/2006 1.01688

09/14/2006.............................. 10/15/2006 1.01391

10/14/2006.............................. 11/15/2006 1.01098

11/14/2006.............................. 12/15/2006 1.00808

12/14/2006.............................. 01/15/2007 1.00526

01/14/2007.............................. 02/15/2007 1.00257

02/14/2007.............................. 03/15/2007 1.00000

03/14/2007.............................. 04/15/2007 0.99745

------------------------------------------------------------------------

For example, the midpoint of a cost reporting period beginning

January 1, 2006, and ending December 31, 2006, is June 30, 2006. An

adjustment factor of 1.02298 would be applied to the wages

[[Page 24147]]

of a hospital with such a cost reporting period. In addition, for the

data for any cost reporting period that began in FY 2006 and covered a

period of less than 360 days or more than 370 days, we annualize the

data to reflect a 1-year cost report. Dividing the data by the number

of days in the cost report and then multiplying the results by 365

accomplishes annualization.

Step 6--Each hospital is assigned to its appropriate urban or rural

labor market area before any reclassifications under section

1886(d)(8)(B), section 1886(d)(8)(E), or section 1886(d)(10) of the

Act. Within each urban or rural labor market area, we add the total

adjusted salaries plus wage-related costs obtained in Step 5 for all

hospitals in that area to determine the total adjusted salaries plus

wage-related costs for the labor market area.

Step 7--We divide the total adjusted salaries plus wage-related

costs obtained under both methods in Step 6 by the sum of the

corresponding total hours (from Step 4) for all hospitals in each labor

market area to determine an average hourly wage for the area.

Step 8--We add the total adjusted salaries plus wage-related costs

obtained in Step 5 for all hospitals in the Nation and then divide the

sum by the national sum of total hours from Step 4 to arrive at a

national average hourly wage. Using the data as described above, the

proposed national average hourly wage (unadjusted for occupational mix)

is $33.5184.

Step 9--For each urban or rural labor market area, we calculate the

hospital wage index value, unadjusted for occupational mix, by dividing

the area average hourly wage obtained in Step 7 by the national average

hourly wage computed in Step 8.

Step 10--Following the process set forth above, we develop a

separate Puerto Rico-specific wage index for purposes of adjusting the

Puerto Rico standardized amounts. (The national Puerto Rico

standardized amount is adjusted by a wage index calculated for all

Puerto Rico labor market areas based on the national average hourly

wage as described above.) We add the total adjusted salaries plus wage-

related costs (as calculated in Step 5) for all hospitals in Puerto

Rico and divide the sum by the total hours for Puerto Rico (as

calculated in Step 4) to arrive at an overall proposed average hourly

wage (unadjusted for occupational mix) of $14.2462 for Puerto Rico. For

each labor market area in Puerto Rico, we calculate the Puerto Rico-

specific wage index value by dividing the area average hourly wage (as

calculated in Step 7) by the overall Puerto Rico average hourly wage.

Step 11--Section 4410 of Public Law 105-33 provides that, for

discharges on or after October 1, 1997, the area wage index applicable

to any hospital that is located in an urban area of a State may not be

less than the area wage index applicable to hospitals located in rural

areas in that State. The areas affected by this provision are

identified in Table 4D-2 of the Addendum to this proposed rule.

In the FY 2005 IPPS final rule (69 FR 49109), we adopted the

``imputed'' floor as a temporary 3-year measure to address a concern by

some individuals that hospitals in all-urban States were disadvantaged

by the absence of rural hospitals to set a wage index floor in those

States. The imputed floor was originally set to expire in FY 2007, but

we extended it an additional year in the FY 2008 IPPS final rule with

comment period (72 FR 47321). In the FY 2009 IPPS final rule (73 FR

48570 through 48574 and 48584), we extended the imputed floor for an

additional 3 years, through FY 2011.

H. Analysis and Implementation of the Proposed Occupational Mix

Adjustment and the Proposed FY 2010 Occupational Mix Adjusted Wage

Index

As discussed in section III.D. of this preamble, for FY 2010, we

are proposing to apply the occupational mix adjustment to 100 percent

of the FY 2010 wage index. We calculated the proposed occupational mix

adjustment using data from the 2007-2008 occupational mix survey data,

using the methodology described in section III.D.3. of this preamble.

Using the occupational mix survey data and applying the

occupational mix adjustment to 100 percent of the proposed FY 2010 wage

index results in a proposed national average hourly wage of $33.4935

and a Puerto-Rico specific average hourly wage of $14.2555. After

excluding data of hospitals that either submitted aberrant data that

failed critical edits, or that do not have FY 2006 Worksheet S-3 cost

report data for use in calculating the proposed FY 2010 wage index, we

calculated the proposed FY 2010 wage index using the occupational mix

survey data from 3,135 hospitals. Using the Worksheet S-3 cost report

data of 3,521 hospitals and occupational mix survey data from 3,135

hospitals represents an 89-percent survey response rate. The proposed

FY 2010 national average hourly wages for each occupational mix nursing

subcategory as calculated in Step 2 of the occupational mix calculation

are as follows:

------------------------------------------------------------------------

Average hourly

Occupational mix nursing subcategory wage

------------------------------------------------------------------------

National RN.......................................... $36.067749019

National LPN and Surgical Technician................. 20.908955714

National Nurse Aide, Orderly, and Attendant.......... 14.610222480

National Medical Assistant........................... 16.358327509

National Nurse Category.............................. 30.484719916

------------------------------------------------------------------------

The proposed national average hourly wage for the entire nurse

category as computed in Step 5 of the occupational mix calculation is

$30.484719916. Hospitals with a nurse category average hourly wage (as

calculated in Step 4) of greater than the national nurse category

average hourly wage receive an occupational mix adjustment factor (as

calculated in Step 6) of less than 1.0. Hospitals with a nurse category

average hourly wage (as calculated in Step 4) of less than the national

nurse category average hourly wage receive an occupational mix

adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the July 2007 through June 2008 occupational mix survey

data, we determined (in Step 7 of the occupational mix calculation)

that the national percentage of hospital employees in the nurse

category is 44.32 percent, and the national percentage of hospital

employees in the all other occupations category is 55.68 percent. At

the CBSA level, the percentage of hospital employees in the nurse

category ranged from a low of 29.08 percent in one CBSA, to a high of

70.76 percent in another CBSA.

We compared the proposed FY 2010 occupational mix adjusted wage

indices for each CBSA to the proposed unadjusted wage indices for each

CBSA. As a result of applying the occupational mix adjustment to the

wage data, the proposed wage index values for 205 (46.8 percent) urban

areas and 33 (70.2 percent) rural areas would increase. One hundred and

nine (24.9 percent) urban areas would increase by 1 percent or more,

and 5 (1.1 percent) urban areas would increase by 5 percent or more.

Nineteen (40.4 percent) rural areas would increase by 1 percent or

more, and no rural areas would increase by 5 percent or more. However,

the proposed wage index values for 185 (42.2 percent) urban areas and

14 (29.8 percent) rural areas would decrease. Eighty-nine (20.3

percent) urban areas would decrease by 1 percent or more, and 1 (0.23

percent) urban area would decrease by 5 percent or more. Six (12.8

percent) rural areas would decrease by 1 percent or more,

[[Page 24148]]

and no rural areas would decrease by 5 percent or more. The largest

positive impacts are 7.86 percent for an urban area and 2.98 percent

for a rural area. The largest negative impacts are 5.68 percent for an

urban area and 2.07 percent for a rural area. One urban area would be

unaffected. These results indicate that a larger percentage of rural

areas (70.2 percent) benefit from the occupational mix adjustment than

do urban areas (46.8 percent). While these results are more positive

overall for rural areas than under the previous occupational mix

adjustment that used survey data from 2006, approximately one-third

(29.8 percent) of rural CBSAs would still experience a decrease in

their wage indices as a result of the occupational mix adjustment.

We also compared the proposed FY 2010 wage data adjusted for

occupational mix from the 2007-2008 survey to the proposed FY 2010 wage

data adjusted for occupational mix from the 2006 survey. This analysis

illustrates the effect on area wage indices of using the 2007-2008

survey data compared to the 2006 survey data; that is, it shows whether

hospitals' wage indices are increasing or decreasing under the current

survey data as compared to the prior survey data. Our analysis shows

that the FY 2010 proposed wage index values for 186 (47.6 percent)

urban areas and 18 (38.3 percent) rural areas would increase. Sixty-

three (16.1 percent) urban areas would increase by 1 percent or more,

and no urban areas would increase by 5 percent or more. One (2.1

percent) rural area would increase by 1 percent or more, and no rural

areas would increase by 5 percent or more. However, the proposed wage

index values for 201 (51.4 percent) urban areas and 28 (59.6 percent)

rural areas would decrease using the 2007-2008 data. Fifty-six (14.3

percent) urban areas would decrease by 1 percent or more, and one (0.26

percent) urban area would decrease by 5 percent or more. Four (8.5

percent) rural areas would decrease by 1 percent or more, and no rural

areas would decrease by 5 percent or more. The largest positive impacts

using the 2007-2008 data compared to the 2006 data are 4.36 percent for

an urban area and 2.39 percent for a rural area. The largest negative

impacts are 6.46 percent for an urban area and 4.39 percent for a rural

area. Four urban areas and one rural area would be unaffected. These

results indicate that a larger percentage of urban areas (47.6 percent)

would benefit from the 2007-2008 occupational mix survey as compared to

the 2006 survey than would rural areas (38.3 percent). Further, the

wage indices of more CBSAs overall (52.3 percent) would be decreasing

due to application of the 2007-2008 occupational mix survey data as

compared to the 2006 survey data to the wage index. However, as noted

in the analysis above, a greater percentage of rural areas (70.2

percent) would benefit from the application of the occupational mix

adjustment than would urban areas.

The proposed wage index values for FY 2010 (except those for

hospitals receiving wage index adjustments under section 1886(d)(13) of

the Act) included in Tables 4A, 4B, 4C, and 4F of the Addendum to this

proposed rule include the proposed occupational mix adjustment.

Tables 3A and 3B in the Addendum to this proposed rule list the 3-

year average hourly wage for each labor market area before the

redesignation of hospitals based on FYs 2008, 2009, and 2010 cost

reporting periods. Table 3A lists these data for urban areas and Table

3B lists these data for rural areas. In addition, Table 2 in the

Addendum to this proposed rule includes the adjusted average hourly

wage for each hospital from the FY 2004 and FY 2005 cost reporting

periods, as well as the FY 2006 period used to calculate the proposed

FY 2010 wage index. The 3-year averages are calculated by dividing the

sum of the dollars (adjusted to a common reporting period using the

method described previously) across all 3 years, by the sum of the

hours. If a hospital is missing data for any of the previous years, its

average hourly wage for the 3-year period is calculated based on the

data available during that period. The average hourly wages in Tables

2, 3A, and 3B in the Addendum to this proposed rule include the

occupational mix adjustment. The proposed wage index values in Tables

4A, 4B, 4C, and 4D-1 also include the proposed State-specific rural

floor and imputed floor budget neutrality adjustments.

I. Revisions to the Wage Index Based on Hospital Redesignations

1. General

Under section 1886(d)(10) of the Act, the MGCRB considers

applications by hospitals for geographic reclassification for purposes

of payment under the IPPS. Hospitals must apply to the MGCRB to

reclassify 13 months prior to the start of the fiscal year for which

reclassification is sought (generally by September 1). Generally,

hospitals must be proximate to the labor market area to which they are

seeking reclassification and must demonstrate characteristics similar

to hospitals located in that area. The MGCRB issues its decisions by

the end of February for reclassifications that become effective for the

following fiscal year (beginning October 1). The regulations applicable

to reclassifications by the MGCRB are located in 42 CFR 412.230 through

412.280.

Section 1886(d)(10)(D)(v) of the Act provides that, beginning with

FY 2001, a MGCRB decision on a hospital reclassification for purposes

of the wage index is effective for 3 fiscal years, unless the hospital

elects to terminate the reclassification. Section 1886(d)(10)(D)(vi) of

the Act provides that the MGCRB must use average hourly wage data from

the 3 most recently published hospital wage surveys in evaluating a

hospital's reclassification application for FY 2003 and any succeeding

fiscal year.

Section 304(b) of Public Law 106-554 provides that the Secretary

must establish a mechanism under which a statewide entity may apply to

have all of the geographic areas in the State treated as a single

geographic area for purposes of computing and applying a single wage

index, for reclassifications beginning in FY 2003. The implementing

regulations for this provision are located at 42 CFR 412.235.

Section 1886(d)(8)(B) of the Act requires the Secretary to treat a

hospital located in a rural county adjacent to one or more urban areas

as being located in the labor market area to which the greatest number

of workers in the county commute, if the rural county would otherwise

be considered part of an urban area under the standards for designating

MSAs and if the commuting rates used in determining outlying counties

were determined on the basis of the aggregate number of resident

workers who commute to (and, if applicable under the standards, from)

the central county or counties of all contiguous MSAs. In light of the

CBSA definitions and the Census 2000 data that we implemented for FY

2005 (69 FR 49027), we undertook to identify those counties meeting

these criteria. Eligible counties are discussed and identified under

section III.I.5. of this preamble.

2. Effects of Reclassification/Redesignation

Section 1886(d)(8)(C) of the Act provides that the application of

the wage index to redesignated hospitals is dependent on the

hypothetical impact that the wage data from these hospitals would have

on the wage index value for the area to which they have been

redesignated. These requirements for determining the wage index values

for

[[Page 24149]]

redesignated hospitals are applicable both to the hospitals deemed

urban under section 1886(d)(8)(B) of the Act and hospitals that were

reclassified as a result of the MGCRB decisions under section

1886(d)(10) of the Act. Therefore, as provided in section 1886(d)(8)(C)

of the Act, the wage index values were determined by considering the

following:

If including the wage data for the redesignated hospitals

would reduce the wage index value for the area to which the hospitals

are redesignated by 1 percentage point or less, the area wage index

value determined exclusive of the wage data for the redesignated

hospitals applies to the redesignated hospitals.

If including the wage data for the redesignated hospitals

reduces the wage index value for the area to which the hospitals are

redesignated by more than 1 percentage point, the area wage index

determined inclusive of the wage data for the redesignated hospitals

(the combined wage index value) applies to the redesignated hospitals.

If including the wage data for the redesignated hospitals

increases the wage index value for the urban area to which the

hospitals are redesignated, both the area and the redesignated

hospitals receive the combined wage index value. Otherwise, the

hospitals located in the urban area receive a wage index excluding the

wage data of hospitals redesignated into the area.

Rural areas whose wage index values would be reduced by excluding

the wage data for hospitals that have been redesignated to another area

continue to have their wage index values calculated as if no

redesignation had occurred (otherwise, redesignated rural hospitals are

excluded from the calculation of the rural wage index). The wage index

value for a redesignated rural hospital cannot be reduced below the

wage index value for the rural areas of the State in which the hospital

is located.

CMS also has adopted the following policies:

The wage data for a reclassified urban hospital is

included in both the wage index calculation of the urban area to which

the hospital is reclassified (subject to the rules described above) and

the wage index calculation of the urban area where the hospital is

physically located.

In cases where hospitals have reclassified to rural areas,

such as urban hospitals reclassifying to rural areas under 42 CFR

412.103, the hospital's wage data are: (a) Included in the rural wage

index calculation, unless doing so would reduce the rural wage index;

and (b) included in the urban area where the hospital is physically

located. The effect of this policy, in combination with the statutory

requirement at section 1886(d)(8)(C)(ii) of the Act, is that rural

areas may receive a wage index based upon the highest of: (1) Wage data

from hospitals geographically located in the rural area; (2) wage data

from hospitals geographically located in the rural area, but excluding

all data associated with hospitals reclassifying out of the rural area

under section 1886(d)(8)(B) or section 1886(d)(10) of the Act; or (3)

wage data associated with hospitals geographically located in the area

plus all hospitals reclassified into the rural area.

In addition, in accordance with the statutory language referring to

``hospitals'' in the plural under sections 1886(d)(8)(C)(i) and

1886(d)(8)(C)(ii) of the Act, our longstanding policy is to consider

reclassified hospitals as a group when deciding whether to include or

exclude them from both urban and rural wage index calculations.

3. FY 2010 MGCRB Reclassifications

Under section 1886(d)(10) of the Act, the MGCRB considers

applications by hospitals for geographic reclassification for purposes

of payment under the IPPS. The specific procedures and rules that apply

to the geographic reclassification process are outlined in 42 CFR

412.230 through 412.280.

At the time this proposed rule was constructed, the MGCRB had

completed its review of FY 2010 reclassification requests. Based on

such reviews, there were 292 hospitals approved for wage index

reclassifications by the MGCRB for FY 2010. Because MGCRB wage index

reclassifications are effective for 3 years, for FY 2010, hospitals

reclassified during FY 2008 or FY 2009 are eligible to continue to be

reclassified to a particular labor market area based on such prior

reclassifications. There were 313 hospitals approved for wage index

reclassifications in FY 2008 and 271 hospitals approved for wage index

reclassifications in FY 2009. Of all of the hospitals approved for

reclassification for FY 2008, FY 2009, and FY 2010, based upon the

review at the time of the proposed rule, 876 hospitals are in a

reclassification status for FY 2010.

Under 42 CFR 412.273, hospitals that have been reclassified by the

MGCRB are permitted to withdraw their applications within 45 days of

the publication of a proposed rule. Generally stated, the request for

withdrawal of an application for reclassification or termination of an

existing 3-year reclassification that would be effective in FY 2010

must be received by the MGCRB within 45 days of the publication of the

proposed rule. Hospitals may also cancel prior reclassification

withdrawals or terminations in certain circumstances. For further

information about withdrawing, terminating, or canceling a previous

withdrawal or termination of a 3-year reclassification for wage index

purposes, we refer the reader to 42 CFR 412.273, as well as the FY 2002

IPPS final rule (66 FR 39887) and the FY 2003 IPPS final rule (67 FR

50065).

Changes to the wage index that result from withdrawals of requests

for reclassification, wage index corrections, appeals, and the

Administrator's review process will be incorporated into the wage index

values published in the FY 2010 IPPS final rule. These changes affect

not only the wage index value for specific geographic areas, but also

the wage index value redesignated hospitals receive; that is, whether

they receive the wage index that includes the data for both the

hospitals already in the area and the redesignated hospitals. Further,

the wage index value for the area from which the hospitals are

redesignated may be affected.

Applications for FY 2011 reclassifications are due to the MGCRB by

September 1, 2009 (the first working day of September 2009). We note

that this is also the deadline for canceling a previous wage index

reclassification withdrawal or termination under 42 CFR 412.273(d).

Applications and other information about MGCRB reclassifications may be

obtained, beginning in mid-July 2009, via the CMS Internet Web site at:

http://cms.hhs.gov/providers/prrb/mgcinfo.asp, or by calling the MGCRB

at (410) 786-1174. The mailing address of the MGCRB is: 2520 Lord

Baltimore Drive, Suite L, Baltimore, MD 21244-2670.

4. Redesignations of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B) of the Act requires us to treat a hospital

located in a rural county adjacent to one or more urban areas as being

located in the MSA if certain criteria are met. Effective beginning FY

2005, we use OMB's 2000 CBSA standards and the Census 2000 data to

identify counties in which hospitals qualify under section

1886(d)(8)(B) of the Act to receive the wage index of the urban area.

Hospitals located in these counties have been known as ``Lugar''

hospitals and the counties themselves are often referred to as

``Lugar'' counties. We provide the FY 2010 chart below with the listing

of the rural counties containing the hospitals designated as urban

under section

[[Page 24150]]

1886(d)(8)(B) of the Act. For discharges occurring on or after October

1, 2009, hospitals located in the rural county in the first column of

this chart will be redesignated for purposes of using the wage index of

the urban area listed in the second column.

Rural Counties Containing Hospitals Redesignated as Urban under Section

1886(d)(8)(B) of the Act

[Based on CBSAs and Census 2000 Data]

------------------------------------------------------------------------

Rural County CBSA

------------------------------------------------------------------------

Cherokee, AL.............................. Rome, GA.

Macon, AL................................. Auburn-Opelika, AL.

Talladega, AL............................. Anniston-Oxford, AL.

Hot Springs, AR........................... Hot Springs, AR.

Windham, CT............................... Hartford-West Hartford-East

Hartford, CT.

Bradford, FL.............................. Gainesville, FL.

Hendry, FL................................ West Palm Beach-Boca Raton-

Boynton, FL.

Levy, FL.................................. Gainesville, FL.

Walton, FL................................ Fort Walton Beach-Crestview-

Destin, FL.

Banks, GA................................. Gainesville, GA.

Chattooga, GA............................. Chattanooga, TN-GA.

Jackson, GA............................... Atlanta-Sandy Springs-

Marietta, GA.

Lumpkin, GA............................... Atlanta-Sandy Springs-

Marietta, GA.

Morgan, GA................................ Atlanta-Sandy Springs-

Marietta, GA.

Peach, GA................................. Macon, GA.

Polk, GA.................................. Atlanta-Sandy Springs-

Marietta, GA.

Talbot, GA................................ Columbus, GA-AL.

Bingham, ID............................... Idaho Falls, ID.

Christian, IL............................. Springfield, IL.

DeWitt, IL................................ Bloomington-Normal, IL.

Iroquois, IL.............................. Kankakee-Bradley, IL.

Logan, IL................................. Springfield, IL.

Mason, IL................................. Peoria, IL.

Ogle, IL.................................. Rockford, IL.

Clinton, IN............................... Lafayette, IN.

Henry, IN................................. Indianapolis-Carmel, IN.

Spencer, IN............................... Evansville, IN-KY.

Starke, IN................................ Gary, IN.

Warren, IN................................ Lafayette, IN.

Boone, IA................................. Ames, IA.

Buchanan, IA.............................. Waterloo-Cedar Falls, IA.

Cedar, IA................................. Iowa City, IA.

Allen, KY................................. Bowling Green, KY.

Assumption Parish, LA..................... Baton Rouge, LA.

St. James Parish, LA...................... Baton Rouge, LA.

Allegan, MI............................... Holland-Grand Haven, MI.

Montcalm, MI.............................. Grand Rapids-Wyoming, MI.

Oceana, MI................................ Muskegon-Norton Shores, MI.

Shiawassee, MI............................ Lansing-East Lansing, MI.

Tuscola, MI............................... Saginaw-Saginaw Township

North, MI.

Fillmore, MN.............................. Rochester, MN.

Dade, MO.................................. Springfield, MO.

Pearl River, MS........................... Gulfport-Biloxi, MS.

Caswell, NC............................... Burlington, NC.

Davidson, NC.............................. Greensboro-High Point, NC.

Granville, NC............................. Durham, NC.

Harnett, NC............................... Raleigh-Cary, NC.

Lincoln, NC............................... Charlotte-Gastonia-Concord,

NC-SC.

Polk, NC.................................. Spartanburg, SC.

Los Alamos, NM............................ Santa Fe, NM.

Lyon, NV.................................. Carson City, NV.

Cayuga, NY................................ Syracuse, NY.

Columbia, NY.............................. Albany-Schenectady-Troy, NY.

Genesee, NY............................... Rochester, NY.

Greene, NY................................ Albany-Schenectady-Troy, NY.

Schuyler, NY.............................. Ithaca, NY.

Sullivan, NY.............................. Poughkeepsie-Newburgh-

Middletown, NY.

Wyoming, NY............................... Buffalo-Niagara Falls, NY.

Ashtabula, OH............................. Cleveland-Elyria-Mentor, OH.

Champaign, OH............................. Springfield, OH.

Columbiana, OH............................ Youngstown-Warren-Boardman,

OH-PA.

Cotton, OK................................ Lawton, OK.

Linn, OR.................................. Corvallis, OR.

Adams, PA................................. York-Hanover, PA.

Clinton, PA............................... Williamsport, PA.

Greene, PA................................ Pittsburgh, PA.

Monroe, PA................................ Allentown-Bethlehem-Easton,

PA-NJ.

Schuylkill, PA............................ Reading, PA.

Susquehanna, PA........................... Binghamton, NY.

Clarendon, SC............................. Sumter, SC.

Lee, SC................................... Sumter, SC.

Oconee, SC................................ Greenville, SC.

Union, SC................................. Spartanburg, SC.

Meigs, TN................................. Cleveland, TN.

Bosque, TX................................ Waco, TX.

Falls, TX................................. Waco, TX.

Fannin, TX................................ Dallas-Plano-Irving, TX.

Grimes, TX................................ College Station-Bryan, TX.

Harrison, TX.............................. Longview, TX.

Henderson, TX............................. Dallas-Plano-Irving, TX.

Milam, TX................................. Austin-Round Rock, TX.

Van Zandt, TX............................. Dallas-Plano-Irving, TX.

Willacy, TX............................... Brownsville-Harlingen, TX.

Buckingham, VA............................ Charlottesville, VA.

Floyd, VA................................. Blacksburg-Christiansburg-

Radford, VA.

Middlesex, VA............................. Virginia Beach-Norfolk-

Newport News, VA.

Page, VA.................................. Harrisonburg, VA.

Shenandoah, VA............................ Winchester, VA-WV.

Island, WA................................ Seattle-Bellevue-Everett,

WA.

Mason, WA................................. Olympia, WA.

Wahkiakum, WA............................. Longview, WA.

Jackson, WV............................... Charleston, WV.

Roane, WV................................. Charleston, WV.

Green, WI................................. Madison, WI.

Green Lake, WI............................ Fond du Lac, WI.

Jefferson, WI............................. Milwaukee-Waukesha-West

Allis, WI.

Walworth, WI.............................. Milwaukee-Waukesha-West

Allis, WI.

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As in the past, hospitals redesignated under section 1886(d)(8)(B)

of the Act are also eligible to be reclassified to a different area by

the MGCRB. Affected hospitals are permitted to compare the reclassified

wage index for the labor market area in Table 4C in the Addendum to

this proposed rule into which they have been reclassified by the MGCRB

to the wage index for the area to which they are redesignated under

section 1886(d)(8)(B) of the Act. Hospitals may withdraw from an MGCRB

reclassification within 45 days of the publication of this proposed

rule.

5. Reclassifications Under Section 1886(d)(8)(B) of the Act

As discussed in the FY 2009 IPPS final rule (73 FR 48588), Lugar

hospitals are treated like reclassified hospitals for purposes of

determining their applicable wage index and receive the reclassified

wage index for the urban area to which they have been redesignated.

Because Lugar hospitals are treated like reclassified hospitals, when

they are seeking reclassification by the MGCRB, they are subject to the

rural reclassification rules set forth at 42 CFR 412.230. The

procedural rules set forth at Sec. 412.230 list the criteria that a

hospital must meet in order to reclassify as a rural hospital. Lugar

hospitals are subject to the proximity criteria and payment thresholds

that apply to rural hospitals. Specifically, the hospital must be no

more than 35 miles from the area to which it seeks reclassification

[[Page 24151]]

(Sec. 412.230(b)(1)); and the hospital must show that its average

hourly wage is at least 106 percent of the average hourly wage of all

other hospitals in the area in which the hospital is located (Sec.

412.230(d)(1)(iii)(C)). In accordance with policy adopted in the FY

2009 IPPS final rule (73 FR 48568 and 48569), beginning with

reclassifications for the FY 2010 wage index, a Lugar hospital must

also demonstrate that its average hourly wage is equal to at least 84

percent (for FY 2010 reclassifications) and 86 percent (for

reclassifications for FY 2011 and subsequent fiscal years) of the

average hourly wage of hospitals in the area to which it seeks

redesignation (Sec. 412.230(d)(1)(iv)(C)).

Hospitals not located in a Lugar county seeking reclassification to

the urban area where the Lugar hospitals have been redesignated are not

permitted to measure to the Lugar county to demonstrate proximity (no

more than 15 miles for an urban hospital, and no more than 35 miles for

a rural hospital or the closest urban or rural area for RRCs or SCHs)

in order to be reclassified to such urban area. These hospitals must

measure to the urban area exclusive of the Lugar County to meet the

proximity or nearest urban or rural area requirement. We treat New

England deemed counties in a manner consistent with how we treat Lugar

counties. (We refer readers to FY 2008 IPPS final rule with comment

period (72 FR 47337) for a discussion of this policy.)

6. Reclassifications Under Section 508 of Public Law 108-173

Section 508 of Public Law 108-173 allowed certain qualifying

hospitals to receive wage index reclassifications and assignments that

they otherwise would not have been eligible to receive under the law.

Although section 508 originally was scheduled to expire after a 3-year

period, Congress extended the provision several times, as well as

certain special exceptions that would have otherwise expired. For a

discussion of the original section 508 provision and its various

extensions, we refer readers to the FY 2009 IPPS final rule (73 FR

48443). The most recent extension of the provision was included in

section 124 of Public Law 110-275 (MIPPA). Section 124 extended,

through FY 2009, section 508 reclassifications as well as certain

special exceptions. Because the latest extension of these provisions

expires on September 30, 2009, and will not be applicable in FY 2010,

in this proposed rule, we are not proposing to make any changes related

to these provisions.

J. Proposed FY 2010 Wage Index Adjustment Based on Commuting Patterns

of Hospital Employees

In accordance with the broad discretion under section 1886(d)(13)

of the Act, as added by section 505 of Public Law 108-173, beginning

with FY 2005, we established a process to make adjustments to the

hospital wage index based on commuting patterns of hospital employees

(the ``out-migration'' adjustment). The process, outlined in the FY

2005 IPPS final rule (69 FR 49061), provides for an increase in the

wage index for hospitals located in certain counties that have a

relatively high percentage of hospital employees who reside in the

county but work in a different county (or counties) with a higher wage

index. Such adjustments to the wage index are effective for 3 years,

unless a hospital requests to waive the application of the adjustment.

A county will not lose its status as a qualifying county due to wage

index changes during the 3-year period, and counties will receive the

same wage index increase for those 3 years. However, a county that

qualifies in any given year may no longer qualify after the 3-year

period, or it may qualify but receive a different adjustment to the

wage index level. Hospitals that receive this adjustment to their wage

index are not eligible for reclassification under section 1886(d)(8) or

section 1886(d)(10) of the Act. Adjustments under this provision are

not subject to the budget neutrality requirements under section

1886(d)(3)(E) of the Act.

Hospitals located in counties that qualify for the wage index

adjustment are to receive an increase in the wage index that is equal

to the average of the differences between the wage indices of the labor

market area(s) with higher wage indices and the wage index of the

resident county, weighted by the overall percentage of hospital workers

residing in the qualifying county who are employed in any labor market

area with a higher wage index. Beginning with the FY 2008 wage index,

we use post-reclassified wage indices when determining the out-

migration adjustment (72 FR 47339).

For the FY 2010 wage index, we are proposing to calculate the out-

migration adjustment using the same formula described in the FY 2005

IPPS final rule (69 FR 49064), with the addition of using the post-

reclassified wage indices, to calculate the out-migration adjustment.

This adjustment is calculated as follows:

Step 1--Subtract the wage index for the qualifying county from the

wage index of each of the higher wage area(s) to which hospital workers

commute.

Step 2--Divide the number of hospital employees residing in the

qualifying county who are employed in such higher wage index area by

the total number of hospital employees residing in the qualifying

county who are employed in any higher wage index area. For each of the

higher wage index areas, multiply this result by the result obtained in

Step 1.

Step 3--Sum the products resulting from Step 2 (if the qualifying

county has workers commuting to more than one higher wage index area).

Step 4--Multiply the result from Step 3 by the percentage of

hospital employees who are residing in the qualifying county and who

are employed in any higher wage index area.

These adjustments will be effective for each county for a period of

3 fiscal years. For example, hospitals that received the adjustment for

the first time in FY 2009 will be eligible to retain the adjustment for

FY 2010. For hospitals in newly qualified counties, adjustments to the

wage index are effective for 3 years, beginning with discharges

occurring on or after October 1, 2009.

Hospitals receiving the wage index adjustment under section

1886(d)(13)(F) of the Act are not eligible for reclassification under

sections 1886(d)(8) or (d)(10) of the Act unless they waive the out-

migration adjustment. Consistent with our FY 2005, 2006, 2007, 2008,

and 2009 IPPS final rules, we are specifying that hospitals

redesignated under section 1886(d)(8) of the Act or reclassified under

section 1886(d)(10) of the Act will be deemed to have chosen to retain

their redesignation or reclassification. Section 1886(d)(10) hospitals

that wish to receive the out-migration adjustment, rather than their

reclassification adjustment, should follow the termination/withdrawal

procedures specified in 42 CFR 412.273 and section III.I.3. of the

preamble of this proposed rule. Otherwise, they will be deemed to have

waived the out-migration adjustment. Hospitals redesignated under

section 1886(d)(8) of the Act will be deemed to have waived the out-

migration adjustment unless they explicitly notify CMS within 45 days

from the publication of this proposed rule that they elect to receive

the out-migration adjustment instead. These notifications should be

sent to the following address: Centers for Medicare and Medicaid

Services, Center for Medicare Management, Attention: Wage Index

Adjustment Waivers, Division of

[[Page 24152]]

Acute Care, room C4-08-06, 7500 Security Boulevard, Baltimore, MD

21244-1850.

Table 4J in the Addendum to this proposed rule lists the proposed

out-migration wage index adjustments for FY 2010. Hospitals that are

not otherwise reclassified or redesignated under section 1886(d)(8) or

section 1886(d)(10) of the Act will automatically receive the listed

adjustment. In accordance with the procedures discussed above,

redesignated/reclassified hospitals will be deemed to have waived the

out-migration adjustment unless CMS is otherwise notified within the

necessary timeframe. In addition, hospitals eligible to receive the

out-migration wage index adjustment and that withdraw their application

for reclassification would automatically receive the wage index

adjustment listed in the final Table 4J in the Addendum to this

proposed rule.

K. Process for Requests for Wage Index Data Corrections

The preliminary, unaudited Worksheet S-3 wage data and occupational

mix survey data files for the FY 2010 wage index were made available on

October 6, 2008, through the Internet on the CMS Web site at: http://

www.cms.hhs.gov/AcuteInpatientPPS/WIFN/list.asp#TopOfPage.

In the interest of meeting the data needs of the public, beginning

with the proposed FY 2009 wage index, we post an additional public use

file on our Web site that reflects the actual data that are used in

computing the proposed wage index. The release of this new file does

not alter the current wage index process or schedule. We notified the

hospital community of the availability of these data as we do with the

current public use wage data files through our Hospital Open Door

forum. We encourage hospitals to sign up for automatic notifications of

information about hospital issues and the scheduling of the Hospital

Open Door forums at: http://www.cms.hhs.gov/OpenDoorForums/.

In a memorandum dated October 6, 2008, we instructed all fiscal

intermediaries/MACs to inform the IPPS hospitals they service of the

availability of the wage index data files and the process and timeframe

for requesting revisions (including the specific deadlines listed

below). We also instructed the fiscal intermediaries/MACs to advise

hospitals that these data were also made available directly through

their representative hospital organizations.

If a hospital wished to request a change to its data as shown in

the October 6, 2008 wage and occupational mix data files, the hospital

was to submit corrections along with complete, detailed supporting

documentation to its fiscal intermediary/MAC by December 8, 2008.

Hospitals were notified of this deadline and of all other possible

deadlines and requirements, including the requirement to review and

verify their data as posted on the preliminary wage index data files on

the Internet, through the October 6, 2008 memorandum referenced above.

In the October 6, 2008 memorandum, we also specified that a

hospital requesting revisions to its first and/or second quarter

occupational mix survey data was to copy its record(s) from the CY

2007-2008 occupational mix preliminary files posted to our Web site in

October, highlight the revised cells on its spreadsheet, and submit its

spreadsheet(s) and complete documentation to its fiscal intermediary/

MAC no later than December 8, 2008.

The fiscal intermediaries/MACs notified the hospitals by mid-

February 2009 of any changes to the wage index data as a result of the

desk reviews and the resolution of the hospitals' early-December

revision requests. The fiscal intermediaries/MACs also submitted the

revised data to CMS by mid-February 2009. CMS published the proposed

wage index public use files that included hospitals' revised wage index

data on February 23, 2009. In a memorandum also dated February 23,

2009, we instructed fiscal intermediaries/MACs to notify all hospitals

regarding the availability of the proposed wage index public use files

and the criteria and process for requesting corrections and revisions

to the wage index data. Hospitals had until March 10, 2009, to submit

requests to the fiscal intermediaries/MACs for reconsideration of

adjustments made by the fiscal intermediaries/MACs as a result of the

desk review, and to correct errors due to CMS's or the fiscal

intermediary's (or, if applicable, the MAC's) mishandling of the wage

index data. Hospitals also were required to submit sufficient

documentation to support their requests.

After reviewing requested changes submitted by hospitals, fiscal

intermediaries/MACs are to transmit any additional revisions resulting

from the hospitals' reconsideration requests by April 15, 2009. The

deadline for a hospital to request CMS intervention in cases where the

hospital disagrees with the fiscal intermediary's (or, if applicable,

the MAC's) policy interpretations is April 15, 2009.

Hospitals should also examine Table 2 in the Addendum to this

proposed rule. Table 2 in the Addendum to this proposed rule contains

each hospital's adjusted average hourly wage used to construct the wage

index values for the past 3 years, including the FY 2006 data used to

construct the proposed FY 2010 wage index. We noted that the hospital

average hourly wages shown in Table 2 only reflect changes made to a

hospital's data and transmitted to CMS by March 2, 2009.

We will release the final wage index data public use files in early

May 2009 on the Internet at http://www.cms.hhs.gov/AcuteInpatientPPS/

WIFN/list.asp#TopOfPage. The May 2009 public use files will be made

available solely for the limited purpose of identifying any potential

errors made by CMS or the fiscal intermediary/MAC in the entry of the

final wage index data that resulted from the correction process

described above (revisions submitted to CMS by the fiscal

intermediaries/MACs by April 15, 2009). If, after reviewing the May

2009 final files, a hospital believes that its wage or occupational mix

data are incorrect due to a fiscal intermediary/MAC or CMS error in the

entry or tabulation of the final data, the hospital should send a

letter to both its fiscal intermediary/MAC and CMS that outlines why

the hospital believes an error existed and to provide all supporting

information, including relevant dates (for example, when it first

became aware of the error). CMS and the fiscal intermediaries (or, if

applicable, the MACs) must receive these requests no later than June 8,

2009.

Each request also must be sent to the fiscal intermediary/MAC. The

fiscal intermediary/MAC will review requests upon receipt and contact

CMS immediately to discuss any findings.

At this point in the process, that is, after the release of the May

2009 wage index data files, changes to the wage and occupational mix

data will only be made in those very limited situations involving an

error by the fiscal intermediary/MAC or CMS that the hospital could not

have known about before its review of the final wage index data files.

Specifically, neither the fiscal intermediary/MAC nor CMS will approve

the following types of requests:

Requests for wage index data corrections that were

submitted too late to be included in the data transmitted to CMS by

fiscal intermediaries or the MACs on or before April 15, 2009.

Requests for correction of errors that were not, but could

have been, identified during the hospital's review

[[Page 24153]]

of the February 23, 2009 wage index public use files.

Requests to revisit factual determinations or policy

interpretations made by the fiscal intermediary or the MAC or CMS

during the wage index data correction process.

Verified corrections to the wage index data received timely by CMS

and the fiscal intermediaries or the MACs (that is, by June 8, 2009)

will be incorporated into the final wage index in the FY 2010 IPPS

final rule, which will be effective October 1, 2009.

We created the processes described above to resolve all substantive

wage index data correction disputes before we finalize the wage and

occupational mix data for the FY 2010 payment rates. Accordingly,

hospitals that did not meet the procedural deadlines set forth above

will not be afforded a later opportunity to submit wage index data

corrections or to dispute the fiscal intermediary's (or, if applicable

the MAC's) decision with respect to requested changes. Specifically,

our policy is that hospitals that do not meet the procedural deadlines

set forth above will not be permitted to challenge later, before the

Provider Reimbursement Review Board, the failure of CMS to make a

requested data revision. (See W. A. Foote Memorial Hospital v. Shalala,

No. 99-CV-75202-DT (E.D. Mich. 2001) and Palisades General Hospital v.

Thompson, No. 99-1230 (D.D.C. 2003).) We refer readers also to the FY

2000 final rule (64 FR 41513) for a discussion of the parameters for

appealing to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described

above provides hospitals with sufficient opportunity to bring errors in

their wage and occupational mix data to the fiscal intermediary's (or,

if applicable, the MAC's) attention. Moreover, because hospitals will

have access to the final wage index data by early May 2009, they have

the opportunity to detect any data entry or tabulation errors made by

the fiscal intermediary or the MAC or CMS before the development and

publication of the final FY 2010 wage index by August 1, 2009, and the

implementation of the FY 2010 wage index on October 1, 2009. If

hospitals availed themselves of the opportunities afforded to provide

and make corrections to the wage and occupational mix data, the wage

index implemented on October 1 should be accurate. Nevertheless, in the

event that errors are identified by hospitals and brought to our

attention after June 8, 2009, we retain the right to make midyear

changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our

existing regulations, we make midyear corrections to the wage index for

an area only if a hospital can show that: (1) The fiscal intermediary

or the MAC or CMS made an error in tabulating its data; and (2) the

requesting hospital could not have known about the error or did not

have an opportunity to correct the error, before the beginning of the

fiscal year. For purposes of this provision, ``before the beginning of

the fiscal year'' means by the June 8 deadline for making corrections

to the wage data for the following fiscal year's wage index. This

provision is not available to a hospital seeking to revise another

hospital's data that may be affecting the requesting hospital's wage

index for the labor market area. As indicated earlier, because CMS

makes the wage index data available to hospitals on the CMS Web site

prior to publishing both the proposed and final IPPS rules, and the

fiscal intermediaries or the MAC notify hospitals directly of any wage

index data changes after completing their desk reviews, we do not

expect that midyear corrections will be necessary. However, under our

current policy, if the correction of a data error changes the wage

index value for an area, the revised wage index value will be effective

prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385), we revised 42 CFR

412.64(k)(2) to specify that, effective on October 1, 2005, that is,

beginning with the FY 2006 wage index, a change to the wage index can

be made retroactive to the beginning of the Federal fiscal year only

when: (1) The fiscal intermediary (or, if applicable, the MAC) or CMS

made an error in tabulating data used for the wage index calculation;

(2) the hospital knew about the error and requested that the fiscal

intermediary (or if applicable the MAC) and CMS correct the error using

the established process and within the established schedule for

requesting corrections to the wage index data, before the beginning of

the fiscal year for the applicable IPPS update (that is, by the June 8,

2009 deadline for the FY 2010 wage index); and (3) CMS agreed that the

fiscal intermediary (or if applicable, the MAC) or CMS made an error in

tabulating the hospital's wage index data and the wage index should be

corrected.

In those circumstances where a hospital requested a correction to

its wage index data before CMS calculates the final wage index (that

is, by the June 8, 2009 deadline), and CMS acknowledges that the error

in the hospital's wage index data was caused by CMS' or the fiscal

intermediary's (or, if applicable, the MAC's) mishandling of the data,

we believe that the hospital should not be penalized by our delay in

publishing or implementing the correction. As with our current policy,

we indicated that the provision is not available to a hospital seeking

to revise another hospital's data. In addition, the provision cannot be

used to correct prior years' wage index data; and it can only be used

for the current Federal fiscal year. In other situations where our

policies would allow midyear corrections, we continue to believe that

it is appropriate to make prospective-only corrections to the wage

index.

We note that, as with prospective changes to the wage index, the

final retroactive correction will be made irrespective of whether the

change increases or decreases a hospital's payment rate. In addition,

we note that the policy of retroactive adjustment will still apply in

those instances where a judicial decision reverses a CMS denial of a

hospital's wage index data revision request.

IV. Proposed Rebasing and Revision of the Hospital Market Baskets for

Acute Care Hospitals

A. Background

Effective for cost reporting periods beginning on or after July 1,

1979, we developed and adopted a hospital input price index (that is,

the hospital market basket for operating costs). Although ``market

basket'' technically describes the mix of goods and services used in

providing hospital care, this term is also commonly used to denote the

input price index (that is, cost category weights and price proxies

combined) derived from that market basket. Accordingly, the term

``market basket'' as used in this document refers to the hospital input

price index.

The percentage change in the market basket reflects the average

change in the price of goods and services hospitals purchase in order

to provide inpatient care. We first used the market basket to adjust

hospital cost limits by an amount that reflected the average increase

in the prices of the goods and services used to provide hospital

inpatient care. This approach linked the increase in the cost limits to

the efficient utilization of resources.

Since the inception of the IPPS, the projected change in the

hospital market basket has been the integral component of the update

factor by which the prospective payment rates are updated every year.

An explanation of the hospital market basket used to develop the

prospective payment rates was

[[Page 24154]]

published in the Federal Register on September 1, 1983 (48 FR 39764).

We also refer readers to the FY 2006 IPPS final rule (70 FR 47387) in

which we discussed the most recent previous rebasing of the hospital

input price index.

The hospital market basket is a fixed-weight, Laspeyres-type price

index that is constructed in three steps. A Laspeyres price index

measures the change in price, over time, of the same mix of goods and

services purchased in the base period. Any changes in the quantity or

mix of goods and services (that is, intensity) purchased over time are

not measured.

The index itself is constructed in three steps. First, a base

period is selected (in this proposed rule, the base period is FY 2006)

and total base period expenditures are estimated for a set of mutually

exclusive and exhaustive spending categories based upon type of

expenditure. Then the proportion of total operating costs that each

category represents is determined. These proportions are called cost or

expenditure weights. Second, each expenditure category is matched to an

appropriate price or wage variable, referred to as a price proxy. In

nearly every instance, these price proxies are price levels derived

from publicly available statistical series that are published on a

consistent schedule (preferably at least on a quarterly basis).

Finally, the expenditure weight for each cost category is multiplied by

the level of its respective price proxy. The sum of these products

(that is, the expenditure weights multiplied by their price levels) for

all cost categories yields the composite index level of the market

basket in a given period. Repeating this step for other periods

produces a series of market basket levels over time. Dividing an index

level for a given period by an index level for an earlier period

produces a rate of growth in the input price index over that timeframe.

The market basket is described as a fixed-weight index because it

represents the change in price over time of the same mix (quantity and

intensity) of goods and services purchased to provide hospital services

in a base period. The effects on total expenditures resulting from

changes in the mix of goods and services purchased subsequent to the

base period are not measured. For example, shifting a traditionally

inpatient type of care to an outpatient setting might affect the volume

of inpatient goods and services purchased by the hospital, but would

not be factored into the price change measured by a fixed-weight

hospital market basket. In this manner, the market basket measures pure

price change only. Only when the index is rebased would changes in the

quantity and intensity be captured in the cost weights. Therefore, we

rebase the market basket periodically so the cost weights reflect

recent changes in the mix of goods and services that hospitals purchase

(hospital inputs) to furnish inpatient care between base periods. We

last rebased the hospital market basket cost weights effective for FY

2006 (70 FR 47387), with FY 2002 data used as the base period for the

construction of the market basket cost weights.

We are inviting public comments on our proposed methodological

changes to both the IPPS operating market basket and the capital input

price index (CIPI). We note that this section addresses only the

rebasing and revision of the IPPS market basket and CIPI for acute care

hospitals and for children's and cancer hospitals and RNHCIs, which are

excluded from the IPPS. We address the proposed market basket that

would be applicable to LTCHs in section VIII.C.2. of the preamble of

this proposed rule. Separate documents will address the market basket

for other hospitals that are excluded from the IPPS.

B. Rebasing and Revising the IPPS Market Basket

The terms ``rebasing'' and ``revising,'' while often used

interchangeably, actually denote different activities. ``Rebasing''

means moving the base year for the structure of costs of an input price

index (for example, in this proposed rule, we are shifting the base

year cost structure for the IPPS hospital index from FY 2002 to FY

2006). ``Revising'' means changing data sources, or price proxies, used

in the input price index. As published in the FY 2006 IPPS final rule

(70 FR 47387), in accordance with section 404 of Public Law 108-173,

CMS determined a new frequency for rebasing the hospital market basket.

We established a rebasing frequency of every 4 years and, therefore,

for the FY 2010 IPPS update, we are proposing to rebase and revise the

IPPS market basket and the CIPI.

1. Development of Cost Categories and Weights

a. Medicare Cost Reports

The major source of expenditure data for developing the rebased and

revised hospital market basket cost weights is the FY 2006 Medicare

cost reports. As was done in previous rebasings, these cost reports are

from IPPS hospitals only (hospitals excluded from the IPPS and CAHs are

not included) and are based on IPPS Medicare-allowable operating costs.

IPPS Medicare-allowable operating costs are costs that are eligible to

be paid for under the IPPS. For example, the IPPS market basket

excludes home health agency (HHA) costs as these costs would be paid

under the HHA PPS and, therefore, these costs are not IPPS Medicare-

allowable costs.

The IPPS cost reports yield seven major expenditure or cost

categories--the same as in the FY 2002-based hospital market basket:

Wages and salaries, employee benefits, contract labor, pharmaceuticals,

professional liability insurance (malpractice), blood and blood

products, and a residual ``all other.'' The cost weights that were

obtained directly from the Medicare cost reports are reported in Chart

1. These Medicare cost report cost weights are then supplemented with

information obtained from other data sources to derive the proposed

IPPS market basket cost weights.

Chart 1.--Major Cost Categories and Their Respective Cost Weights Found

in the Medicare Cost Reports

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Proposed 2006-

Major cost categories FY 2002-based based market

market basket basket

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Wages and salaries.................. 45.590 45.156

Employee benefits................... 11.189 11.873

Contract labor...................... 3.214 2.598

Professional liability insurance 1.589 1.661

(malpractice)......................

Pharmaceuticals..................... 5.855 5.380

Blood and blood products............ 1.082 1.078

All other........................... 31.481 32.254

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[[Page 24155]]

b. Other Data Sources

In addition to the Medicare cost reports, the other data source we

used to develop the IPPS market basket cost weights was the Benchmark

Input-Output (I-O) Tables created by the Bureau of Economic Analysis

(BEA), U.S. Department of Commerce. The BEA Benchmark I-O data are

scheduled for publication every 5 years. The most recent data available

are for 2002. BEA also produces Annual I-O estimates; however, the 2002

Benchmark I-O data represent a much more comprehensive and complete set

of data that are derived from the 2002 Economic Census. The Annual I-O

is simply an update of the Benchmark I-O tables. For the FY 2006 market

basket rebasing, we used the 1997 Benchmark I-O data. We are proposing

to use the 2002 Benchmark I-O data in the FY 2006-based IPPS market

basket, to be effective for FY 2010. Instead of using the less

detailed, less accurate Annual I-O data, we aged the 2002 Benchmark I-O

data forward to FY 2006. The methodology we used to age the data

forward involves applying the annual price changes from the respective

price proxies to the appropriate cost categories. We repeat this

practice for each year.

The ``all other'' cost category obtained directly from the Medicare

cost reports is divided into other hospital expenditure category shares

using the 2002 Benchmark I-O data. Therefore, the ``all other'' cost

category expenditure shares are proportional to their relationship to

``all other'' totals in the 2002 Benchmark I-O data. For instance, if

the cost for telephone services was to represent 10 percent of the sum

of the ``all other'' Benchmark I-O (see below) hospital expenditures,

then telephone services would represent 10 percent of the IPPS market

basket's ``all other'' cost category. Following publication of this FY

2010 IPPS proposed rule, and in an effort to provide greater

transparency, we will be posting on the CMS market basket Web page at

http://www.cms.hhs.gov/MedicareProgramRatesStats/05\_

MarketBasketResearch.asp#TopOfPage an illustrative spreadsheet that

shows how the detailed cost weights (that is, those not calculated

using Medicare cost reports) are determined using the 2002 Benchmark I-

O data.

2. Final Cost Category Computation

As stated previously, for this rebasing we used the Medicare cost

reports to derive seven major cost categories. The proposed FY 2006-

based IPPS market basket includes three additional cost categories that

were not broken out separately in the FY 2002-based IPPS market basket.

The first is lifted directly from the Medicare cost reports: Blood and

blood products. The remaining two are derived using the Benchmark I-O

data: Administrative and business support services and financial

services. We are proposing to break out the latter two categories so we

can better match their respective expenses with price proxies. A

thorough discussion of our rationale for each of these cost categories

is provided in the section IV.B.3. of this proposed rule. Also, the

proposed FY 2006-based IPPS market basket excludes one cost category:

Photo supplies. The 2002 Benchmark I-O weight for this category is

considerably smaller than the 1997 Benchmark I-O weight, presently

accounting for less than one-tenth of one percentage point of the IPPS

market basket. Therefore, we are proposing to include the photo

supplies costs in the chemical cost category weight with other similar

chemical products.

We are not proposing to change our definition of the labor-related

share. However, we are proposing to rename our aggregate cost

categories from ``labor-intensive'' and ``non-labor-intensive''

services to ``labor-related'' and ``nonlabor-related'' services. As

discussed in more detail below and similar to the previous rebasing, we

classify a cost category as labor-related and include it in the labor-

related share if the cost category is defined as being labor-intensive

and its cost varies with the local labor market. In previous

regulations, we grouped cost categories that met both of these criteria

into labor-intensive services. We believe the proposed new labels more

accurately reflect the concepts that they are intended to convey. We

are not proposing to change to our definition of the labor-related

share because we continue to classify a cost category as labor-related

if the costs are labor-intensive and vary with the local labor market.

3. Selection of Price Proxies

After computing the FY 2006 cost weights for the proposed rebased

hospital market basket, it was necessary to select appropriate wage and

price proxies to reflect the rate of price change for each expenditure

category. With the exception of the proxy for professional liability,

all the proxies are based on Bureau of Labor Statistics (BLS) data and

are grouped into one of the following BLS categories:

Producer Price Indexes--Producer Price Indexes (PPIs)

measure price changes for goods sold in markets other than the retail

market. PPIs are preferable price proxies for goods and services that

hospitals purchase as inputs because these PPIs better reflect the

actual price changes faced by hospitals. For example, we use a special

PPI for prescription drugs, rather than the Consumer Price Index (CPI)

for prescription drugs, because hospitals generally purchase drugs

directly from a wholesaler. The PPIs that we use measure price changes

at the final stage of production.

Consumer Price Indexes--Consumer Price Indexes (CPIs)

measure change in the prices of final goods and services bought by the

typical consumer. Because they may not represent the price faced by a

producer, we used CPIs only if an appropriate PPI was not available, or

if the expenditures were more similar to those faced by retail

consumers in general rather than by purchasers of goods at the

wholesale level. For example, the CPI for food purchased away from home

is used as a proxy for contracted food services.

Employment Cost Indexes--Employment Cost Indexes (ECIs)

measure the rate of change in employee wage rates and employer costs

for employee benefits per hour worked. These indexes are fixed-weight

indexes and strictly measure the change in wage rates and employee

benefits per hour. Appropriately, they are not affected by shifts in

employment mix.

We evaluated the price proxies using the criteria of reliability,

timeliness, availability, and relevance. Reliability indicates that the

index is based on valid statistical methods and has low sampling

variability. Timeliness implies that the proxy is published regularly,

preferably at least once a quarter. Availability means that the proxy

is publicly available. Finally, relevance means that the proxy is

applicable and representative of the cost category weight to which it

is applied. The CPIs, PPIs, and ECIs selected meet these criteria.

Chart 2 sets forth the proposed FY 2006-based IPPS market basket

including cost categories, weights, and price proxies. For comparison

purposes, the corresponding FY 2002-based IPPS market basket is listed

as well. A summary outlining the choice of the various proxies follows

the chart.

[[Page 24156]]

Chart 2.--Proposed FY 2006-Based IPPS Hospital Market Basket Cost Categories, Weights, and Price Proxies with FY

2002-Based IPPS Market Basket Included for Comparison

----------------------------------------------------------------------------------------------------------------

Proposed

FY 2002-based rebased FY

hospital 2006-based Proposed rebased FY 2006-based

Cost categories market basket hospital hospital market basket price

cost weights market basket proxies

cost weights

----------------------------------------------------------------------------------------------------------------

1. Compensation............................ 59.993 59.627

A. Wages and Salaries (1).............. 48.171 47.213 ECI for Wages and Salaries,

Civilian Hospital Workers.

B. Employee Benefits (1)............... 11.822 12.414 ECI for Benefits, Civilian Hospital

Workers.

2. Utilities............................... 1.251 2.180

A. Fuel, Oil, and Gasoline............. 0.206 0.418 PPI for Petroleum Refineries.

B. Electricity......................... 0.669 1.645 PPI for Commercial Electric Power.

C. Water and Sewage.................... 0.376 0.117 CPI-U for Water & Sewerage

Maintenance.

3. Professional Liability Insurance........ 1.589 1.661 CMS Professional Liability

Insurance Premium Index.

4. All Other............................... 37.167 36.533

A. All Other Products.................. 20.336 19.473

(1) Pharmaceuticals.................... 5.855 5.380 PPI for Pharmaceutical Preparations

(Prescriptions).

(2) Food: Direct Purchases............. 1.664 3.982 PPI for Processed Foods & Feeds.

(3) Food: Contract Services............ 1.180 0.575 CPI-U for Food Away From Home.

(4) Chemicals (2)...................... 2.096 1.538 Blend of Chemical PPIs.

(5) Blood and Blood Products (3)....... .............. 1.078 PPI for Blood and Organ Banks.

(6) Medical Instruments................ 1.932 2.762 PPI for Medical, Surgical, and

Personal Aid Devices.

(7) Photographic Supplies.............. 0.183 ..............

(8) Rubber and Plastics................ 2.004 1.659 PPI for Rubber & Plastic Products.

(9) Paper and Printing Products........ 1.905 1.492 PPI for Converted Paper &

Paperboard Products.

(10) Apparel........................... 0.394 0.325 PPI for Apparel.

(11) Machinery and Equipment........... 0.565 0.163 PPI for Machinery & Equipment.

(12) Miscellaneous Products (3)........ 2.558 0.519 PPI for Finished Goods less Food

and Energy.

B. Labor-related Services.............. 9.738 7.435

(1) Professional Fees: Labor-related 5.510 3.616 ECI for Compensation for

(4). Professional and Related

Occupations.

(2) Administrative and Business Support n/a 0.626 ECI for Compensation for Office and

Services (5). Administrative Services.

(3) All Other: Labor-Related Services 4.228 3.193 ECI for Compensation for Private

(5). Service Occupations.

C. Nonlabor-Related Services........... 7.093 9.625

(1) Professional Fees: Nonlabor-Related n/a 5.814 ECI for Compensation for

(4). Professional and Related

Occupations.

(2) Financial Services (6)............. n/a 1.281 ECI for Compensation for Financial

Activities.

(3) Telephone Services................. 0.458 0.627 CPI-U for Telephone Services.

(4) Postage............................ 1.300 0.963 CPI-U for Postage.

(5) All Other: Nonlabor-Related 5.335 0.940 CPI-U for All Items less Food and

Services (6). Energy.

--------------------------------

Total.............................. 100.000 100.000

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Note: Detail may not add to total due to rounding.

(1) Contract labor is distributed to wages and salaries and employee benefits based on the share of total

compensation that each category represents.

(2) To proxy the ``chemicals'' cost category, we are proposing to use a blended PPI composed of the PPI for

industrial gases, the PPI for other basic inorganic chemical manufacturing, the PPI for other basic organic

chemical manufacturing, and the PPI for soap and cleaning compound manufacturing. For more detail about this

proxy, see section IV.B.3.j. of the preamble of this proposed rule.

(3) The ``blood and blood products'' cost category was contained within ``miscellaneous products'' cost category

in the FY 2002-based IPPS market basket.

(4) The ``professional fees: labor-related'' and ``professional fees: nonlabor-related'' cost categories were

included in one cost category called ``professional fees'' in the FY 2002-based IPPS market basket. For more

detail about how these new categories were derived, we refer readers to sections IV.B.3.s. and v. of the

preamble of this proposed rule, on the labor-related share.

(5) The ``administrative and business support services'' cost category was contained within ``all other: labor-

intensive services'' cost category in the FY 2002-based IPPS market basket. The ``all other: labor-intensive

services'' cost category is renamed the ``all other: labor-related services'' cost category for the proposed

FY 2006-based IPPS market basket.

(6) The ``financial services'' cost category was contained within the ``all other: non-labor intensive

services'' cost category in the FY 2002-based IPPS market basket. The ``all other: nonlabor intensive

services'' cost category is renamed the ``all other: nonlabor-related services'' cost category for the

proposed FY 2006-based IPPS market basket.

a. Wages and Salaries

We are proposing to use the ECI for wages and salaries for hospital

workers (all civilian) (series code CIU1026220000000I) to

measure the price growth of this cost category. This same proxy was

used in the FY 2002-based IPPS market basket.

b. Employee Benefits

We are proposing to use the ECI for employee benefits for hospital

workers (all civilian) to measure the price growth of this cost

category. This same proxy was used in the FY 2002-based IPPS market

basket.

c. Fuel, Oil, and Gasoline

For the FY 2002-based market basket, this category only included

expenses classified under North American Industry Classification System

(NAICS)

[[Page 24157]]

21 (Mining). We proxied this category using the PPI for commercial

natural gas (series code WPU0552). For the proposed FY 2006-

based market basket, we are proposing to add costs to this category

that had previously been grouped in other categories. The added costs

include petroleum-related expenses under NAICS 324110 (previously

captured in the miscellaneous category), as well as petrochemical

manufacturing classified under NAICS 325110 (previously captured in the

chemicals category). These added costs represent 80 percent of the

hospital industry's fuel, oil, and gasoline expenses (or 80 percent of

this category). Because the majority of the industry's fuel, oil, and

gasoline expenses originate from petroleum refineries (NAICS 324110),

we are proposing to use the PPI for petroleum refineries (series code

PCU324110) as the proxy for this cost category.

d. Electricity

We are proposing to use the PPI for commercial electric power

(series code WPU0542). This same proxy was used in the FY

2002-based IPPS market basket.

e. Water and Sewage

We are proposing to use the CPI for water and sewerage maintenance

(all urban consumers) (series code CUUR0000SEHG01) to measure

the price growth of this cost category. This same proxy was used in the

FY 2002-based IPPS market basket.

f. Professional Liability Insurance

We are proposing to proxy price changes in hospital professional

liability insurance premiums (PLI) using percentage changes as

estimated by the CMS Hospital Professional Liability Index. To generate

these estimates, we collect commercial insurance premiums for a fixed

level of coverage while holding nonprice factors constant (such as a

change in the level of coverage). This method is also used to proxy PLI

price changes in the Medicare Economic Index (68 FR 63244). This same

proxy was used in the FY 2002-based IPPS market basket.

g. Pharmaceuticals

We are proposing to use the PPI for pharmaceutical preparations

(prescription) (series code PCU32541DRX) to measure the price

growth of this cost category. This is a special index produced by BLS

and is the same proxy used in the FY 2002-based IPPS market basket.

h. Food: Direct Purchases

We are proposing to use the PPI for processed foods and feeds

(series code WPU02) to measure the price growth of this cost

category. This same proxy was used in the FY 2002-based IPPS market

basket.

i. Food: Contract Services

We are proposing to use the CPI for food away from home (all urban

consumers) (series code CUUR0000SEFV) to measure the price

growth of this cost category. This same proxy was used in the FY 2002-

based IPPS market basket.

j. Chemicals

We are proposing to use a blended PPI composed of the PPI for

industrial gases (NAICS 325120), the PPI for other basic inorganic

chemical manufacturing (NAICS 325180), the PPI for other basic organic

chemical manufacturing (NAICS 325190), and the PPI for soap and

cleaning compound manufacturing (NAICS 325610). Using the 2002

Benchmark I-O data, we found that these NAICS industries accounted for

approximately 90 percent of the hospital industry's chemical expenses.

Therefore, we are proposing to use this blended index because we

believe its composition better reflects the composition of the

purchasing patterns of hospitals than does the PPI for industrial

chemicals (series code WPU061), the proxy used in the FY 2002-

based IPPS market basket. Chart 3 below shows the weights for each of

the four PPIs used to create the blended PPI, which we determined using

the 2002 Benchmark I-O data.

Chart 3--Blended Chemical PPI Weights

------------------------------------------------------------------------

Weights

Name (in NAICS

percent)

------------------------------------------------------------------------

PPI for Industrial Gases...................... 35 325120

PPI for Other Basic Inorganic Chemical 25 325180

Manufacturing................................

PPI for Other Basic Organic Chemical 30 325190

Manufacturing................................

PPI for Soap and Cleaning Compound 10 325610

Manufacturing................................

------------------------------------------------------------------------

k. Blood and Blood Products

In the FY 2002-based IPPS market basket, we classified blood and

blood products into the miscellaneous products category and used the

PPI for finished goods less food and energy to proxy the price changes

associated with these expenses. At the time of the rebasing of the FY

2002-based IPPS market basket, we noticed an apparent divergence

between the PPI for blood and blood derivatives, the price proxy used

in the FY 1997-based IPPS market basket, and blood costs faced by

hospitals over the recent time period. A thorough discussion of this

analysis is found in the FY 2006 IPPS final rule (70 FR 47390).

Since the last rebasing of the market basket, BLS began collecting

data and publishing an industry PPI for blood and organ banks (NAICS

621991). For the proposed FY 2006-based IPPS market basket, we are

proposing to incorporate this series (series code PCU621991)

into the market basket and use it to proxy the blood and blood products

cost category.

l. Medical Instruments

We are proposing to use the PPI for medical, surgical, and personal

aid devices (series code WPU156) to measure the price growth

of this cost category. In the 1997 Benchmark I-O data, approximately

half of the expenses classified in this category were for surgical and

medical instruments. Thus, we used the PPI for surgical and medical

instruments and equipment (series code WPU1562) to proxy this

category in the FY 2002-based IPPS market basket. The 2002 Benchmark I-

O data show that this category now represents only 33 percent of these

expenses and the largest expense category is surgical appliance and

supplies manufacturing (corresponding to series code WPU1563).

Due to this reallocation of costs over time, we are proposing to change

the price proxy for this cost category to the more aggregated PPI for

medical, surgical, and personal aid devices.

m. Photographic Supplies

We are proposing to eliminate the cost category specific to

photographic supplies for the proposed FY 2006-based IPPS market

basket. These costs will now be included in the chemicals cost category

because the costs are presently reported as all other chemical

products. Notably, although we are eliminating the specific cost

category, these costs will still be accounted for within the IPPS

market basket.

n. Rubber and Plastics

We are proposing to use the PPI for rubber and plastic products

(series code WPU07) to measure price growth of this cost

category. This same proxy was

[[Page 24158]]

used in the FY 2002-based IPPS market basket.

o. Paper and Printing Products

We are proposing to use the PPI for converted paper and paperboard

products (series code WPU0915) to measure the price growth of

this cost category. This same proxy was used in the FY 2002-based IPPS

market basket.

p. Apparel

We are proposing to use the PPI for apparel (series code

WPU0381) to measure the price growth of this cost category.

This same proxy was used in the FY 2002-based IPPS market basket.

q. Machinery and Equipment

We are proposing to use the PPI for machinery and equipment (series

code WPU11) to measure the price growth of this cost category.

This same proxy was used in the FY 2002-based IPPS market basket.

r. Miscellaneous Products

We are proposing to use the PPI for finished goods less food and

energy (series code WPUSOP3500) to measure the price growth of

this cost category. Using this index removes the double-counting of

food and energy prices, which are already captured elsewhere in the

market basket. This same proxy was used in the FY 2002-based IPPS

market basket.

s. Professional Fees: Labor-Related

We are proposing to use the ECI for compensation for professional

and related occupations (private industry) (series code

CIS2020000120000I) to measure the price growth of this

category. It includes occupations such as legal, accounting, and

engineering services. This same proxy was used in the FY 2002-based

IPPS market basket.

t. Administrative and Business Support Services

We are proposing to use the ECI for compensation for office and

administrative support services (private industry) (series code

CIU2010000220000I) to measure the price growth of this

category. Previously these costs were included in the ``all other:

Labor-intensive cost'' category (now renamed the ``all other: Labor-

related cost'' category), and were proxied by the ECI for compensation

for service occupations. We believe that this compensation index better

reflects the changing price of labor associated with the provision of

administrative services and its incorporation represents a technical

improvement to the market basket.

u. All Other: Labor-Related Services

We are proposing to use the ECI for compensation for service

occupations (private industry) (series code CIU2010000300000I)

to measure the price growth of this cost category. This same proxy was

used in the FY 2002-based IPPS market basket.

v. Professional Fees: Nonlabor-Related

We are proposing to use the ECI for compensation for professional

and related occupations (private industry) (series code

CIS2020000120000I) to measure the price growth of this

category. This is the same price proxy that we are proposing to use for

the professional fees: Labor-related cost category.

w. Financial Services

We are proposing to use the ECI for compensation for financial

activities (private industry) (series code CIU201520A000000I)

to measure the price growth of this cost category. Previously these

costs were included in the ``all other: Nonlabor-intensive cost''

category (now renamed the ``all other: nonlabor-related cost''

category), and were proxied by the CPI for all items. We believe that

this compensation index better reflects the changing price of labor

associated with the provision of financial services and its

incorporation represents a technical improvement to the market basket.

x. Telephone Services

We are proposing to use the CPI for telephone services (series code

CUUR0000SEED) to measure the price growth of this cost

category. This same proxy was used in the FY 2002-based IPPS market

basket.

y. Postage

We are proposing to use the CPI for postage (series code

CUUR0000SEEC01) to measure the price growth of this cost

category. This same proxy was used in the FY 2002-based IPPS market

basket.

z. All Other: Nonlabor-Related Services

We are proposing to use the CPI for all items less food and energy

(series code CUUR0000SA0L1E) to measure the price growth of

this cost category. Previously these costs were proxied by the CPI for

all items in the FY 2002-based IPPS market basket. We believe that

using the CPI for all items less food and energy will remove any

double-counting of food and energy prices, which are already captured

elsewhere in the market basket. Consequently, we believe that the

incorporation of this proxy represents a technical improvement to the

market basket.

Chart 4 compares both the historical and forecasted percent changes

in the FY 2002-based IPPS market basket and the proposed FY 2006-based

IPPS market basket.

Chart 4--FY 2002-Based and Proposed FY 2006-Based Prospective Payment Hospital Operating Index Percent Change,

FY 2004 Through FY 2012

----------------------------------------------------------------------------------------------------------------

Proposed FY 2006-based

FY 2002-based IPPS IPPS market basket

Fiscal year (FY) market basket operating operating index

index percent change percent change

----------------------------------------------------------------------------------------------------------------

Historical data:

FY 2004..................................................... 4.0 4.0

FY 2005..................................................... 4.3 3.9

FY 2006..................................................... 4.3 4.0

FY 2007..................................................... 3.4 3.6

FY 2008..................................................... 4.3 4.0

Average FYs 2004-2008....................................... 4.1 3.9

Forecast:

FY 2009..................................................... 2.0 2.5

FY 2010..................................................... 2.3 2.1

FY 2011..................................................... 2.9 2.8

FY 2012..................................................... 3.1 3.0

[[Page 24159]]

Average FYs 2009-2012....................................... 2.6 2.6

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Source: IHS Global Insight, Inc.1st Quarter 2009, USMACRO/CONTROL0209@CISSIM/TL0505.SIM.

The differences between the FY 2002-based and the proposed FY 2006-

based IPPS market basket increases are mostly stemming from the

proposal to revise the proxy used for the chemicals cost category. As

stated earlier, we are proposing to adopt a blended chemical index that

is comprised of four industry-based chemical price proxies that

represent approximately 90 percent of the hospital's industry chemical

expenses. The FY 2002-based IPPS market basket used the PPI for

industrial chemicals. The PPI for industrial chemicals attributes more

weight to direct petroleum expenses, which is not consistent with a

hospital's most recent purchasing pattern according to the 2002

Benchmark I-O data. The lower weight for direct petroleum expenses in

the blended chemical index results in less volatile price movements. We

believe the proposed blended index represents a technical improvement

because it better reflects the purchasing patterns of hospitals.

Also contributing to the differences between the FY 2002-based and

the proposed FY 2006-based IPPS market basket increases is the larger

weight associated with the professional fees category. In both market

baskets, these expenditures are proxied by the ECI for compensation for

professional and related services. The weight for professional fees in

the FY 2002-based IPPS market basket is 5.5 percent compared to 9.4

percent in the proposed FY 2006-based IPPS market basket.

4. Labor-Related Share

Under section 1886(d)(3)(E) of the Act, the Secretary estimates

from time to time the proportion of payments that are labor-related.

``The Secretary shall adjust the proportion (as estimated by the

Secretary from time to time) of hospitals' costs which are attributable

to wages and wage-related costs of the DRG prospective payment rates \*

\* \* .'' We refer to the proportion of hospitals' costs that are

attributable to wages and wage-related costs as the ``labor-related

share.''

The labor-related share is used to determine the proportion of the

national PPS base payment rate to which the area wage index is applied.

We continue to classify a cost category as labor-related if the costs

are labor-intensive and vary with the local labor market. Given this,

based on our definition of the labor-related share, we are proposing to

include in the labor-related share the national average proportion of

operating costs that are attributable to wages and salaries, employee

benefits, contract labor, the labor-related portion of professional

fees, administrative and business support services, and all other:

Labor-related services (previously referred to in the FY 2002-based

IPPS market basket as labor-intensive). Consistent with previous

rebasings, the ``all other: Labor-related services'' cost category is

mostly comprised of building maintenance and security services

(including, but not limited to, commercial and industrial machinery and

equipment repair, nonresidential maintenance and repair, and

investigation and security services). Because these services tend to be

labor-intensive and are mostly performed at the hospital facility (and,

therefore, unlikely to be purchased in the national market), we believe

that they meet our definition of labor-related services.

For the rebasing of the FY 2002-based IPPS market basket in the FY

2006 IPPS final rule, we included in the labor-related share the

national average proportion of operating costs that are attributable to

wages and salaries, employee benefits, contract labor, professional

fees, and labor-intensive services (70 FR 47393). For the proposed FY

2006-based IPPS market basket rebasing, the proposed inclusion of the

administrative and business support services cost category into the

labor-related share remains consistent with the current labor-related

share because this cost category was previously included in the labor-

intensive cost category. As previously stated, we are proposing to

establish a separate administrative and business support service cost

category so that we can use the ECI for compensation for office and

administrative support services to more precisely proxy these specific

expenses.

For the FY 2002-based IPPS market basket, we assumed that all

nonmedical professional services (including accounting and auditing

services, engineering services, legal services, and management and

consulting services) were purchased in the local labor market and,

therefore, all of their associated fees varied with the local labor

market. As a result, we previously included 100 percent of these costs

in the labor-related share. In an effort to more accurately determine

the share of professional fees that should be included in the labor-

related share, we surveyed hospitals regarding the proportion of those

fees that go to companies that are located beyond their own local labor

market (the results are discussed below).

We continue to look for ways to refine our market basket approach

to more accurately account for the proportion of costs influenced by

the local labor market. To that end, we conducted a survey of hospitals

to empirically determine the proportion of contracted professional

services purchased by the industry that are attributable to local firms

and the proportion that are purchased from national firms. We notified

the public of our intent to conduct this survey on December 9, 2005 (70

FR 73250) and received no comments (71 FR 8588).

With approval from the OMB, we contacted the industry and received

responses to our survey from 108 hospitals. Using data on FTEs to

allocate responding hospitals across strata (region of the country and

urban/rural status), we calculated poststratification weights. Based on

these weighted results, we determined that hospitals purchase, on

average, the following portions of contracted professional services

outside of their local labor market:

34 percent of accounting and auditing services;

30 percent of engineering services;

33 percent of legal services; and

42 percent of management consulting services.

We applied each of these percentages to its respective Benchmark I-

O cost category underlying the professional

[[Page 24160]]

fees cost category. This is the methodology that we used to separate

the FY 2006-based IPPS market basket professional fees category into

professional fees: Labor-related and professional fees: Nonlabor-

related cost categories. In addition to the professional services

listed above, we also classified expenses under NAICS 55, Management of

Companies and Enterprises, into the professional fees cost category as

was done in previous rebasings. The NAICS 55 data are mostly comprised

of corporate, subsidiary, and regional managing offices, or otherwise

referred to as home offices. Formerly, all of the expenses within this

category were considered to vary with, or be influenced by, the local

labor market and were thus included in the labor-related share. Because

many hospitals are not located in the same geographic area as their

home office, we analyzed data from a variety of sources in order to

determine what proportion of these costs should be appropriately

included in the labor-related share.

Using data primarily from the Medicare cost reports and a CMS

database of Home Office Medicare Records (HOMER) (a database that

provides city and state information (addresses) for home offices), we

were able to determine that 27 percent of hospitals that had home

offices had those home offices located in their respective local labor

markets--defined as being in the same MSA.

The Medicare cost report requires hospitals to report their home

office provider numbers. Using the HOMER database to determine the home

office location for each home office provider number, we compared the

location of the hospital with the location of the hospital's home

office. We then placed hospitals into one of the following three

groups:

Group 1--Hospital and home office are located in different

States;

Group 2--Hospital and home office are located in the same

State and same city; and

Group 3--Hospital and home office are located in the same

State and different city.

We found that 54 percent of the hospitals with home offices were

classified into Group 1 (that is, different State) and, thus, these

hospitals were determined to not be located in the same local labor

market as their home office. Although there were a very limited number

of exceptions (that is, hospitals located in different States but the

same MSA as their home office), the 54 percent estimate was unchanged.

We found that 13 percent of all hospitals with home offices were

classified into Group 2 (that is, same State and same city and,

therefore, the same MSA). Consequently, these hospitals were determined

to be located in the same local labor market as their home offices.

We found that 33 percent of all hospitals with home offices were

classified into Group 3 (that is, same State and different city). Using

data from the Census Bureau to determine the specific MSA for both the

hospital and its home office, we found that 14 percent of all hospitals

with home offices were identified as being in the same State, a

different city, but the same MSA.

Pooling these results, we were able to determine that approximately

27 percent of hospitals with home offices had home offices located

within their local labor market (that is, 13 percent of hospitals with

home offices had their home offices in the same State and city (and,

thus, the same MSA), and 14 percent of hospitals with home offices had

their home offices in the same State, a different city, but the same

MSA). We are proposing to apportion the NAICS 55 expense data by this

percentage. Thus, we are proposing to classify 27 percent of these

costs into the professional fees: labor-related cost category and the

remaining 73 percent into the professional fees: nonlabor-related cost

category.

Below is a chart comparing the proposed FY 2006-based and the FY

2002-based labor-related share.

Chart 5--Comparison of the Proposed FY 2006-Based Labor-Related Share and the FY 2002-Based Labor-Related Shares

----------------------------------------------------------------------------------------------------------------

Proposed FY 2006-based

FY 2002-based market market basket cost

basket cost weights weights

----------------------------------------------------------------------------------------------------------------

Wages and Salaries............................................ 48.171 47.213

Employee Benefits............................................. 11.822 12.414

Professional Fees: Labor-Related.............................. 5.510 3.616

Administrative and Business Support Services.................. ....................... 0.626

All Other: Labor-Related Services............................. 4.228 3.193

-------------------------------------------------

Total Labor-Related Share................................. 69.731 67.062

----------------------------------------------------------------------------------------------------------------

Using the proposed cost category weights from the proposed FY 2006-

based IPPS market basket, we calculated a labor-related share of 67.062

percent, approximately 3 percentage points lower than the current

labor-related share of 69.731.

We continue to believe, as we have stated in the past, that these

operating cost categories are related to, influenced by, or vary with

the local markets. Therefore, our definition of the labor-related share

continues to be consistent with section 1886(d)(3) of the Act.

Using the cost category weights that we determined in section

IV.B.1. of this preamble, we calculated a labor-related share of 67.062

percent, using the proposed FY 2006-based IPPS market basket.

Accordingly, we are proposing to implement a labor-related share of

67.1 percent for discharges occurring on or after October 1, 2009. We

note that section 403 of Public Law 108-173 amended sections

1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the

Secretary must employ 62 percent as the labor-related share unless this

employment ``would result in lower payments than would otherwise be

made.''

We also are proposing to update the labor-related share for Puerto

Rico. Consistent with our methodology for determining the national

labor-related share, we add the Puerto Rico-specific relative weights

for wages and salaries, employee benefits, and contract labor. Because

there are no Puerto Rico-specific relative weights for professional

fees and labor intensive services, we use the national weights. Below

is a chart comparing the proposed FY 2006-based Puerto Rico-specific

labor-related share and the FY 2002-based Puerto Rico-specific labor-

related share.

[[Page 24161]]

Chart 6--Comparison of the Proposed FY 2006-Based Puerto Rico-Specific Labor-Related Share and FY 2002-Based

Puerto Rico-Specific Labor-Related Share

----------------------------------------------------------------------------------------------------------------

Proposed FY 2006-based

FY 2002-based market market basket cost

basket cost weights weights

----------------------------------------------------------------------------------------------------------------

Wages and Salaries............................................ 40.201 44.221

Benefits...................................................... 8.782 8.691

Professional Fees: Labor-Related.............................. 5.510 3.616

Administrative and Business Support Services.................. ....................... 0.626

All Other: Labor-Related Services............................. 4.228 3.193

-------------------------------------------------

Total Labor-Related Share................................. 58.721 60.347

----------------------------------------------------------------------------------------------------------------

Using the proposed FY 2006-based Puerto Rico cost category weights,

we calculated a labor-related share of 60.347 percent, approximately 2

percentage points higher than the current Puerto-Rico specific labor-

related share of 58.721. Accordingly, we are proposing to adopt an

updated Puerto Rico labor-related share of 60.3 percent.

C. Separate Market Basket for Certain Hospitals Presently Excluded from

the IPPS

In the FY 2006 IPPS final rule (70 FR 47396), we adopted the use of

the FY 2002-based IPPS operating market basket to update the target

amounts for children's and cancer hospitals and religious nonmedical

health care institutions (RNHCIs). Children's and cancer hospitals and

RNHCIs are still reimbursed solely under the reasonable cost-based

system, subject to the rate-of-increase limits. Under these limits, an

annual target amount (expressed in terms of the inpatient operating

cost per discharge) is set for each hospital based on the hospital's

own historical cost experience trended forward by the applicable rate-

of-increase percentages.

Under the broad authority in sections 1886(b)(3)(A) and (B),

1886(b)(3)(E), and 1871 of the Act and section 4454 of the BBA,

consistent with our use of the IPPS operating market basket percentage

increase to update target amounts, we are proposing to use the proposed

FY 2006-based IPPS operating market basket percentage increase to

update the target amounts for children's and cancer hospitals and

RNHCIs.

Due to the small number of children's and cancer hospitals and

RNHCIs that receive, in total, less than 1 percent of all Medicare

payments to hospitals and because these hospitals provide limited

Medicare cost report data, we are unable to create a separate market

basket specifically for these hospitals. Based on the limited data

available, we believe that the proposed FY 2006-based IPPS operating

market basket most closely represents the cost structure of children's

and cancer hospitals and RNHCIs. Therefore, we believe that the

percentage change in the FY 2006-based IPPS operating market basket is

the best available measure of the average increase in the prices of the

goods and services purchased by cancer and children's hospitals and

RNHCIs in order to provide care.

D. Rebasing and Revising the Capital Input Price Index (CIPI)

The CIPI was originally described in the FY 1993 IPPS final rule

(57 FR 40016). There have been subsequent discussions of the CIPI

presented in the IPPS proposed and final payment rules. The FY 2006

IPPS final rule (70 FR 47387) discussed the most recent rebasing and

revision of the CIPI to a FY 2002 base year, which reflected the

capital cost structure of the hospital industry in that year.

We are proposing to rebase and revise the CIPI to a FY 2006 base

year to reflect the more current structure of capital costs in

hospitals. As with the FY 2002-based index, we have developed two sets

of weights in order to calculate the proposed FY 2006-based CIPI. The

first set of weights identifies the proportion of hospital capital

expenditures attributable to each expenditure category, while the

second set of weights is a set of relative vintage weights for

depreciation and interest. The set of vintage weights is used to

identify the proportion of capital expenditures within a cost category

that is attributable to each year over the useful life of the capital

assets in that category. A more thorough discussion of vintage weights

is provided later in this section.

Both sets of weights are developed using the best data sources

available. In reviewing source data, we determined that the Medicare

cost reports provided accurate data for all capital expenditure cost

categories. We used the FY 2006 Medicare cost reports for IPPS

hospitals to determine weights for all three cost categories:

depreciation, interest, and other capital expenses.

Lease expenses are unique in that they are not broken out as a

separate cost category in the CIPI, but rather are proportionally

distributed among the cost categories of depreciation, interest, and

other, reflecting the assumption that the underlying cost structure of

leases is similar to that of capital costs in general. As was done in

previous rebasings of the CIPI, we first assumed 10 percent of lease

expenses represents overhead and assigned them to the other capital

expenses cost category accordingly. The remaining lease expenses were

distributed across the three cost categories based on the respective

weights of depreciation, interest, and other capital not including

lease expenses.

Depreciation contains two subcategories: (1) Building and fixed

equipment; and (2) movable equipment. The apportionment between

building and fixed equipment and movable equipment was determined using

the Medicare cost reports. This methodology was also used to compute

the apportionment used in the FY 2002-based index.

The total interest expense cost category is split between

government/nonprofit interest and for-profit interest. The FY 2002-

based CIPI allocated 75 percent of the total interest cost weight to

government/nonprofit interest and proxied that category by the average

yield on domestic municipal bonds. The remaining 25 percent of the

interest cost weight was allocated to for-profit interest and was

proxied by the average yield on Moody's Aaa bonds (70 FR 47387).

For this rebasing, we derived the split using the relative FY 2006

Medicare cost report data on interest expenses for government/nonprofit

and for-profit hospitals. Based on these data, we calculated an 85/15

split between government/nonprofit and for-profit interest. We believe

it is important that

[[Page 24162]]

this split reflects the latest relative cost structure of interest

expenses.

Chart 7 presents a comparison of the proposed FY 2006-based CIPI

cost weights and the FY 2002-based CIPI cost weights.

Chart 7--Proposed FY 2006-Based CIPI Cost Categories, Weights, and Price

Proxies With FY 2002-Based CIPI Included for Comparison

------------------------------------------------------------------------

Proposed FY

Cost categories FY 2002 2006 Price proxy

weights weights

------------------------------------------------------------------------

Total........................ 100.00 100.00

Total depreciation........... 74.583 75.154

Building and fixed equipment 36.234 35.789 BEA chained

depreciation. price index

for

nonresidential

construction

for hospitals

and special

care

facilities--vi

ntage weighted

(25 years).

Movable equipment 38.349 39.365 PPI for

depreciation. machinery and

equipment--vin

tage weighted

(12 years).

Total interest............... 19.863 17.651

Government/nonprofit interest 14.896 15.076 Average yield

on domestic

municipal

bonds (Bond

Buyer 20

bonds)--vintag

e-weighted (25

years).

For-profit interest.......... 4.967 2.575 Average yield

on Moody's Aaa

bonds--vintage-

weighted (12

years).

Other........................ 5.554 7.195 CPI-U for

residential

rent.

------------------------------------------------------------------------

Because capital is acquired and paid for over time, capital

expenses in any given year are determined by both past and present

purchases of physical and financial capital. The vintage-weighted CIPI

is intended to capture the long-term consumption of capital, using

vintage weights for depreciation (physical capital) and interest

(financial capital). These vintage weights reflect the proportion of

capital purchases attributable to each year of the expected life of

building and fixed equipment, movable equipment, and interest. We used

the vintage weights to compute vintage-weighted price changes

associated with depreciation and interest expense. Following

publication of this FY 2010 IPPS proposed rule, and in order to provide

greater transparency, we will be posting on the CMS market basket Web

page at http://www.cms.hhs.gov/MedicareProgramRatesStats/05\_

MarketBasketResearch.asp#TopOfPage an illustrative spreadsheet that

contains an example of how the vintage-weighted price indexes are

calculated.

Vintage weights are an integral part of the CIPI. Capital costs are

inherently complicated and are determined by complex capital purchasing

decisions, over time, based on such factors as interest rates and debt

financing. In addition, capital is depreciated over time instead of

being consumed in the same period it is purchased. The CIPI accurately

reflects the annual price changes associated with capital costs, and is

a useful simplification of the actual capital investment process. By

accounting for the vintage nature of capital, we are able to provide an

accurate, stable annual measure of price changes. Annual nonvintage

price changes for capital are unstable due to the volatility of

interest rate changes and, therefore, do not reflect the actual annual

price changes for Medicare capital-related costs. The CIPI reflects the

underlying stability of the capital acquisition process and provides

hospitals with the ability to plan for changes in capital payments.

To calculate the vintage weights for depreciation and interest

expenses, we needed a time series of capital purchases for building and

fixed equipment and movable equipment. We found no single source that

provides a uniquely best time series of capital purchases by hospitals

for all of the above components of capital purchases. The early

Medicare cost reports did not have sufficient capital data to meet this

need. Data we obtained from the American Hospital Association (AHA) do

not include annual capital purchases. However, AHA does provide a

consistent database back to 1963. We used data from the AHA Panel

Survey and the AHA Annual Survey to obtain a time series of total

expenses for hospitals. We then used data from the AHA Panel Survey

supplemented with the ratio of depreciation to total hospital expenses

obtained from the Medicare cost reports to derive a trend of annual

depreciation expenses for 1963 through 2006.

In order to estimate capital purchases using data on depreciation

expenses, the expected life for each cost category (building and fixed

equipment, movable equipment, and interest) is needed to calculate

vintage weights. We used FY 2006 Medicare cost reports to determine the

expected life of building and fixed equipment and of movable equipment.

The expected life of any piece of equipment can be determined by

dividing the value of the asset (excluding fully depreciated assets) by

its current year depreciation amount. This calculation yields the

estimated useful life of an asset if depreciation were to continue at

current year levels, assuming straight-line depreciation. From the FY

2006 Medicare cost reports, the expected life of building and fixed

equipment was determined to be 25 years, and the expected life of

movable equipment was determined to be 12 years. The FY 2002-based CIPI

was based on an expected life of building and fixed equipment of 23

years. It used 11 years as the expected life for movable equipment.

We are proposing to use the building and fixed equipment and

movable equipment weights derived from FY 2006 Medicare cost reports to

separate the depreciation expenses into annual amounts of building and

fixed equipment depreciation and movable equipment depreciation. Year-

end asset costs for building and fixed equipment and movable equipment

were determined by multiplying the annual depreciation amounts by the

expected life calculations from the FY 2006 Medicare cost reports. We

then calculated a time series back to 1963 of annual capital purchases

by subtracting the previous year asset costs from the current year

asset costs. From this capital purchase time series, we were able to

calculate the vintage weights for building and fixed equipment and for

movable equipment. Each of these sets of vintage weights is explained

in more detail below.

For building and fixed equipment vintage weights, we used the real

annual capital purchase amounts for building and fixed equipment to

capture the

[[Page 24163]]

actual amount of the physical acquisition, net of the effect of price

inflation. This real annual purchase amount for building and fixed

equipment was produced by deflating the nominal annual purchase amount

by the building and fixed equipment price proxy, BEA's chained price

index for nonresidential construction for hospitals and special care

facilities. Because building and fixed equipment have an expected life

of 25 years, the vintage weights for building and fixed equipment are

deemed to represent the average purchase pattern of building and fixed

equipment over 25-year periods. With real building and fixed equipment

purchase estimates available back to 1963, we averaged nineteen 25-year

periods to determine the average vintage weights for building and fixed

equipment that are representative of average building and fixed

equipment purchase patterns over time. Vintage weights for each 25-year

period are calculated by dividing the real building and fixed capital

purchase amount in any given year by the total amount of purchases in

the 25-year period. This calculation is done for each year in the 25-

year period, and for each of the nineteen 25-year periods. We used the

average of each year across the nineteen 25-year periods to determine

the average building and fixed equipment vintage weights for the

proposed FY 2006-based CIPI.

For movable equipment vintage weights, the real annual capital

purchase amounts for movable equipment were used to capture the actual

amount of the physical acquisition, net of price inflation. This real

annual purchase amount for movable equipment was calculated by

deflating the nominal annual purchase amounts by the movable equipment

price proxy, the PPI for machinery and equipment. Based on our

determination that movable equipment has an expected life of 12 years,

the vintage weights for movable equipment represent the average

expenditure for movable equipment over a 12-year period. With real

movable equipment purchase estimates available back to 1963, thirty-two

12-year periods were averaged to determine the average vintage weights

for movable equipment that are representative of average movable

equipment purchase patterns over time. Vintage weights for each 12-year

period are calculated by dividing the real movable capital purchase

amount for any given year by the total amount of purchases in the 12-

year period. This calculation was done for each year in the 12-year

period and for each of the thirty-two 12-year periods. We used the

average of each year across the thirty-two 12-year periods to determine

the average movable equipment vintage weights for the proposed FY 2006-

based CIPI.

For interest vintage weights, the nominal annual capital purchase

amounts for total equipment (building and fixed, and movable) were used

to capture the value of the debt instrument. Because we have determined

that hospital debt instruments have an expected life of 25 years, the

vintage weights for interest are deemed to represent the average

purchase pattern of total equipment over 25-year periods. With nominal

total equipment purchase estimates available back to 1963, nineteen 25-

year periods were averaged to determine the average vintage weights for

interest that are representative of average capital purchase patterns

over time. Vintage weights for each 25-year period are calculated by

dividing the nominal total capital purchase amount for any given year

by the total amount of purchases in the 25-year period. This

calculation is done for each year in the 25-year period and for each of

the nineteen 25-year periods. We used the average of each year across

the nineteen 25-year periods to determine the average interest vintage

weights for the proposed FY 2006-based CIPI. The vintage weights for

the FY 2002-based CIPI and the proposed FY 2006-based CIPI are

presented in Chart 8.

Chart 8--FY 2002 Vintage Weights and Proposed FY 2006 Vintage Weights for Capital-Related Price Proxies

--------------------------------------------------------------------------------------------------------------------------------------------------------

Building and fixed equipment Movable equipment Interest

-----------------------------------------------------------------------------------------------

Year FY 2002 23 Proposed FY FY 2002 11 Proposed FY FY 2002 23 Proposed FY

years 2006 25 years years 2006 12 years years 2006 25 years

--------------------------------------------------------------------------------------------------------------------------------------------------------

1....................................................... 0.021 0.021 0.065 0.063 0.010 0.010

2....................................................... 0.022 0.023 0.071 0.067 0.012 0.012

3....................................................... 0.025 0.025 0.077 0.071 0.014 0.014

4....................................................... 0.027 0.027 0.082 0.075 0.016 0.016

5....................................................... 0.029 0.029 0.086 0.079 0.019 0.018

6....................................................... 0.031 0.031 0.091 0.082 0.023 0.020

7....................................................... 0.033 0.032 0.095 0.085 0.026 0.023

8....................................................... 0.035 0.033 0.100 0.086 0.029 0.025

9....................................................... 0.038 0.036 0.106 0.090 0.033 0.028

10...................................................... 0.040 0.038 0.112 0.093 0.036 0.031

11...................................................... 0.042 0.040 0.117 0.102 0.039 0.034

12...................................................... 0.045 0.042 .............. 0.106 0.043 0.038

13...................................................... 0.047 0.044 .............. .............. 0.048 0.041

14...................................................... 0.049 0.045 .............. .............. 0.053 0.044

15...................................................... 0.051 0.046 .............. .............. 0.056 0.047

16...................................................... 0.053 0.047 .............. .............. 0.059 0.050

17...................................................... 0.056 0.048 .............. .............. 0.062 0.053

18...................................................... 0.057 0.050 .............. .............. 0.064 0.057

19...................................................... 0.058 0.050 .............. .............. 0.066 0.059

20...................................................... 0.060 0.050 .............. .............. 0.070 0.060

21...................................................... 0.060 0.048 .............. .............. 0.071 0.060

22...................................................... 0.061 0.048 .............. .............. 0.074 0.062

23...................................................... 0.061 0.047 .............. .............. 0.076 0.063

24...................................................... .............. 0.049 .............. .............. .............. 0.068

25...................................................... .............. 0.048 .............. .............. .............. 0.069

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[[Page 24164]]

Total............................................... 1.000 1.000 1.000 1.000 1.000 1.000

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Note: Detail may not add to total due to rounding.

After the capital cost category weights were computed, it was

necessary to select appropriate price proxies to reflect the rate-of-

increase for each expenditure category. We are proposing to use the

same price proxies for the proposed FY 2006-based CIPI that were used

in the FY 2002-based CIPI with the exception of the Boeckh Construction

Index. We are proposing to replace the Boeckh Construction Index with

BEA's chained price index for nonresidential construction for hospitals

and special care facilities. The BEA index represents construction of

facilities such as hospitals, nursing homes, hospices, and

rehabilitation centers. Although these price indices move similarly

over time, we believe that it is more technically appropriate to use an

index that is more specific to the hospital industry. We believe these

are the most appropriate proxies for hospital capital costs that meet

our selection criteria of relevance, timeliness, availability, and

reliability. The rationale for selecting the price proxies, excluding

the building and fixed equipment price proxy, was explained more fully

in the FY 1997 IPPS final rule (61 FR 46196). The price proxies are

presented in Chart 7.

Chart 9 below compares both the historical and forecasted percent

changes in the FY 2002-based CIPI and the proposed FY 2006-based CIPI.

Chart 9--Comparison of FY 2002-Based and Proposed FY 2006-Based Capital

Input Price Index, Percent Change, FY 2004 Through FY 2012

------------------------------------------------------------------------

CIPI,

Fiscal year CIPI, FY proposed FY

2002-based 2006-based

------------------------------------------------------------------------

FY 2004..................................... 0.5 0.8

FY 2005..................................... 0.6 0.9

FY 2006..................................... 0.9 1.1

FY 2007..................................... 1.2 1.3

FY 2008..................................... 1.4 1.4

Forecast:

FY 2009..................................... 1.6 1.5

FY 2010..................................... 1.5 1.2

FY 2011..................................... 1.6 1.5

FY 2012..................................... 1.6 1.5

Average:

FYs 2004-2009............................... 0.9 1.1

FYs 2010-2012............................... 1.6 1.4

------------------------------------------------------------------------

Source: IHS Global Insight, Inc, 1st Quarter 2009; USMACRO/

CONTROL0209@CISSIM/TL0209.SIM.

IHS Global Insight, Inc. forecasts a 1.2 percent increase in the

proposed FY 2006-based CIPI for FY 2010, as shown in Chart 9. The

underlying vintage-weighted price increases for depreciation (including

building and fixed equipment and movable equipment) and interest

(including government/nonprofit and for-profit) are included in Chart

10.

Chart 10--CMS Capital Input Price Index Percent Changes, Total and Depreciation and Interest Components, FYs

2004 Through 2012

----------------------------------------------------------------------------------------------------------------

Fiscal year Total Depreciation Interest

----------------------------------------------------------------------------------------------------------------

FY 2004....................................................... 0.8 1.5 -2.6

FY 2005....................................................... 0.9 1.7 -3.1

FY 2006....................................................... 1.1 2.0 -3.2

FY 2007....................................................... 1.3 2.1 -3.4

FY 2008....................................................... 1.4 2.1 -2.6

Forecast:

FY 2009....................................................... 1.5 2.0 -1.8

FY 2010....................................................... 1.2 1.7 -1.7

FY 2011....................................................... 1.5 1.8 -0.3

FY 2012....................................................... 1.5 1.7 -0.2

----------------------------------------------------------------------------------------------------------------

Rebasing the CIPI from FY 2002 to FY 2006 decreased the percent

change in the FY 2010 forecast by 0.3 percentage point, from 1.5 to

1.2, as shown in Chart 9. The difference in the forecast of the

proposed FY 2010 market basket increase is primarily due to the

proposed change in the price proxy for building and fixed equipment as

well as the proposed change in the vintage weights applied to the price

proxy for interest. As mentioned above, we are proposing to change the

price proxy used for building and fixed equipment to BEA's chained

price index for nonresidential construction for hospitals and special

care facilities. We believe this proposed change represents a technical

improvement as the BEA price index is an index that is more

representative of the hospital industry. For the proposed FY 2010

update, the result of this proposed change is a forecasted price change

in total depreciation of 1.7 percent in the proposed FY 2006-based CIPI

compared to 1.9 percent in the FY 2002-based CIPI. The other primary

factor contributing to the difference is the proposed change in the

vintage weights used to calculate the vintage-weighted price proxy for

interest. The forecasted price change in total interest is -1.7

[[Page 24165]]

percent in the proposed FY 2006-based CIPI compared to -1.2 percent in

the FY 2002-based CIPI. This is a result of changing the expected life

of hospital debt instruments from 23 years to 25 years.

V. Other Decisions and Proposed Changes to the IPPS for Operating Costs

and GME Costs

A. Reporting of Hospital Quality Data for Annual Hospital Payment

Update

1. Background

a. Overview

CMS is seeking to promote higher quality and more efficient health

care for Medicare beneficiaries. This effort is supported by the

adoption of an increasing number of widely-agreed upon quality

measures. CMS has worked with relevant stakeholders to define measures

of quality in almost every setting and currently measures some aspect

of care for almost all Medicare beneficiaries. These measures assess

structural aspects of care, clinical processes, patient experiences

with care, and, increasingly, outcomes.

CMS has implemented quality measure reporting programs for multiple

settings of care. The Reporting Hospital Quality Data for Annual

Payment Update (RHQDAPU) program implements a quality reporting program

for hospital inpatient services. In addition, CMS has implemented

quality reporting programs for hospital outpatient services, the

Hospital Outpatient Quality Data Reporting Program (HOP QDRP), and for

physicians and other eligible professionals, the Physician Quality

Reporting Initiative (PQRI). CMS has also implemented quality reporting

programs for home health agencies and skilled nursing facilities that

are based on conditions of participation, and an end-stage renal

disease quality reporting program that is based on conditions for

coverage.

b. Hospital Quality Data Reporting Under Section 501(b) of Public Law

108-173

Section 501(b) of the Medicare Prescription Drug, Improvement, and

Modernization Act of 2003 (MMA), Public Law 108-173, added section

1886(b)(3)(B)(vii) of the Act. This section established the authority

for the RHQDAPU program and revised the mechanism used to update the

standardized payment amount for inpatient hospital operating costs.

Specifically, section 1886(b)(3)(B)(vii)(I) of the Act, before it was

amended by section 5001(a) of Public Law 109-171, provided for a

reduction of 0.4 percentage points to the update percentage increase

(also known as the market basket update) for FY 2005 through FY 2007

for any subsection (d) hospital that did not submit data on a set of 10

quality indicators established by the Secretary as of November 1, 2003.

It also provides that any reduction would apply only to the fiscal year

involved, and would not be taken into account in computing the

applicable percentage increase for a subsequent fiscal year. The

statute thereby established an incentive for IPPS hospitals to submit

data on the quality measures established by the Secretary, and also

built upon the previously established Voluntary Hospital Quality Data

Reporting Program that we described in the FY 2009 IPPS final rule (73

FR 48598).

We implemented section 1886(b)(3)(B)(vii) of the Act in the FY 2005

IPPS final rule (69 FR 49078) and codified the applicable percentage

change in Sec. 412.64(d) of our regulations. We adopted additional

requirements under the RHQDAPU program in the FY 2006 IPPS final rule

(70 FR 47420).

c. Hospital Quality Data Reporting under Section 5001(a) of Public Law

109-171

Section 5001(a) of the Deficit Reduction Act of 2005 (DRA), Public

Law 109-171, further amended section 1886(b)(3)(B) of the Act to revise

the mechanism used to update the standardized payment amount for

hospital inpatient operating costs, in particular, by adding new

section 1886(b)(3)(B)(viii) to the Act. Specifically, sections

1886(b)(3)(B)(viii)(I) and (II) of the Act provide that the payment

update for FY 2007 and each subsequent fiscal year be reduced by 2.0

percentage points for any subsection (d) hospital that does not submit

quality data in a form and manner, and at a time, specified by the

Secretary. Section 1886(b)(3)(B)(viii)(I) of the Act also provides that

any reduction in a hospital's payment update will apply only with

respect to the fiscal year involved, and will not be taken into account

for computing the applicable percentage increase for a subsequent

fiscal year. In the FY 2007 IPPS final rule (71 FR 48045), we amended

our regulations at Sec. 412.64(d)(2) to reflect the 2.0 percentage

point reduction in the payment update for FY 2007 and subsequent fiscal

years for subsection (d) hospitals that do not comply with requirements

for reporting quality data, as provided for under section

1886(b)(3)(B)(viii) of the Act.

(1) Quality Measures

Section 1886(b)(3)(B)(viii)(III) of the Act requires that the

Secretary expand the ``starter set'' of 10 quality measures that was

established by the Secretary as of November 1, 2003, as the Secretary

determines to be appropriate for the measurement of the quality of care

furnished by a hospital in inpatient settings. In expanding this set of

measures, section 1886(b)(3)(B)(viii)(IV) of the Act requires that,

effective for payments beginning with FY 2007, the Secretary begin to

adopt the baseline set of performance measures as set forth in a report

issued by the Institute of Medicine (IOM) of the National Academy of

Sciences under section 238(b) of Public Law 108-173.\6\

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\6\ Institute of Medicine, ``Performance Measurement:

Accelerating Improvement,'' December 1, 2005, available at: http://

www.iom.edu/CMS/3809/19805/31310.aspx. IOM set forth these baseline

measures in a November 2005 report. However, the IOM report was not

released until December 1, 2005 on the IOM Web site.

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The IOM measures include: 21 Hospital Quality Alliance (HQA)

quality measures (including the ``starter set'' of 10 quality

measures); the Hospital Consumer Assessment of Health Providers and

Systems (HCAHPS) patient experience of care survey; and 3 structural

measures.\7\ The structural measures are: (1) Adoption of computerized

provider order entry for prescriptions; (2) staffing of intensive care

units with intensivists; and (3) evidence-based hospital referrals.

These structural measures constitute the Leapfrog Group's original

``three leaps,'' and are part of the National Quality Forum's (NQF's)

30 Safe Practices for Better Healthcare.

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\7\ Structural measures assess characteristics linked to the

capacity of the provider to deliver quality healthcare. Institute of

Medicine: Division of Health Care Services. Measuring the Quality of

Health Care: A Statement by the National Roundtable on Healthcare

Quality. National Academy Press; Washington D.C. 1999.

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Section 1886(b)(3)(B)(viii)(V) of the Act requires that, effective

for payments beginning with FY 2008, the Secretary add other quality

measures that reflect consensus among affected parties, and to the

extent feasible and practicable, have been set forth by one or more

national consensus building entities. The NQF is a voluntary consensus

standard-setting organization with a diverse representation of

consumer, purchaser, provider, academic, clinical, and other health

care stakeholder organizations. NQF was established to standardize

health care quality measurement and reporting through its consensus

development process. We have generally adopted NQF-endorsed

[[Page 24166]]

measures. However, we believe that consensus among affected parties

also can be reflected by other means, including, consensus achieved

during the measure development process, consensus shown through broad

acceptance and use of measures, and consensus through public comment.

Section 1886(b)(3)(B)(viii)(VI) of the Act authorizes the Secretary

to replace any quality measures or indicators in appropriate cases,

such as where all hospitals are effectively in compliance with a

measure, or the measures or indicators have been subsequently shown to

not represent the best clinical practice. Thus, the Secretary is

granted broad discretion to replace measures that are no longer

appropriate for the RHQDAPU program.

In the FY 2007 IPPS final rule, we began to expand the RHQDAPU

program measures by adding 11 quality measures to the 10-measure

starter set to establish an expanded set of 21 quality measures for the

FY 2007 payment determination (71 FR 48033 through 48037, 48045).

In the CY 2007 OPPS/ASC final rule (71 FR 68201), we adopted six

additional quality measures for the FY 2008 payment determination, for

a total of 27 measures. Two of these measures (30-Day Risk Standardized

Mortality Rates for Heart Failure and 30-Day Risk Standardized

Mortality Rates for AMI) were calculated using existing administrative

Medicare claims data; thus, no additional data submission by hospitals

was required for these two measures. The measures used for the FY 2008

payment determination included, for the first time, the HCAHPS patient

experience of care survey.

In the FY 2008 IPPS final rule (72 FR 47348 through 47358) and the

CY 2008 OPPS/ASC final rule with comment period (72 FR 66875 through

66877), we added three additional process measures to the RHQDAPU

program measure set. (These three measures are SCIP-Infection-4:

Cardiac Surgery Patients with Controlled 6AM Postoperative Serum

Glucose, SCIP-Infection-6: Surgery Patients with Appropriate Hair

Removal, and Pneumonia 30-day mortality (Medicare patients).) The

addition of these three measures brought the total number of RHQDAPU

program measures to be used for the FY 2009 payment determination to 30

(72 FR 66876). The 30 measures used for the FY 2009 annual payment

determination are listed in the FY 2009 IPPS final rule (73 FR 48600

through 48601).

For the FY 2010 payment determination, we added 15 new measures to

the RHQDAPU program measure set and retired one. Of the new measures,

13 were adopted in the FY 2009 IPPS final rule (73 FR 48602 through

48611) and two additional measures were finalized in the CY 2009 OPPS/

ASC final rule with comment period (73 FR 68780 through 68781). This

resulted in an expansion of the RHQDAPU program measures from 30

measures for the FY 2009 payment determination to 44 measures for the

FY 2010 payment determination. The RHQDAPU program measures for the FY

2010 payment determination consist of: 26 chart-abstracted process

measures, which measure care provided for Acute Myocardial Infarction

(AMI), Heart Failure (HF), Pneumonia (PN), or Surgical Infection

Prevention (SCIP); 6 claims-based measures, which evaluate 30-day

mortality or 30-day readmission rates for AMI, HF, or PN; 9 AHRQ

claims-based patient safety/inpatient quality indicator measures; 1

claims-based nursing sensitive measure; 1 structural measure that

assesses participation in a systematic database for cardiac surgery;

and the HCAHPS patient experience of care survey. The measures are

listed below.

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RHQDAPU program quality measures for the

Topic FY 2010 payment determination

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Acute Myocardial Infarction

(AMI)

AMI-1 Aspirin at arrival.

AMI-2 Aspirin prescribed at

discharge.

AMI-3 Angiotensin Converting

Enzyme Inhibitor (ACE-I) or Angiotensin

II Receptor Blocker (ARB) for left

ventricular systolic dysfunction.

AMI-4 Adult smoking cessation

advice/counseling.

AMI-5 Beta blocker prescribed at

discharge.

AMI-6 Beta blocker at arrival.

AMI-7a Fibrinolytic

(thrombolytic) agent received within 30

minutes of hospital arrival.

AMI-8a Timing of Receipt of

Primary Percutaneous Coronary

Intervention (PCI).

Heart Failure (HF)

HF-1 Discharge instructions.

HF-2 Left ventricular function

assessment.

HF-3 Angiotensin Converting

Enzyme Inhibitor (ACE-I) or Angiotensin

II Receptor Blocker (ARB) for left

ventricular systolic dysfunction.

HF-4 Adult smoking cessation

advice/counseling.

Pneumonia (PN)

PN-2 Pneumococcal vaccination

status.

PN-3b Blood culture performed

before first antibiotic received in

hospital.

PN-4 Adult smoking cessation

advice/counseling.

PN-5c Timing of receipt of

initial antibiotic following hospital

arrival.

PN-6 Appropriate initial

antibiotic selection.

PN-7 Influenza vaccination

status.

Surgical Care Improvement

Project (SCIP)

SCIP-1 Prophylactic antibiotic

received within 1 hour prior to surgical

incision.

SCIP-3 Prophylactic antibiotics

discontinued within 24 hours after

surgery end time.

SCIP-VTE-1: Venous

thromboembolism (VTE) prophylaxis

ordered for surgery patients.

SCIP-VTE-2: VTE prophylaxis

within 24 hours pre/post surgery.

SCIP-Infection-2: Prophylactic

antibiotic selection for surgical

patients.

SCIP-Infection-4: Cardiac

Surgery Patients with Controlled 6AM

Postoperative Serum Glucose.

SCIP-Infection-6: Surgery

Patients with Appropriate Hair Removal.

SCIP-Cardiovascular-2: Surgery

Patients on a Beta Blocker Prior to

Arrival Who Received a Beta Blocker

During the Perioperative Period.

Mortality Measures (Medicare

Patients)

MORT-30-AMI: Acute Myocardial

Infarction 30-day mortality--Medicare

patients.

[[Page 24167]]

MORT-30-HF: Heart Failure 30-day

mortality--Medicare patients.

MORT-30-PN: Pneumonia 30-day

mortality--Medicare patients.

Patients' Experience of Care

HCAHPS patient survey.

Readmission Measure (Medicare

Patients)

READ-30-HF: Heart Failure 30-Day

Risk Standardized Readmission Measure

(Medicare patients).

READ-30-AMI: Acute Myocardial

Infarction 30-Day Risk Standardized

Readmission Measure (Medicare patients).

READ-30-PN: Pneumonia 30-Day

Risk Standardized Readmission Measure

(Medicare patients).

AHRQ Patient Safety

Indicators (PSIs), Inpatient

Quality Indicators (IQIs)

and Composite Measures

PSI 04: Death among surgical

patients with treatable serious

complications.

PSI 06: Iatrogenic pneumothorax,

adult.

PSI 14: Postoperative wound

dehiscence.

PSI 15: Accidental puncture or

laceration.

IQI 11: Abdominal aortic

aneurysm (AAA) mortality rate (with or

without volume).

IQI 19: Hip fracture mortality

rate.

Mortality for selected surgical

procedures (composite).

Complication/patient safety for

selected indicators (composite).

Mortality for selected medical

conditions (composite).

Nursing Sensitive

Failure to Rescue (Medicare

claims only).

Cardiac Surgery

Participation in a Systematic

Database for Cardiac Surgery.

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On December 31, 2008, CMS advised hospitals that they would no

longer be required to submit data for the RHQDAPU program measure AMI-6

Beta blocker at arrival, beginning with discharges occurring on April

1, 2009. This change was based on the evolving evidence regarding AMI

patient care, as well as changes in the American College of Cardiology/

American Heart Association (ACC/AHA) practice guidelines for ST-segment

elevation myocardial infarction and non-ST segment elevation myocardial

infarction, upon which AMI-6 is based. The new guideline recommends

that early intravenous beta-blockers specifically should be avoided in

certain patient populations due to increased mortality risk. These

patients are identified by a complex set of contraindications that we

believe would make revision of the measure impractical and might result

in unintended consequences, including harm to patients based on

misinterpretation of an overly complex measure in the clinical setting.

Based on the new studies, the ACC/AHA Task Force on Performance

Measures removed this measure from the set of AMI performance measures

as of November 10, 2008 and did not replace the measure. CMS took

action to remove the measure from reporting initiatives based on the

lack of support by the measure developer and the considerations

identified above.

We discussed considerations relating to retiring or replacing

measures in the FY 2008 final rule with comment period and the FY 2009

IPPS final rule, including the ``topping out'' of hospitals'

performance under a measure (72 FR 47358-47359, and 73 FR 48603-48604).

In this instance, however, the measure no longer ``represent[s] the

best clinical practice,'' an additional basis under section

1886(b)(3)(B)(viii)(VI) of the Act for retiring a measure. For the FY

2010 payment determination and subsequent payment determinations, we

have formally retired the AMI-6 measure from the RHQDAPU program.

Therefore, hospitals participating in the RHQDAPU program are not

required to submit data on the AMI-6 measure beginning with April 1,

2009 discharges. However, we are seeking public comment on the

retirement of the AMI-6 measure.

(2) Maintenance of Technical Specifications for Quality Measures

The technical specifications for each RHQDAPU program measure are

listed in the CMS/Joint Commission Specifications Manual for National

Hospital Inpatient Quality Measures (Specifications Manual). This

Specifications Manual is posted on the CMS QualityNet Web site at

https://www.QualityNet.org/. We maintain the technical specifications

by updating this Specifications Manual semiannually, or more frequently

in unusual cases, and include detailed instructions and calculation

algorithms for hospitals to use when collecting and submitting data on

required measures. We are inviting public comment on our process of

notifying the public about the technical specifications for RHQDAPU

program quality measures and whether it can be improved to enable more

meaningful public comment on our proposed measures. We also are

inviting public comment on whether the information posted on the

https://www.QualityNet.org Web site--including the frequency with which

this information is updated--provides hospitals enough information and

time to implement the collection of data necessary for these required

quality measures.

(3) Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act requires that the

Secretary establish procedures for making quality data available to the

public after ensuring that a hospital has the opportunity to review its

data before these data are made public. Data from the RHQDAPU program

are included on the Hospital Compare Web site, http://

www.hospitalcompare.hhs.gov. The RHQDAPU program includes process of

care measures, risk adjusted outcome measures, the HCAHPS patient

experience of care survey, and a structural measure regarding cardiac

surgery registry participation. This Web site assists beneficiaries and

the general public by providing information on hospital quality of care

to consumers who need to select a hospital. It further serves to

encourage consumers to work with their doctors and hospitals to

[[Page 24168]]

discuss the quality of care hospitals provide to patients, thereby

providing an additional incentive to hospitals to improve the quality

of care that they furnish.

2. Retirement of RHQDAPU Program Measures

As stated above, we retired AMI-6 from the RHQDAPU program measure

set on December 1, 2008 because we believed, based on new evidence,

that the continued use of the measure raised specific patient safety

concerns. In situations such as this, we do not believe that it is

appropriate to wait for the annual rulemaking cycle. Rather, we propose

to promptly retire the measure and notify hospitals and the public of

the retirement of the measure and the reasons for its retirement

through the usual hospital and QIO communication channels used for the

RHQDAPU program, which include e-mail blasts to hospitals and the

dissemination of Standard Data Processing System (SDPS) memoranda to

QIOs, as well as posting the information on the QualityNet Web site. We

propose to confirm the retirement of the measure in the next IPPS

rulemaking. In other circumstances where we do not believe that

continued use of a measure raises specific patient safety concerns, we

intend to use the regular rulemaking process to retire a measure.

We are inviting public comment on whether any other RHQDAPU program

measures should be retired from the RHQDAPU program, as well as on the

criteria that should be used in retiring measures. To the extent that

performance has improved because of the collection and public display

of quality measures, we also are inviting public comment on how

performance could be maintained on the topped out measures once they

are retired. We note that many of the measures in the existing program

have experienced improved performance rates over the years. On our Web

site, http://www.cms.hhs.gov/HospitalQualityInits/, we have posted the

performance rates for the existing measures over the years that they

have been collected through the RHQDAPU program. However, thus far,

only one measure, the pneumonia oxygenation assessment measure, has

reached such a high level of compliance (nearly 100 percent for the

vast majority of hospitals) that we retired the measure.

3. Quality Measures for the FY 2011 Payment Determination and

Subsequent Years

a. Considerations in Expanding and Updating Quality Measures under the

RHQDAPU Program

In the FY 2009 IPPS proposed rule, we solicited comments on several

considerations related to expanding and updating quality measures,

including how to reduce the burden on the hospitals participating in

the RHQDAPU program and which approaches to measurement and collection

would be most useful while minimizing burden (73 FR 23653 through

23654).

In the FY 2009 IPPS final rule, we responded to public comments we

received on these issues (73 FR 48613 through 48616). We also stated

that in future expansions and updates to the RHQDAPU program measure

set, we would be taking into consideration several important goals.

These goals include: (a) Expanding the types of measures beyond process

of care measures to include an increased number of outcome measures,

efficiency measures, and patients' experience-of-care measures; (b)

expanding the scope of hospital services to which the measures apply;

(c) considering the burden on hospitals in collecting chart-abstracted

data; (d) harmonizing the measures used in the RHQDAPU program with

other CMS quality programs to align incentives and promote coordinated

efforts to improve quality; (e) seeking to use measures based on

alternative sources of data that do not require chart abstraction or

that utilize data already being reported by many hospitals, such as

data that hospitals report to clinical data registries, or all-payer

claims data bases; and (f) weighing the relevance and utility of the

measures compared to the burden on hospitals in submitting data under

the RHQDAPU program. Specifically, we give priority to quality measures

that assess performance on: (a) Conditions that result in the greatest

mortality and morbidity in the Medicare population; (b) conditions that

are high volume and high cost for the Medicare program; and (c)

conditions for which wide cost and treatment variations have been

reported, despite established clinical guidelines. We have used and

continue to use these criteria to guide our decisions regarding what

measures to add to the RHQDAPU program measure set.

Although RHQDAPU program payment decisions were initially based

solely on a hospital's submission of chart-abstracted quality measure

data, in recent years we have adopted measures, including structural

and claims-based quality measures that do not require a hospital to

submit chart-abstracted clinical data. This supports our stated goal to

expand the measures for the RHQDAPU program while minimizing the burden

on hospitals and, in particular, without significantly increasing the

chart abstraction burden.

In addition to claims-based measures, we are considering registries

\8\ and electronic health records (EHRs) as alternative ways to collect

data from hospitals. Many hospitals submit data to and participate in

existing registries. In addition, registries often capture outcome

information and provide ongoing quality improvement feedback to

registry participants. Instead of requiring hospitals to submit the

same data to CMS that they are already submitting to registries, we

believe that we could collect the data directly from the registries,

thereby enabling us to expand the RHQDAPU program measure set without

increasing the burden of data collection for those hospitals

participating in the registries. Examples of registries actively used

by hospitals include the Society of Thoracic Surgeons (STS) Cardiac

Surgery Registry (with approximately 90 percent participation by

cardiac surgery programs), the AHA Stroke Registry (with approximately

1200 hospitals participating), and the American Nursing Association

(ANA) Nursing Sensitive Measures Registry (with approximately 1400

hospitals participating). In the FY 2009 IPPS final rule, we adopted

the first RHQDAPU program measure related to registries: Participation

in a Systematic Database for Cardiac Surgery. We continue to evaluate

whether it is feasible to adopt measures that rely on one or more

registries as a source for data collection.

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\8\ A registry is a collection of clinical data for purposes of

assessing clinical performance, quality of care, and opportunities

for quality improvement.

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We also stated our intention to explore mechanisms for data

submission using EHRs (73 FR 48614). Establishing such a system will

require interoperability between EHRs and CMS data collection systems,

additional infrastructure development on the part of hospitals and CMS

and the adoption of standards for the capturing, formatting, and

transmission of data elements that make up the measures. However, once

these activities are accomplished, the adoption of measures that rely

on data obtained directly from EHRs will enable us to expand the

RHQDAPU program measure set with less cost and burden to hospitals.

[[Page 24169]]

In the FY 2009 IPPS final rule, we adopted nine AHRQ measures for

the RHQDAPU program. Although we stated that we would initially

calculate the measures using Medicare claims data (73 FR 48608), we

also stated that we remained interested in using all-payer claims data

to calculate them and that we might propose to collect such data in the

future. We invite input and suggestions on how all-payer claims data

can be collected and used by CMS to calculate these measures, as well

as on additional AHRQ measures that we should consider adopting for

future RHQDAPU program payment determinations.

We continue to use these criteria to guide our decisions on what

measures to propose for the RHQDAPU program measure set. Therefore, in

commenting on the new quality measures we have proposed to include in

future payment years and on measures to retire, we are inviting public

comments on these criteria.

b. Proposed RHQDAPU Program Quality Measures for the FY 2011 Payment

Determination

(1) Proposed Retention of Existing RHQDAPU Program Quality Measures

For the FY 2011 payment determination, we are proposing to retain

the following RHQDAPU program quality measures that we are using for

the FY 2010 payment determination:

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RHQDAPU program quality measures for FY

Topic 2010 payment determination proposed for

FY 2011 payment determination

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Acute Myocardial Infarction AMI-1 Aspirin at arrival.

(AMI)

AMI-2 Aspirin prescribed at

discharge.

AMI-3 Angiotensin Converting

Enzyme Inhibitor (ACE-I) or Angiotensin

II Receptor Blocker (ARB) for left

ventricular systolic dysfunction.

AMI-4 Adult smoking cessation

advice/counseling.

AMI-5 Beta blocker prescribed at

discharge.

AMI-7a Fibrinolytic

(thrombolytic) agent received within 30

minutes of hospital arrival.

AMI-8a Timing of Receipt of

Primary Percutaneous Coronary

Intervention (PCI).

Heart Failure (HF)

HF-1 Discharge instructions.

HF-2 Left ventricular function

assessment.

HF-3 Angiotensin Converting

Enzyme Inhibitor (ACE-I) or Angiotensin

II Receptor Blocker (ARB) for left

ventricular systolic dysfunction.

HF-4 Adult smoking cessation

advice/counseling.

Pneumonia (PN)

PN-2 Pneumococcal vaccination

status.

PN-3b Blood culture performed

before first antibiotic received in

hospital.

PN-4 Adult smoking cessation

advice/counseling.

PN-5c Timing of receipt of

initial antibiotic following hospital

arrival.

PN-6 Appropriate initial

antibiotic selection.

PN-7 Influenza vaccination

status.

Surgical Care Improvement

Project (SCIP)

SCIP-1 Prophylactic antibiotic

received within 1 hour prior to surgical

incision.

SCIP-3 Prophylactic antibiotics

discontinued within 24 hours after

surgery end time.

SCIP-VTE-1: Venous

thromboembolism (VTE) prophylaxis

ordered for surgery patients.

SCIP-VTE-2: VTE prophylaxis

within 24 hours pre/post surgery.

SCIP-Infection-2: Prophylactic

antibiotic selection for surgical

patients.

SCIP-Infection-4: Cardiac

Surgery Patients with Controlled 6AM

Postoperative Serum Glucose.

SCIP-Infection-6: Surgery

Patients with Appropriate Hair Removal.

SCIP-Cardiovascular-2: Surgery

Patients on a Beta Blocker Prior to

Arrival Who Received a Beta Blocker

During the Perioperative Period.

Mortality Measures (Medicare

Patients)

MORT-30-AMI: Acute Myocardial

Infarction 30-day mortality--Medicare

patients.

MORT-30-HF: Heart Failure 30-day

mortality--Medicare patients.

MORT-30-PN: Pneumonia 30-day

mortality--Medicare patients.

Patients' Experience of Care

HCAHPS patient survey.

Readmission Measure (Medicare

Patients)

READ-30-HF: Heart Failure 30-Day

Risk Standardized Readmission Measure

(Medicare patients).

READ-30-AMI: Acute Myocardial

Infarction 30-Day Risk Standardized

Readmission Measure (Medicare patients).

READ-30-PN: Pneumonia 30-Day

Risk Standardized Readmission Measure

(Medicare patients).

AHRQ Patient Safety

Indicators (PSIs), Inpatient

Quality Indicators (IQIs)

and Composite Measures.

PSI 06: Iatrogenic pneumothorax,

adult.

PSI 14: Postoperative wound

dehiscence.

PSI 15: Accidental puncture or

laceration.

IQI 11: Abdominal aortic

aneurysm (AAA) mortality rate (with or

without volume).

IQI 19: Hip fracture mortality

rate.

Mortality for selected surgical

procedures (composite).

Complication/patient safety for

selected indicators (composite).

Mortality for selected medical

conditions (composite).

Cardiac Surgery

[[Page 24170]]

Participation in a Systematic

Database for Cardiac Surgery.

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As we discussed above, we retired AMI-6 Beta blocker at arrival

from the RHQDAPU program measure set for the FY 2010 payment

determination and subsequent years. In addition, as discussed below, we

propose to harmonize two current RHQDAPU program measures for the FY

2011 payment determination: PSI 04: Death among surgical patients with

treatable serious complications; and Nursing Sensitive--Failure to

Rescue.

(2) NQF Harmonization of Two Existing RHQDAPU Program Measures

In May 2008, the NQF reviewed the specifications for two of the

RHQDAPU program measures that we adopted for the FY 2010 payment

determination: PSI 04-Death among surgical patients with treatable

serious complications; and Nursing Sensitive--Failure to rescue

(Medicare claims only). This was part of an NQF project titled

``National Voluntary Consensus Standards for Hospital Care 2007:

Performance Measures.'' As a result of this project by the NQF, these

two measures now have the same name: ``Death among surgical inpatients

with serious, treatable complications'' and share a single set of

measure specifications.

In order to maintain consistency with national voluntary consensus

standards with respect to referencing the measure, we are proposing to

combine PSI 04-Death among surgical patients with treatable serious

complications; and Nursing Sensitive--Failure to rescue (Medicare

claims only) into a single measure, Death among surgical inpatients

with serious, treatable complications, and to list the measure under

proposed topic name--AHRQ PSI and Nursing Sensitive Care. This measure,

as well as its specifications, would replace, for purposes of hospital

reporting, the two RHQDAPU program measures that we adopted for the FY

2010 payment determination: PSI 04: Death among surgical patients with

treatable serious complications; and Nursing Sensitive--Failure to

rescue (Medicare claims only). However, we may continue to publicly

report the measure in two different topics areas on Hospital Compare--

Nursing Sensitive Care and AHRQ PSIs, IQIs and Composite Measures. We

are inviting public comment on this proposal.

(3) Proposed New Chart-Abstracted Measures

For the FY 2011 payment determination, we are proposing to add two

new chart-abstracted measures. These proposed new measures, SCIP-

Infection-9 Postoperative Urinary Catheter Removal on Post Operative

Day 1 or 2, and SCIP-Infection-10: Perioperative Temperature

Management, are additions to the existing SCIP measure set. The SCIP

Infection measures are designed to assess practices that reduce the

risk of infections that surgical patients could acquire in the

hospital. They have high relevance to the Medicare population, and

address the growing concern regarding hospital acquired infections.\9\

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\9\ U.S. Government Accountability Office. Health-Care

Associated Infections in Hospitals: An Overview of State Reporting

Programs and Individual Hospital Initiatives to Reduce Certain

Infections. September 2008.

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Although these two measures require that hospitals abstract data

from medical records, they add to the scope of the existing SCIP

measurement set. Hospitals currently collect and report data elements

for eight SCIP measures. Additional data elements required for these

two proposed new SCIP measures are minimal, and would be abstracted

from the same records hospitals use to abstract data for the other SCIP

measures. Therefore, we expect the additional burden on hospitals to be

minimal. The two measures are NQF-endorsed. We are inviting public

comment on our proposal to include SCIP-Infection-9 and SCIP-Infection-

10 as RHQDAPU program measures to be used for the FY 2011 payment

determination. The collection of new chart-abstracted measures for the

FY 2011 payment determination would begin with 1st calendar quarter

2010 discharges, for which the submission deadline would be August 15,

2010.

(4) Proposed New Structural Measures

We also are proposing to adopt two additional structural measures

for the FY 2011 payment determination. Structural measures assess the

characteristics and capacity of the provider to deliver quality health

care. We are proposing to add two additional registry participation

measures. The two structural measures are: (1) Participation in a

Systematic Clinical Database Registry for Stroke Care; and (2)

Participation in a Systematic Clinical Database Registry for Nursing

Sensitive Care. These measures are specific applications for the

inpatient setting of a structural measure entitled ``Participation by a

physician or other clinician in a systematic clinical database registry

that includes consensus endorsed measures,'' which received NQF

endorsement under a project titled ``National Voluntary Consensus

Standards for Health IT: Structural Measures 2008.'' The proposed

measures are appropriate applications of the NQF-endorsed measure

because the NQF has endorsed measures for Stroke Care and Nursing

Sensitive Care which are currently being collected by widely used

stroke and nursing sensitive care registries. Therefore, we believe

that the proposed Stroke Registry Participation structural measure and

Nursing Sensitive Care Registry Participation structural measure meet

the consensus requirement in section 1886(b)(3)(B)(viii)(V) of the Act.

As we have previously stated, we also believe that participation in

registries reflects a commitment to assessing the quality of care

provided and identifying opportunities for improvement. Many registries

also collect outcome data and provide feedback to hospitals about their

performance. Moreover, registries offer a potential future data source

from which we can collect quality data.

The Participation in a Systematic Clinical Database Registry for

Stroke structural measure would require each hospital that participates

in the RHQDAPU program to indicate whether it is participating in a

systematic qualified clinical database registry for inpatient stroke

care and, if so, to identify the registry.

The Participation in a Systematic Clinical Database Registry for

Nursing Sensitive Care structural measure would similarly require each

hospital participating in the RHQDAPU program to indicate whether it is

participating in a systematic qualified clinical database registry

measuring nursing sensitive care quality for inpatient care and, if so,

to identify the registry.

We are soliciting public comment on these registry structural

measures. Specifically, we are inviting public comment on whether

``systematic qualified clinical database registry'' is adequately

defined and, if not, how it should be defined. In defining

[[Page 24171]]

``systematic qualified clinical database registry,'' should registries

that do not collect outcome measures and/or do not provide feedback to

hospitals about their performance be excluded? Are there other

registries that we should consider in future rulemakings, beyond stroke

and nursing sensitive registries, particularly for conditions where

there is high mortality/morbidity in the Medicare population, high cost

to the health care system, and widespread treatment variations despite

established clinical guidelines? Finally, we welcome more precise data

on what percentage of hospitals already participate in a stroke

registry or a nursing sensitive registry.\10\ Because we also retire

measures when performance has reached a sufficiently high level, we are

inviting public comment on whether reporting on stroke registry and

nursing sensitive care registry structural measures has sufficient

relevance and utility to justify the reporting burden, if a substantial

proportion of hospitals already participate in these registries.

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\10\ Examples of registries that we are aware of that are being

actively used by hospitals include the Society of Thoracic Surgeons

(STS) Cardiac Surgery Registry (with approximately 90 percent

participation by cardiac surgery programs), the AHA Stroke Registry

(with approximately 1200 hospitals participating), and the American

Nursing Association (ANA) Nursing Sensitive Measures Registry (with

approximately 1400 hospitals participating).

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Both proposed structural measures can be submitted using a Web-

based collection tool that we will make available on the QualityNet Web

site. We are inviting public comment on our proposal to adopt these two

structural measures for the FY 2011 payment determination.

In summary, we are proposing for the FY 2011 payment determination

to retain 41 of the measures we adopted for the FY 2010 payment

determination. With respect to the other three measures we adopted for

the FY 2010 payment determination, we retired AMI-6 Beta blocker at

arrival measure and are proposing to harmonize an AHRQ measure and a

Nursing Sensitive measure by combining these measures into a single

measure entitled Death among surgical inpatients with serious,

treatable complications. Finally, we are proposing to add four measures

(two SCIP Infection measures and two structural measures) to the

RHQDAPU program measure set. Set out below are the 46 RHQDAPU program

quality measures proposed for the FY 2011 payment determination:

------------------------------------------------------------------------

Proposed RHQDAPU program quality measures

Topic for the FY 2011 payment determination

------------------------------------------------------------------------

Acute Myocardial Infarction

(AMI)

AMI-1 Aspirin at arrival.

AMI-2 Aspirin prescribed at

discharge.

AMI-3 Angiotensin Converting

Enzyme Inhibitor (ACE-I) or Angiotensin

II Receptor Blocker (ARB) for left

ventricular systolic dysfunction.

AMI-4 Adult smoking cessation

advice/counseling.

AMI-5 Beta blocker prescribed at

discharge.

AMI-7a Fibrinolytic

(thrombolytic) agent received within 30

minutes of hospital arrival.

AMI-8a Timing of Receipt of

Primary Percutaneous Coronary

Intervention (PCI).

Heart Failure (HF)

HF-1 Discharge instructions.

HF-2 Left ventricular function

assessment.

HF-3 Angiotensin Converting

Enzyme Inhibitor (ACE-I) or Angiotensin

II Receptor Blocker (ARB) for left

ventricular systolic dysfunction.

HF-4 Adult smoking cessation

advice/counseling.

Pneumonia (PN)

PN-2 Pneumococcal vaccination

status.

PN-3b Blood culture performed

before first antibiotic received in

hospital.

PN-4 Adult smoking cessation

advice/counseling.

PN-5c Timing of receipt of

initial antibiotic following hospital

arrival.

PN-6 Appropriate initial

antibiotic selection.

PN-7 Influenza vaccination

status.

Surgical Care Improvement

Project (SCIP)

SCIP-1 Prophylactic antibiotic

received within 1 hour prior to surgical

incision.

SCIP-3 Prophylactic antibiotics

discontinued within 24 hours after

surgery end time.

SCIP-VTE-1: Venous

thromboembolism (VTE) prophylaxis

ordered for surgery patients.

SCIP-VTE-2: VTE prophylaxis

within 24 hours pre/post surgery.

SCIP-Infection-2: Prophylactic

antibiotic selection for surgical

patients.

SCIP-Infection-4: Cardiac

Surgery Patients with Controlled 6AM

Postoperative Serum Glucose.

SCIP-Infection-6: Surgery

Patients with Appropriate Hair Removal.

SCIP-Infection-9: Postoperative

Urinary Catheter Removal on Post

Operative Day 1 or 2.\*

SCIP-Infection-10: Perioperative

Temperature Management.\*

SCIP-Cardiovascular-2: Surgery

Patients on a Beta Blocker Prior to

Arrival Who Received a Beta Blocker

During the Perioperative Period.

Mortality Measures (Medicare

Patients)

MORT-30-AMI: Acute Myocardial

Infarction 30-day mortality--Medicare

patients.

MORT-30-HF: Heart Failure 30-day

mortality--Medicare patients.

MORT-30-PN: Pneumonia 30-day

mortality--Medicare patients.

Patients' Experience of Care

HCAHPS patient survey.

Readmission Measure (Medicare

Patients)

READ-30-HF: Heart Failure 30-Day

Risk Standardized Readmission Measure

(Medicare patients).

READ-30-AMI: Acute Myocardial

Infarction 30-Day Risk Standardized

Readmission Measure (Medicare patients).

[[Page 24172]]

READ-30-PN: Pneumonia 30-Day

Risk Standardized Readmission Measure

(Medicare patients).

AHRQ Patient Safety

Indicators (PSIs), Inpatient

Quality Indicators (IQIs)

and Composite Measures.

PSI 06: Iatrogenic pneumothorax,

adult.

PSI 14: Postoperative wound

dehiscence.

PSI 15: Accidental puncture or

laceration.

IQI 11: Abdominal aortic

aneurysm (AAA) mortality rate (with or

without volume).

IQI 19: Hip fracture mortality

rate.

Mortality for selected surgical

procedures (composite).

Complication/patient safety for

selected indicators (composite).

Mortality for selected medical

conditions (composite).

AHRQ PSI and Nursing

Sensitive Care\*\*

Death among surgical inpatients

with serious, treatable complications.

Cardiac Surgery

Participation in a Systematic

Database for Cardiac Surgery.

Stroke Care

Participation in a Systematic

Clinical Database Registry for Stroke

Care.\*

Nursing Sensitive Care

Participation in a Systematic

Clinical Database Registry for Nursing

Sensitive Care.\*

------------------------------------------------------------------------

\* Proposed new measure for FY 2011 payment determination.

\*\* Proposed harmonized measure. This measure may be publicly reported

under two topics--the AHRQ PSIs, IQIs, and Composite Measures topic

and the Nursing Sensitive Care topic.

4. Possible New Quality Measures for the FY 2012 Payment Determination

and Subsequent Years

We are inviting public comment on the following quality measures

and topics that we might consider adopting beginning with the FY 2012

payment determination. We also are seeking suggestions and rationales

to support the adoption of measures and topics for the RHQDAPU program

that are not included in this list.

------------------------------------------------------------------------

Measure topic Measure description

------------------------------------------------------------------------

AMI.................................. Statin at discharge.

ED--Throughput....................... Median time from admit decision

time to time of departure from

the emergency department for

emergency department patients

admitted to inpatient status.

ED--Throughput....................... Median time from emergency

department arrival to time of

departure from the emergency

room for patients admitted to

the facility from the emergency

department.

Complications........................ Lower Extremity Bypass

Complications.

Complications........................ Comorbidity Adjusted Complication

Index.

PCI.................................. PCI mortality rate for patients

without ST segment elevation

myocardial infarction (STEMI)

and without cardiogenic shock.

Stroke............................... Patients with an ischemic stroke

or a hemorrhagic stroke and who

are non-ambulatory should start

receiving DVT prophylaxis by end

of hospital day two.

Stroke............................... Patients with an ischemic stroke

prescribed antithrombotic

therapy at discharge.

Stroke............................... Patients with an ischemic stroke

with atrial fibrillation

discharged on anticoagulation

therapy.

Stroke............................... Acute ischemic stroke patients

who arrive at the hospital

within 120 minutes (2 hours) of

time last known well and for

whom IV t-PA was initiated at

this hospital within 180 minutes

(3 hours) of time last known

well.

Stroke............................... Patients with ischemic stroke who

receive antithrombotic therapy

by the end of hospital day two.

Stroke............................... Ischemic stroke patients with LDL

>/= 100 mg/dL, or LDL not

measured, or, who were on

cholesterol reducing therapy

prior to hospitalization are

discharged on a statin

medication.

Stroke............................... Patients with ischemic or

hemorrhagic stroke or their

caregivers who were given

education or educational

materials during the hospital

stay addressing all of the

following: personal risk factors

for stroke, warning signs for

stroke, activation of emergency.

Stroke............................... Patients with an ischemic stroke

or hemorrhagic stroke who were

assessed for rehabilitation

services.

VTE.................................. This measure assesses the number

of patients that receive VTE

prophylaxis or have

documentation why no VTE

prophylaxis was given within 24

hours after the initial

admission (or transfer) to the

Intensive Care Unit (ICU) or

surgery end time.

VTE.................................. Patients who received parenteral

and warfarin therapy (overlap

therapy):

(1) For at least 5 days, with an

INR greater than or equal to 2

prior to discontinuation of

parenteral therapy OR (2) For

more than 5 days, with an INR

less than 2, but were discharged

on overlap therapy OR (3) Who

were discharged in less than

five days on overlap therapy.

VTE.................................. This measure assesses the number

of patients receiving

intravenous (IV) UFH therapy

with documentation that the

dosages and platelet counts are

monitored by protocol (or

nomogram).

VTE.................................. This measure assesses the number

of VTE patients that are

discharged home, home care, or

home hospice on warfarin with

written discharge instructions

that addresses all four

criteria: Follow-up Monitoring;

Compliance Issues; Dietary

Restrictions; and, Potential for

Adverse Drug Reactions/

Interactions.

[[Page 24173]]

VTE.................................. This measure assesses the number

of patients that were diagnosed

with VTE during hospitalization

(not present at admission) that

did not receive VTE prophylaxis.

Cardiac Surgery...................... Post-operative Renal Failure.

Cardiac Surgery...................... Surgical Re-exploration.

Cardiac Surgery...................... Anti-Platelet Medication at

Discharge.

Cardiac Surgery...................... Beta Blockade at Discharge.

Cardiac Surgery...................... Anti-Lipid Treatment Discharge.

Cardiac Surgery...................... Risk-Adjusted Operative Mortality

for CABG.

Cardiac Surgery...................... Risk-Adjusted Operative Mortality

for Aortic Valve Replacement

(AVR).

Cardiac Surgery...................... Risk-Adjusted Operative Mortality

for Mitral Valve Replacement/

Repair (MVR).

Cardiac Surgery...................... Risk-Adjusted Operative Mortality

MVR+CABG Surgery.

Cardiac Surgery...................... Risk-Adjusted Operative Mortality

for AVR+CABG.

Cardiac Surgery...................... Pre-Operative Beta Blockade.

Cardiac Surgery...................... Duration of Prophylaxis for

Cardiac Surgery Patients.

Cardiac Surgery...................... Prolonged Intubation

(ventilation).

Cardiac Surgery...................... Deep Sternal Wound Infection

Rate.

Cardiac Surgery...................... Stroke/Cerebrovascular Accident.

Nursing Sensitive.................... Patient Falls: All documented

falls with or without injury,

experienced by patients on an

eligible unit in a calendar

month.

Nursing Sensitive.................... Falls with Injury: All documented

patient falls with an injury

level of minor or greater.

Nursing Sensitive/HAI................ Catheter Associated Urinary Tract

Infection.

Nursing Sensitive/HAI................ Central Line Associated Blood

Stream Infection in the ICU and

high risk neonatal intensive

care unit.

Nursing Sensitive/HAI................ Ventilator Associated Pneumonia

in the ICU.

Nursing Sensitive.................... Pressure Ulcer Prevalence.

Nursing Sensitive.................... Restraint Prevalence (vest and

limb).

Nursing Sensitive.................... Skill Mix: Percentage of hours

worked by: RN, LPN/LVN, UAP,

Contract/Agency.

Nursing Sensitive.................... Hours per patient day worked by

RN, LPN, and UAP.

Nursing Sensitive.................... Practice Environment Scale-

Nursing Work Index.

Nursing Sensitive.................... Voluntary turnover for RN, APN,

LPN, UAP.

Outcomes............................. PSI 03: Decubitus Ulcer.

Outcomes............................. PSI 07: Infection Due to Medical

Care.

Outcomes............................. PSI 08: Post Operative Hip

Fracture.

Outcomes............................. PSI 09: Post Operative Hemorrhage

or Hematoma\*.

Outcomes............................. PSI 10: Post Operative

Physiologic Metabolic

Derangement\*.

Outcomes............................. PSI 11: Post Operative

Respiratory Failure.

Outcomes............................. PSI 12: Post Operative PE or DVT.

Outcomes............................. PSI 13: Post Operative Sepsis.

Outcomes............................. IQI 08: In-hospital Mortality for

Esophageal Resection.

Outcomes............................. IQI 09: In-hospital Mortality for

Pancreatic Resection.

Outcomes............................. IQI 12: In-hospital Mortality for

CABG.

Outcomes............................. IQI 13: In-hospital Mortality for

Craniotomy\*.

Outcomes............................. IQI 14: In-hospital Mortality for

Hip Replacement.

Outcomes............................. IQI 15: In-hospital Mortality for

AMI.

Outcomes............................. IQI 16: In-hospital Mortality for

CHF.

Outcomes............................. IQI 17: In-hospital Mortality for

Stroke.

Outcomes............................. IQI 18: In-hospital Mortality for

GI Hemorrhage\*.

Outcomes............................. IQI 20: In-hospital Mortality for

Pneumonia.

SCIP................................. Short Half-Life prophylactic

administered preoperatively

redosed within 4 hours after

preoperative dose.

PCI Readmission...................... Hospital-specific 30-day risk-

standardized readmission rate

following Percutaneous Coronary

Intervention (PCI) among

patients aged 18 years or older.

PCI Mortality for STEMI/shock

patients: Hospital-specific 30-

day all-cause risk-standardized

mortality rate following

Percutaneous Coronary

Intervention (PCI) among

patients aged 18 years or older

with ST segment elevation

myocardial infarction (STEMI) or

cardiogenic shock at the time of

procedure.

PCI Mortality........................ PCI Mortality for non-STEMI/non-

shock patients: Hospital-

specific 30-day all-cause risk-

standardized mortality rate

following Percutaneous Coronary

Intervention (PCI) among

patients aged 18 years or older

without ST segment elevation

myocardial infarction (STEMI)

and without cardiogenic shock at

the time of procedure.

ICD Complications.................... Hospital-specific risk-

standardized complication rate

following implantable

cardioverter defibrillator (ICD)

implantation among patients aged

18 years or older.

Hospital Acquired Infections......... Methicillin-Resistant

Staphylococcus Aureus (MRSA).

Hospital Acquired Infections......... Clostridium Difficile Associated

Diseases (CDAD).

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\* AHRQ is currently working with to improve and refine these measures,

after which they will be updated to reflect the most current evidence

learned as a result of validation efforts and empirical analyses.

We are inviting public comment on these measures for potential

future use in the RHQDAPU program, as well as suggestions and

supporting rationales for additional measures to consider using in the

program at a future time.

5. Form, Manner, and Timing of Quality Data Submission

Section 1886(b)(3)(B)(viii)(I) of the Act requires that subsection

(d)

[[Page 24174]]

hospitals submit data on measures selected under that clause with

respect to the applicable fiscal year. In addition, section

1886(b)(3)(B)(viii)(II) of the Act requires that each subsection (d)

hospital submit data on measures selected under that clause to the

Secretary in a form and manner, and at a time, specified by the

Secretary. The data submission requirements, Specifications Manual, and

submission deadlines are posted on the QualityNet Web site at: http://

www.QualityNet.org. CMS requires that hospitals submit data in

accordance with the specifications for the appropriate discharge

periods.

Hospitals submit quality data through the secure portion of the

QualityNet Web site (formerly known as QualityNet Exchange) (http://

www.QualityNet.org). This Web site meets or exceeds all current Health

Insurance Portability and Accountability Act requirements for security

of protected health information.

a. Proposed RHQDAPU Program Procedures for the FY 2011 Payment

Determination

For the FY 2011 payment determination, we are proposing that the

following procedures will apply to hospitals participating in the

RHQDAPU program. These procedures are, for the most part, the same as

the procedures that apply to the FY 2010 payment determination. We

identify below where we have proposed to modify a procedure.

Register with QualityNet, before participating hospitals

initially begin reporting data, regardless of the method used for

submitting data.

Identify a QualityNet Administrator who follows the

registration process located on the QualityNet Web site (http://

www.qualitynet.org).

Notice of Participation. New subsection (d) hospitals and

existing hospitals that wish to participate in the RHQDAPU program for

the first time must complete a revised ``Reporting Hospital Quality

Data for Annual Payment Update Notice of Participation'' form (Notice

of Participation form) that includes the name and address of each

hospital campus that shares the same CMS Certification Number (CCN).

We are proposing that any hospital that receives a new CCN on or

after October 15, 2009 (including new subsection (d) hospitals and

hospitals that have merged) that wishes to participate in the RHQDAPU

program and has not otherwise submitted a Notice of Participation form

using that CCN must submit a completed Notice of Participation form no

later than 180 days from the date identified as the ``open date'' on

the approved CMS Online System Certification and Reporting (OSCAR)

system. We believe that this deadline will give these hospitals a

sufficient amount of time to get their operations up and running while

simultaneously providing CMS with clarity regarding whether they intend

to participate in the RHQDAPU program for FY 2011.

We also are proposing that hospitals having an open date (as noted

on the approved CMS OSCAR system) before October 15, 2009 that did not

participate in the RHQDAPU program in FY 2010 but that wish to

participate in the RHQDAPU program for the FY 2011 payment

determination must submit a completed Notice of Participation form to

CMS on or before December 31, 2009. These hospitals, unlike hospitals

that receive a new CCN, do not need to get their operations up and

running. Therefore, we believe this is a reasonable deadline that will

enable these hospitals to decide whether they want to participate in

the RHQDAPU program while also enabling CMS to collect enough data from

them to make an accurate FY 2011 payment determination.

We note that under our current requirements, hospitals must begin

submitting RHQDAPU program data starting with the first day of the

quarter following the date when the hospital registers to participate

in the program. For purposes of meeting this requirement, we interpret

the registration date to be the date that the hospital submits a

completed Notice of Participation form. As proposed previously in this

section, hospitals must also register with QualityNet and identify a

QualityNet Administrator who follows the QualityNet registration

process before submitting RHQDAPU program data.

Collect and report data for each of the quality measures

under the topic areas that require chart abstraction. For the FY 2011

payment determination, these topic areas are AMI, HF, PN, and SCIP.

Hospitals must report these data by each quarterly deadline. Hospitals

must submit the data to the QIO Clinical Warehouse using the CMS

Abstraction & Reporting Tool (CART), The Joint Commission ORYX [supreg]

Core Measures Performance Measurement System, or another third-party

vendor tool that meets the measurement specification requirements for

data transmission to QualityNet. All submissions will be executed

through My QualityNet, the secure part of the QualityNet Web site.

Because the information in the QIO Clinical Warehouse is considered QIO

information, it is subject to the stringent QIO confidentiality

regulations in 42 CFR Part 480. The QIO Clinical Warehouse will submit

the data to CMS on behalf of the hospitals.

Submit complete data for each quality measure that

requires chart abstraction in accordance with the joint CMS/Joint

Commission sampling requirements located on the QualityNet Web site.

These requirements specify that hospitals must submit a random sample

or complete population of cases for each of the topics covered by the

quality measures. Hospitals must meet the sampling requirements for

these quality measures for discharges in each quarter.

Submit to CMS on a quarterly basis aggregate population

and sample size counts for Medicare and non-Medicare discharges for the

topic areas for which chart-abstracted data must be submitted

(currently AMI, HF, PN, and SCIP). However, in order to reduce the

burden on hospitals that treat a low number of patients in a RHQDAPU

program topic area, a hospital that has five or fewer discharges

(Medicare and non-Medicare combined) in a topic area during a quarter

in which data must be submitted is not required to submit patient-level

data for that topic area for the quarter. The hospital must still

submit its aggregate population and sample size counts for Medicare and

non-Medicare discharges for the four topic areas each quarter. We also

note that hospitals meeting the five or fewer patient discharge

exception may voluntarily submit these data.

Continuously collect and submit HCAHPS data in accordance

with the HCAHPS Quality Assurance Guidelines, V4.0 (the most current

version of the guidelines), located at the Web site http://

www.hcahpsonline.org. The QIO Clinical Warehouse will accept zero

HCAHPS-eligible discharges. However, in order to reduce the burden on

hospitals that treat a low number of patients that would be otherwise

covered by the HCAHPS submission requirements, a hospital that has five

or fewer HCAHPS-eligible discharges during a month is not required to

submit HCAHPS surveys for that month. However, hospitals that meet this

exception may voluntarily submit this data. The hospital must still

submit its total number of HCAHPS-eligible cases for that month as part

of its quarterly HCAHPS data submission.

The quarterly data submission deadline for hospitals to

submit patient level data for the proposed measures that require chart

abstraction is 4\1/2\ months following the last discharge date in the

calendar quarter. CMS will post the quarterly submission deadline

[[Page 24175]]

schedule on the QualityNet Web site (http://www.QualityNet.org). The

collection of new chart-abstracted measures for FY 2011 payment

determination would begin with 1st calendar quarter 2010 discharges,

for which the submission deadline would be August 15, 2010.

The data submission deadline for hospitals to submit

aggregate population and sample size count data for the measures

requiring chart abstraction is four months following the last discharge

date in the calendar quarter. This requirement allows CMS to advise

hospitals regarding their submission status in enough time for them to

make appropriate revisions before the data submission deadline. We will

post the aggregate population and sample size count data submission

deadlines on the QualityNet Web site (http://www.QualityNet.org).

CMS strongly recommends that hospitals review the QIO Clinical

Warehouse Feedback Reports and the RHQDAPU Program Provider

Participation Reports that are available after patient level data are

submitted to the QIO Clinical Warehouse. CMS generally updates these

reports on a daily basis to provide accurate information to hospitals

about their submissions. These reports enable hospitals to ensure that

their data were submitted on time and accepted into the QIO Clinical

Warehouse.

Hospitals are encouraged to regularly check the QualityNet Web

site, http://www.QualityNet.org for program updates and information.

The following RHQDAPU program claims-based measures will

be calculated using Medicare claims:

------------------------------------------------------------------------

FY 2011 Payment determination:

proposed claims-based quality

Topic measures (no hospital data

submission required)

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Mortality Measures (Medicare Patients)

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MORT-30-AMI Acute

Myocardial Infarction 30-day

mortality--Medicare patients.

MORT-30-HF Heart Failure

30-day mortality--Medicare

patients.

MORT-30-PN Pneumonia 30-

day mortality--Medicare

patients.

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Readmission Measures (Medicare Patients)

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READ-30-HF Heart Failure

(HF) 30-Day Risk Standardized

Readmission Measure (Medicare

patients).

READ-30-AMI Acute

Myocardial Infarction (AMI) 30-

Day Risk Standardized

Readmission Measure (Medicare

patients).

READ-30-PN Pneumonia

(PN) 30-Day Risk Standardized

Readmission Measure (Medicare

patients).

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AHRQ Patient Safety Indicators (PSIs), Inpatient Quality Indicators

(IQIs) and Composite Measures

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PSI 06: Iatrogenic

pneumothorax, adult.

PSI 14: Postoperative

wound dehiscence.

PSI 15: Accidental

puncture or laceration.

IQI 11: Abdominal aortic

aneurysm (AAA) mortality rate

(with or without volume).

IQI 19: Hip fracture

mortality rate.

Mortality for selected

surgical procedures (composite).

Complication/patient

safety for selected indicators

(composite).

Mortality for selected

medical conditions (composite).

------------------------------------------------------------------------

AHRQ Patient Safety Indicator (PSI) and Nursing Sensitive Care

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Death among surgical

inpatients with serious,

treatable complications.

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For the claims-based RHQDAPU program measures listed in the table

above, hospitals are not required to submit the data to the QIO

Clinical Warehouse. CMS uses the existing Medicare fee-for-service

claims to calculate the measures. For the FY 2011 payment

determination, CMS will use three years of discharges from July 1, 2006

through June 30, 2009 for the 30-day mortality and 30-day readmission

measures. For the AHRQ PSI, IQI and Composite measures (including the

AHRQ PSI and Nursing Sensitive Care measure, Death among surgical

inpatients with serious, treatable complications), we will use one year

of claims from July 1, 2008 through June 30, 2009 to calculate these

measures.

We are proposing that hospitals report the information

needed to calculate the three proposed structural measures directly

onto the QualityNet Web site on a quarterly basis starting with 1st

calendar quarter 2010. The quarterly submission deadline for reporting

these measures will be 4\1/2\ months following the last date in the

quarter covered by the data report. For example, the reporting deadline

for these structural measures covering 1st calendar quarter 2010 is

August 15, 2010. The 4\1/2\ month lag between the end of the quarter

and the reporting deadline is intended to provide hospitals with

sufficient time to collect the information needed to accurately report

the proposed structural measures, and aligns with the quarterly

submission deadlines for the measures for which chart-abstraction is

required.

The following is the list of three structural measures proposed for

the FY 2011 payment determination:

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FY 2011 Payment determination:

Topic proposed structural measures

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Cardiac Surgery

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Participation in a

Systematic Database for Cardiac

Surgery.

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[[Page 24176]]

Stroke Care

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Participation in a

Systematic Clinical Database

Registry for Stroke Care.

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Nursing Sensitive Care

------------------------------------------------------------------------

Participation in a

Systematic Clinical Database

Registry for Nursing Sensitive

Care.

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We will add a link on the QualityNet Web site to the Web page(s)

hospitals can use to report the proposed structural measures after we

issue the FY 2010 IPPS final rule.

b. RHQDAPU Program Disaster Extensions and Waivers

We are soliciting public comment about rules we could adopt that

would enable hospitals to request either an extension or a waiver of

various RHQDAPU program requirements in the event of a disaster (such

as a hurricane that damages or destroys the hospital).

Specifically, we welcome public comment on the following issues:

Recommendations for rules that we could follow when

considering whether to grant an extension or waiver of RHQDAPU program

requirements in the event of a disaster, including suggested criteria

that we should take into account (for example, specific hospital

infrastructure damage, hospital closure time period, degree of

destruction of medical records, impact on data vendors, long-term

evacuation of discharged patients impacting HCAHPS survey

participation).

The role that QIOs and QIO support contractors should play

in the event of a disaster, including communicating with affected

hospitals, communicating with State hospital associations, and

collecting information directly from hospitals.

How CMS extension or waiver decisions should be

communicated to affected hospitals.

Any other issues commenters deem relevant to a hospital's

request for an extension or waiver of RHQDAPU program requirements in

the event of a disaster.

c. HCAHPS Requirements for the FY 2011 Payment Determination

We are proposing that, for the FY 2011 payment determination, the

RHQDAPU program HCAHPS requirements we adopted for FY 2010 would

continue to apply. Under these requirements, a hospital must

continuously collect and submit HCAHPS data in accordance with the

current HCAHPS Quality Assurance Guidelines and the quarterly data

submission deadlines, both of which are posted at http://

www.hcahpsonline.org. In order for a hospital to participate in the

collection of HCAHPS data, a hospital must either: (1) Contract with an

approved HCAHPS survey vendor that will conduct the survey and submit

data on the hospital's behalf to the QIO Clinical Warehouse; or (2)

self-administer the survey without using a survey vendor provided that

the hospital attends HCAHPS training and meets Minimum Survey

Requirements as specified on the Web site at: http://

www.hcahpsonline.org. A current list of approved HCAHPS survey vendors

can be found on the HCAHPS Web site at: http://www.hcahpsonline.org.

Every hospital choosing to contract with a survey vendor should

provide the sample frame of HCAHPS-eligible discharges to its survey

vendor with sufficient time to allow the survey vendor to begin

contacting each sampled patient within 6 weeks of discharge from the

hospital. (We refer readers to the Quality Assurance Guidelines located

at http://www.hcahpsonline.org for details about HCAHPS eligibility and

sample frame creation.) In addition, the hospital must authorize the

survey vendor to submit data via My QualityNet, the secure part of the

QualityNet Web site, on the hospital's behalf.

After the survey vendor submits the data to the QIO Clinical

Warehouse, we strongly recommend that hospitals employing a survey

vendor promptly review the two HCAHPS Feedback Reports (the Provider

Survey Status Summary Report and the Data Submission Detail Report)

that are available. These reports enable a hospital to ensure that its

survey vendor has submitted the data on time and the data has been

accepted into the QIO Clinical Warehouse.

As we stated above, any hospital that has five or fewer HCAHPS-

eligible discharges in any month is no longer required to submit HCAHPS

surveys for that month, although the hospital may voluntarily choose to

submit these data. However, the hospital must still submit its total

number of HCAHPS-eligible cases for that month as part of its quarterly

HCAHPS data submission.

In order to ensure compliance with HCAHPS survey and administration

protocols, hospitals and survey vendors must participate in all

oversight activities. As part of the oversight process, during the

onsite visits or conference calls, the HCAHPS Project Team will review

the hospital's or survey vendor's survey systems and assess protocols

based upon the most recent HCAHPS Quality Assurance Guidelines. All

materials relevant to survey administration will be subject to review.

The systems and program review includes, but is not limited to: (a)

Survey management and data systems; (b) printing and mailing materials

and facilities; (c) telephone and IVR materials and facilities; (d)

data receipt, entry and storage facilities; and (e) written

documentation of survey processes. Organizations will be given a

defined time period in which to correct any problems and provide

follow-up documentation of corrections for review. As needed, hospitals

and survey vendors will be subject to follow-up site visits or

conference calls. If CMS determines that a hospital is not compliant

with HCAHPS program requirements, CMS may determine that the hospital

is not submitting HCAHPS data that meet the requirements of the RHQDAPU

program.

We continue to strongly recommend that each new hospital

participate in an HCAHPS dry run, if feasible, prior to beginning to

collect HCAHPS data on an ongoing basis to meet RHQDAPU program

requirements. New hospitals can conduct a dry run in the last month of

a calendar quarter. We refer readers to the Web site at http://

www.hcahpsonline.org for a schedule of upcoming dry runs. The dry run

will give newly participating hospitals the opportunity to gain first-

hand experience collecting and transmitting HCAHPS data without the

public reporting of results. Using the official survey instrument and

the approved modes of administration and data collection protocols,

hospitals/survey vendors will collect HCAHPS data and submit the data

to My QualityNet, the secure portion of QualityNet.

For FY 2011, we are again encouraging hospitals to regularly check

[[Page 24177]]

the HCAHPS Web site at http://www.hcahpsonline.org, for program updates

and information.

6. Proposed Chart Validation Requirements

a. Proposed Chart Validation Requirements and Methods for the FY 2011

Payment Determination

For the FY 2011 payment determination, we are proposing to

generally continue using the following existing requirements

implemented in previous years. We note below where we are proposing to

modify a requirement. These requirements, as well as additional

information on these requirements, will be posted on the QualityNet Web

site after we issue the FY 2010 final rule.

The Clinical Data Abstraction Center (CDAC) contractor

will, each quarter, ask every participating hospital to submit five

randomly selected medical charts from which the hospital previously

abstracted and submitted data to the QIO Clinical Warehouse.

We are proposing the following timeline with respect to CDAC

contractor requests for paper medical records for the purpose of

validating RHQDAPU program data. Beginning with CDAC requests for

second calendar quarter 2009 paper medical records, the CDAC will

request paper copies of the randomly selected medical charts from each

hospital via certified mail, and the hospital will have 45 days from

the date of the request (as documented on the request letter) to submit

the requested records to the CDAC. If the hospital does not comply

within 30 days, the CDAC will send a second certified letter to the

hospital, reminding the hospital that it must return paper copies of

the requested medical records within 45 calendar days following the

date of the initial CDAC medical record request. If the hospital still

does not comply, then the CDAC will assign a ``zero'' score to each

data element in each missing record.

We are proposing this timeline to provide hospitals with

transparent and documented correspondence about RHQDAPU program

validation paper medical record requests. Hospitals have submitted

numerous questions to CMS about this process, and we believe this

timeline will provide hospitals with adequate notice and time to submit

paper copies of requested medical records to the CDAC contractor. We

also believe that this timeline does not unduly burden hospitals. We

remind hospitals that CMS reimburses up to 12 cents per copied page to

copy the requested medical records, and CMS also pays United States

Postal Service fees for hospitals to mail back a paper copy of the

requested medical records.

Once the CDAC contractor receives the charts, it will

reabstract the same data submitted by the hospitals and calculate the

percentage of matching RHQDAPU program data element values for all of

that data.

The hospital must pass our validation requirement of a

minimum of 80 percent reliability. We use appropriate confidence

intervals to determine if a hospital has achieved 80 percent

reliability. The use of confidence intervals allows us to establish an

appropriate range below the 80 percent reliability threshold that

demonstrates a sufficient level of reliability to allow the data to

still be considered validated. We estimate the percent reliability

based upon a review of the sampled charts, and then calculate the upper

95 percent confidence limit for that estimate. If this upper limit is

above the required 80 percent reliability, the hospital data are

considered validated.

We will pool the quarterly validation estimates for the

four most recently validated quarters (except for the SCIP-

Cardiovascular-2 measure discussed below). For the FY 2011 payment

update, we propose to validate 4th quarter CY 2008 through 3rd quarter

2009 discharge data for the following measures:

------------------------------------------------------------------------

Quality measures

validated using data

from 4th quarter CY Measure ID

quarter CY 2009

discharges

------------------------------------------------------------------------

AMI (Acute Myocardial Aspirin at Arrival... AMI-1.

Infarction).

Aspirin Prescribed at AMI-2.

Discharge.

ACEI or ARB for LVSD. AMI-3.

Adult Smoking AMI-4.

Cessation Advice/

Counseling.

Beta-Blocker AMI-5.

Prescribed at

Discharge.

Fibrinolytic Therapy AMI-7a.

Received Within 30

Minutes of Hospital

Arrival.

Primary PCI Received AMI-8a.

Within 90 Minutes of

Hospital Arrival.

HF (Heart Failure)............ Discharge HF-1.

Instructions.

Evaluation of LVS HF-2.

Function.

ACEI or ARB for LVSD. HF-3.

Adult Smoking HF-4.

Cessation Advice/

Counseling.

PN (Pneumonia)................ Pneumococcal PN-2.

Vaccination.

Blood Cultures PN-3b.

Performed in the

Emergency Department

Prior to Initial

Antibiotic Received

in Hospital.

Adult Smoking PN-4.

Cessation Advice/

Counseling.

Initial Antibiotic PN-5c.

Received Within 6

Hours of Hospital

Arrival.

Initial Antibiotic PN-6.

Selection for

Community-Acquired

Pneumonia (CAP) in

Immunocompetent

Patients.

Influenza Vaccination PN-7.

SCIP (Surgical Care Prophylactic SCIP-Inf-1.

Improvement Project)--named Antibiotic Received

SIP for discharges prior to Within One Hour

July 2006 (3Q06). Prior to Surgical

Incision.

Prophylactic SCIP-Inf-2.

Antibiotic Selection

for Surgical

Patients.

Prophylactic SCIP-Inf-3.

Antibiotics

Discontinued Within

24 Hours After

Surgery End Time.

Cardiac Surgery SCIP-Inf-4.

Patients With

Controlled 6 A.M.

Postoperative Blood

Glucose.

Surgery Patients with SCIP-Inf-6.

Appropriate Hair

Removal.

Surgery Patients with SCIP-VTE-1.

Recommended Venous

Thromboembolism

Prophylaxis Ordered.

Surgery Patients Who SCIP-VTE-2.

Received Appropriate

Venous

Thromboembolism

Prophylaxis Within

24 Hours Prior to

Surgery to 24 Hours

After Surgery.

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[[Page 24178]]

SCIP-Cardiovascular-2 will be validated using data from

2nd and 3rd calendar quarter 2009 discharges. CMS adopted this measure

in the FY 2009 IPPS final rule and hospitals began submitting data for

this measure starting with 1st calendar quarter 2009 discharges (73 FR

48605). However, because we generally strive to provide hospitals with

ample notice before we add a new measure to the list of measures for

which we will validate data, we believe that 2nd quarter discharge data

is an appropriate validation starting point for this measure (these

data are not due to the QIO Clinical Warehouse until November 15,

2009).

We will continue using the design-specific estimate of the

variance for the confidence interval calculation, which, in this case,

is a stratified single stage cluster sample, with unequal cluster

sizes. (For reference, see Cochran, William G.: Sampling Techniques,

John Wiley & Sons, New York, chapter 3, section 3.12 (1977); and Kish,

Leslie.: Survey Sampling, John Wiley & Sons, New York, chapter 3,

section 3.3 (1964).) Each quarter is treated as a stratum for variance

estimation purposes.

b. Proposed Chart Validation Requirements and Methods for the FY 2012

Payment Determination and Subsequent Years

RHQDAPU program data are currently validated by re-abstracting on a

quarterly basis a random sample of five medical records for each

hospital. This quarterly sample generally results in an annual combined

sample of 20 patient records across four calendar quarters per

hospital, but because each sample is random, it might not include

medical records from each of the measure topics (for example, AMI,

SCIP, etc.). As a result, data submitted by a hospital for one or more

measure topics might not be validated for a given quarter or, in some

cases, for an entire year or longer.

In the FY 2009 IPPS proposed rule (73 FR 23658), we solicited

public comments on the impact of adding measures to the validation

process, as well as on modifications to the current validation process

that could improve the reliability and validity of the methodology. We

specifically requested input concerning the following:

Which of the measures or measure sets should be included

in the chart validation process for subsequent years?

What validation challenges are posed by the RHQDAPU

program measures and measure sets? What improvements could be made to

validation or reporting that might offset or otherwise address those

challenges?

Should CMS switch from its current quarterly validation

sample of five charts per hospital to randomly selecting a sample of

hospitals, and selecting more charts on an annual basis to improve the

reliability of hospital level validation estimates?

Should CMS select the validation sample by clinical topic

to ensure that all publicly reported measures are covered by the

validation sample?

In the FY 2009 IPPS final rule, we summarized and responded to

commenters' views on these issues and stated that we will consider the

issues raised by these commenters if we decide to make changes to the

RHQDAPU program chart validation methodology.

Our objective is to validate the accuracy of RHQDAPU program data

collected by hospitals using medical record abstraction. Accurate data

provide consumers with objective publicly reported information about

hospital quality for more informed decision making. Consistent with the

public comments we received in response to the FY 2009 IPPS proposed

rule (73 FR 23658-9) and discussed in the FY 2009 IPPS final rule (73

FR 48623), we believe that the methodology recommended in the CMS

Hospital Value-Based Purchasing Report to Congress is a promising

approach worth consideration in the RHQDAPU program. This approach is

designed to validate the accuracy of hospital reported quality measure

data, and is also directly applicable to validating RHQDAPU program

chart-abstracted quality data.

We recognize that hospitals need ample notification regarding

proposed changes to the current RHQDAPU program validation process. We

believe that the FY 2012 RHQDAPU program annual payment determination

is the earliest opportunity to make significant modifications to our

validation process.

Therefore, we are proposing the following modifications to the

RHQDAPU program validation methodology beginning with the FY 2012

payment determination. Specifically, we propose to do the following:

Randomly select on an annual basis 800 participating

hospitals that submitted chart-abstracted data for at least 100

discharges combined in the measure topics to be validated. To determine

whether a hospital meets this ``100 chart threshold,'' we will look to

the discharge data submitted by the hospital during the calendar year

three years prior to the fiscal year of the relevant payment

determination. For example, if the 100 case threshold applied for the

FY 2011 payment determination (which it will not), the applicable

measure topics would be AMI, HF, PN, and SCIP, and we would choose 800

hospitals that submitted discharge data for at least 100 cases combined

in these topics during calendar year 2008. If a hospital did not submit

discharge data for at least 100 cases in these topics during CY 2008,

we would not select the hospital for validation. We will announce the

topic areas that apply for the FY 2012 payment determination at a later

date, and we plan to select the first 800 hospitals in July 2010. We

will select hospitals for the FY 2012 validation if they meet the 100

chart threshold during CY 2009. We have proposed this 100-chart

threshold because we believe that it strikes the appropriate balance

between ensuring that the selected hospitals have a large enough

patient population to be able to submit sufficient data to allow us to

complete an accurate validation, while not requiring validation for

hospitals with a low number of submitted quarterly cases and relatively

unreliable measure estimates. Based on previously submitted data, we

estimate that 98 percent of participating RHQDAPU program hospitals

will meet this threshold and, thus, be eligible for validation. As

noted below, we are soliciting comments and suggestions on how we might

be able to target the remaining 2 percent of hospitals for validation.

Randomly validate for each of the 800 selected hospitals a

stratified sample each quarter of the validation period. Each quarterly

sample will include 12 cases, with at least one but no more than three

cases per topic for which chart-abstracted data was submitted by the

hospital. However, we recognize that some selected hospitals might not

have enough cases in all of the applicable topics to submit data (for

example, if they have 5 or fewer discharges in a topic area in a

quarter). For those hospitals, we would validate measures in only those

topic areas for which they have submitted data. We have proposed this

100-chart threshold because we believe that it strikes the appropriate

balance between ensuring that the selected hospitals have a large

enough patient population to be able to submit sufficient data to allow

us to complete an accurate validation, while not requiring validation

for hospitals with a low number of submitted quarterly cases and

relatively unreliable measure estimates.

For the FY 2012 payment determination, we will validate 1st

[[Continued on page 24179]]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

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[[pp. 24179-24228]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24178]]

[[Page 24179]]

calendar quarter 2010 through 3rd calendar quarter 2010 discharge data.

We are proposing to validate 3 quarters of data for FY 2012 in order to

provide hospitals with enough time to assess their medical record

documentation and abstraction practices, and to take necessary

corrective actions to improve these practices, before documenting their

1st calendar quarter 2010 discharges into medical records that may be

sampled as part of this proposed validation process.

Beginning with the FY 2013 payment determination, we propose

validating data submitted by hospitals during the four quarters that

make up the fiscal year that occurs two years prior to the year that

applies to the payment determination. For example, for FY 2013, we

would validate 4th calendar quarter 2010 through 3rd quarter 2011

discharge data. This lag between the time a hospital submits data and

the time we can validate that data is necessary because data is not due

to the QIO Clinical Warehouse until 4\1/2\ months after the end of each

quarter, and we need additional time to select hospitals and complete

the validation process.

We are proposing that the CDAC contractor will, each

quarter that applies to the validation, ask each of the 800 selected

hospitals to submit 12 randomly selected medical charts from which data

was abstracted and submitted by the hospital to the QIO Clinical

Warehouse. We note that, under our current requirements, hospitals must

begin submitting RHQDAPU program data starting with the first day of

the quarter following the date when the hospital registers to

participate in the program. For purposes of meeting this requirement,

we interpret the registration date to be the date that the hospital

submits a completed Notice of Participation form. As proposed

previously in this section, hospitals must also register with

QualityNet and identify a QualityNet Administrator who follows the

QualityNet registration process before submitting RHQDAPU program data.

In addition, we are proposing to continue the following timeline

with respect to CDAC contractor requests for paper medical records for

the purpose of validating RHQDAPU program data. Beginning with CDAC

requests for second calendar quarter 2009 paper medical records, the

CDAC will request paper copies of the randomly selected medical charts

from each hospital via certified mail, and the hospital will have 45

days from the date of the request (as documented on the request letter)

to submit the requested records to the CDAC. If the hospital does not

comply within 30 days, the CDAC will send a second certified letter to

the hospital, reminding the hospital that it must return paper copies

of the requested medical records within 45 calendar days following the

date of the initial CDAC medical record request. If the hospital still

does not comply, then the CDAC will assign a ``zero'' score to each

measure in each missing record.

Once the CDAC contractor receives the charts, it will re-

abstract the same data submitted by the hospitals and calculate the

percentage of matching RHQDAPU program measure numerators and

denominators for each measure within each chart submitted by the

hospital. Specifically, we will estimate the accuracy by calculating a

match rate percent agreement for all of the variables submitted in all

of the charts. For any selected record, a measure's numerator and

denominator can have two possible states, included or excluded,

depending on whether the hospital accurately included the cases in the

measure numerator(s) and denominator(s). We will count each measure in

a selected record as a match if the hospital submitted measure

numerator and denominator sets match the measure numerator and

denominator states independently abstracted by our contractor. For

example, one heart failure case from which data has been abstracted for

four RHQDAPU program chart-abstracted measures (that is, HF-1, HF-2,

HF-3, and HF-4) would receive a 75 percent match if three out of four

of the hospital-reported heart failure measure numerator and

denominator states matched the re-abstracted numerator and denominator

states. This proposed scoring approach is the same as recommended in

the CMS Hospital Value-Based Purchasing Report to Congress, and is

illustrated in further detail using an example in pages 83-4 of the

report (http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/

HospitalVBPPlanRTCFINALSUBMITTED2007.pdf). We believe that this

approach is appropriate, as supported by many commenters' support in

the FY 2009 IPPS final rule to our request for input about the RHQDAPU

program validation process (73 FR 48622-3).

Use, as we currently do, each selected case as a cluster

comprising one or multiple measures utilized in a validation score

estimate. Each selected case will have multiple measures included in

the validation score (for example, for the FY 2012 payment

determination, a heart failure record will include 4 heart failure

measures). Specifically, we propose to continue using the design-

specific estimate of the variance for the confidence interval

calculation, which, in this case, is a stratified single stage cluster

sample, with unequal cluster sizes. (For reference, see Cochran,

William G.: Sampling Techniques, John Wiley & Sons, New York, chapter

3, section 3.12 (1977); and Kish, Leslie: Survey Sampling, John Wiley &

Sons, New York, chapter 3, section 3.3 (1964).) Each quarter and

clinical topic is treated as a stratum for variance estimation

purposes.

We believe that the proposed clustering approach is a statistically

appropriate technique for calculating the annual validation confidence

interval. Since CMS will not be validating all hospital records, we

need to calculate a confidence interval that incorporates a potential

sampling error. Our clustering approach incorporates the degree of

correlation at the individual data record level, because our previous

validation experience indicates that hospital data mismatch errors tend

to be clustered in individual data records. CMS has used this

clustering since the inception of the RHQDAPU program validation

requirement to calculate variability estimates needed for calculating

confidence intervals (70 FR 47423).

Use the upper bound of a one-tailed 95 percent confidence

interval to estimate the validation score; and

Require all RHQDAPU program participating hospitals

selected for validation to attain at least a 75 percent validation

score per quarter to pass the validation requirement.

We believe that this proposal incorporates many of the principles

supported by the vast majority of commenters in response to our

solicitation for public comments in the FY 2009 IPPS proposed rule (73

FR 23658 through 23659). Specifically, we believe that the increased

annual sample size per hospital will provide more reliable estimates of

validation accuracy. The proposed sample size of 12 records per quarter

would provide a total of 36 records across the three sampled quarters

for the FY 2012 payment determination, and 48 records in subsequent

years. This estimate would improve the reliability of our validation

estimate, as compared to the current RHQDAPU program annual validation

sample of 20 cases per year. We also believe that modifying the

validation score to reflect measure numerator and denominator accuracy

will ensure that accurate data are posted on the Hospital Compare Web

site.

[[Page 24180]]

In addition, we believe that stratified quarterly samples by topic

will improve the feedback provided to hospitals. CMS would provide

validation feedback to hospitals about all sampled topics submitted by

the hospitals each quarter. Because all relevant data elements

submitted by the hospital must match the independently re-abstracted

data elements to count as a match, we have proposed to reduce the

passing threshold from 80 percent to 75 percent. We are proposing to

use a one-tail confidence interval to calculate the validation score

because we strongly believe that a one-tail test most appropriately

reflects the pass or fail dichotomous nature of the statistical test

regarding whether the confidence interval includes or is completely

above the 75 percent passing validation score.

We are also proposing to continue to allow hospitals that fail to

meet the passing threshold for the quarterly validation an opportunity

to appeal the validation results to their State QIO. QIOs are currently

tasked by CMS to provide education and technical assistance about

RHQDAPU program data abstraction and measures to hospitals, and the

quarterly validation appeals process will provide hospitals with an

opportunity to both appeal their quarterly results and receive

education free of charge from their State QIO. This State QIO quarterly

validation appeals process is independent of the proposed RHQDAPU

program reconsideration procedures for hospital reconsideration

requests involving validation for the FY 2010 payment update proposed

below in section V.A.9. of this proposed rule.

c. Possible Supplements to the Chart Validation Process for the FY 2013

Payment Determination and Subsequent Years

We also are soliciting public comment about criteria we could use

to target hospitals for validation in the future. These targeting

criteria could include abnormal data patterns identified by analyzing

hospital-submitted measure rates and counts for RHQDAPU program

measures. For example:

A high number of years a hospital was not randomly

selected for annual validation (for example, at least 5 years);

Consistently high measure denominator exclusion rates

resulting in unexpectedly low denominator counts;

Consistently high measure rates, relative to national

averages;

Small annual submission number of cases in previous years

resulting in hospital exclusion from RHQDAPU program validation sample;

Failing multiple previous years' RHQDAPU program

validations.

7. Data Accuracy and Completeness Acknowledgement Requirements for the

FY 2011 Payment Determination and Subsequent Years

For the FY 2011 payment determination and subsequent years, we are

proposing to require hospitals to electronically acknowledge on an

annual basis the completeness and accuracy of the data submitted for

the RHQDAPU program payment determination. Hospitals will be able to

submit this acknowledgement on the same Web page that they use to

submit data necessary to calculate the structural measures, and we

believe that this Web page will provide a secure vehicle for hospitals

to directly acknowledge that their information is complete and accurate

to the best of their knowledge. A single annual electronic

acknowledgement will provide us with explicit documentation

acknowledging that the hospital's data is accurate and complete, but

will not unduly burden hospitals. We note that commenters generally

supported the idea of electronic attestation in the FY 2009 IPPS final

rule (73 FR 48625) at the point of data submission to the QIO Clinical

Warehouse.

In addition, the Government Accountability Office (GAO) recommended

in a 2006 report (GAO-06-54) that hospitals self-report that their data

are complete and accurate. Therefore, for the FY 2011 payment

determination, we are proposing to require hospitals to electronically

acknowledge their data accuracy and completeness once between January

1, 2010, and August 15, 2010. Hospitals will acknowledge that all

information that is, or will be, submitted as required by the RHQDAPU

program for the FY 2011 payment determination is complete and accurate

to the best of their knowledge.

8. Public Display Requirements for the FY 2011 Payment Determination

and Subsequent Years

For the FY 2011 payment determination, we are proposing to

generally continue using the following existing requirements

implemented in previous years. Our continued goal for the chart

validation requirements is to validate the reliability of RHQDAPU

program chart-abstracted data. Accurate data are needed to calculate

accurate publicly reported quality measures that are posted on the

Hospital Compare Web site. We added the validation requirement in the

FY 2006 IPPS final rule (70 FR 47421 through 47422) to ensure that

hospitals submit reliable data for RHQDAPU program chart-abstracted

measures, based on our experience in FY 2005 that hospitals vastly

differed in their data reliability. We modified the validation

requirements in the FY 2008 IPPS final rule with comment period (72 FR

47366 and 47367) to update the RHQDAPU program list of validated

measures for FY 2008, and pooled multiple quarterly validation

estimates into a single annual estimate to improve reliability. We

modified these requirements to reflect the changing RHQDAPU list of

chart-abstracted measures and validate all available RHQDAPU program

data.

We note below the circumstances under which we are proposing to

modify a requirement. We are proposing to update the list of validated

RHQDAPU program measures for the FY 2011 payment determination to

incorporate changes to our list of required chart-abstracted RHQDAPU

program measures for CY 2009 discharges. These requirements, as well as

additional information on these requirements, will be posted on the

QualityNet Web site after we issue the FY 2010 IPPS final rule.

Section 1886(b)(3)(B)(viii)(VII) of the Act provides that the

Secretary shall establish procedures for making data submitted under

the RHQDAPU program available to the public. The RHQDAPU program

quality measures are posted on the Hospital Compare Web site (http://

www.hospitalcompare.hhs.gov). We require that hospitals sign a Notice

of Participation form when they first register to participate in the

RHQDAPU program. Once a hospital has submitted a form, the hospital is

considered to be an active RHQDAPU program participant until such time

as the hospital submits a withdrawal form to CMS (72 FR 47360).

Hospitals signing this form agree that they will allow CMS to publicly

report the quality measures included in the RHQDAPU program.

We will continue to display quality information for public viewing

as required by section 1886(b)(3)(B)(viii)(VII) of the Act. Before we

display this information, hospitals will be permitted to review their

information as recorded in the QIO Clinical Warehouse.

Currently, hospital campuses that share the same CCN must combine

data collection and submission across their multiple campuses (for both

clinical measures and HCAHPS). These measures are then publicly

reported on Hospital Compare as if they apply to a single hospital. We

estimate that approximately 5 to 10 percent of the hospitals reported

on the Hospital Compare Web site share CCNs. To

[[Page 24181]]

increase transparency in public reporting and improve the usefulness of

the Hospital Compare Web site, we propose note on the Web site

instances where publicly reported measures combine results from two or

more hospitals.

9. Proposed Reconsideration and Appeal Procedures for the FY 2010

Payment Determination

The general deadline for submitting a request for reconsideration

in connection with the FY 2010 payment determination is November 1,

2009. As discussed more fully below, we are proposing that all

hospitals submit a request for reconsideration and receive a decision

on that request before they can file an appeal with the Provider

Reimbursement Review Board (PRRB).

For the FY 2010 payment determination, we are proposing to continue

utilizing most of the same procedures that we utilized in FY 2009.

Under these proposed procedures, the hospital must--

Submit to CMS, via QualityNet, a Reconsideration Request

form (available on the QualityNet Web site) containing the following

information:

--Hospital CMS Certification number (CCN).

--Hospital Name.

--CMS-identified reason for failure (as provided in the CMS

notification of failure letter to the hospital).

--Hospital basis for requesting reconsideration. This must identify the

hospital's specific reason(s) for believing it met the RHQDAPU program

requirements and should receive the full FY 2010 IPPS annual payment

update.

--CEO contact information, including name, e-mail address, telephone

number, and mailing address (must include the physical address, not

just the post office box). We are proposing to no longer require that

the hospital's CEO sign the RHQDAPU program reconsideration request. We

have found that this requirement increases the burden for hospitals

because it prevents them from electronically submitting the RHQDAPU

program reconsideration request forms. In addition, to the extent that

a hospital can submit a request for reconsideration on-line, the burden

on our staff is reduced and, as a result, we can more quickly review

the request.

--QualityNet System Administrator contact information, including name,

e-mail address, telephone number, and mailing address (must include the

physical address, not just the post office box).

--Paper medical record requirement for reconsideration requests

involving validation. We are proposing that if a hospital asks us to

reconsider an adverse RHQDAPU program payment decision made because the

hospital failed the validation requirement, the hospital must submit

paper copies of all the medical records that it submitted to the CDAC

contractor each quarter for purposes of the validation. Hospitals must

submit this documentation to a CMS contractor, which will redact all

patient identifying information and forward the redacted copies to CMS.

The contractor will be a QIO support contractor, which has authority to

review patient level information under 42 CFR Part 480. We will post

the address where hospitals can ship the paper charts on the QualityNet

Web site after we issue the FY 2010 IPPS final rule. Hospitals

submitting a RHQDAPU program validation reconsideration request will

have all mismatched data reviewed by CMS, and not their State QIO. (As

discussed in section V.A.6.b. of this preamble, the State QIO is

available to conduct a quarterly validation appeal if so requested by a

hospital.)

For the FY 2010 payment determination, the RHQDAPU program data

that will be validated is 4th calendar quarter 2007 through 3rd quarter

calendar year 2008 discharge data, except for SCIP-Infection-4 and

Infection-6, which will be validated using 2nd and 3rd calendar quarter

2008 discharges (73 FR 48621-2). Hospitals must provide a written

justification for each appealed data element classified during the

validation process as a mismatch. We will review the data elements that

were labeled as mismatched, as well as the written justifications

provided by the hospitals, and make a decision on the reconsideration

request. As we mentioned above, we are proposing that all hospitals

submit a reconsideration request to CMS and receive a decision on that

request prior to submitting a PRRB appeal. We believe that the

reconsideration process is less costly for both CMS and hospitals, and

that this requirement will decrease the number of PRRB appeals by

resolving issues earlier in the appeals process.

Following receipt of a request for reconsideration, we will--

Provide an e-mail acknowledgement, using the contact

information provided in the reconsideration request, to the CEO and the

QualityNet Administrator that the request has been received.

Provide written notification to the hospital CEO, using

the contact information provided in the reconsideration request,

regarding our decision. We expect the process to take approximately 60

to 90 days from the reconsideration request due date of November 1,

2009.

If a hospital is dissatisfied with the result of a RHQDAPU program

reconsideration decision, the hospital may file a claim under 42 CFR

Part 405, Subpart R (a PRRB appeal). We are soliciting public comments

on the extent to which these proposed procedures will be less costly

for hospitals, and whether they will lead to fewer PRRB appeals.

10. RHQDAPU Program Withdrawal Deadlines

We are proposing to accept RHQDAPU program withdrawal forms for the

FY 2011 payment determination from hospitals until August 15, 2010. We

are proposing this deadline to provide CMS with sufficient time to

update the FY 2011 payment to hospitals starting on October 1, 2010. If

a hospital withdraws from the program for the FY 2011 payment

determination, it will receive a 2.0 percentage point reduction in its

FY 2011 annual payment update. We note that once a hospital has

submitted a Notice of Participation form, it is considered to be an

active RHQDAPU program participant until such time as the hospital

submits a withdrawal form to CMS.

11. Electronic Health Records

a. Background

Starting with the FY 2006 IPPS final rule, we have encouraged

hospitals to take steps toward the adoption of EHRs (also referred to

in previous rulemaking documents as electronic medical records) that

will allow for reporting of clinical quality data from the EHRs

directly to a CMS data repository (70 FR 47420 through 47421). We

encouraged hospitals that are implementing, upgrading, or developing

EHR systems to ensure that the technology obtained, upgraded, or

developed conforms to standards adopted by HHS. We suggested that

hospitals also take due care and diligence to ensure that the EHR

systems accurately capture quality data and that, ideally, such systems

provide point-of-care decision support that promotes optimal levels of

clinical performance.

In the FY 2008 IPPS final rule with comment period (72 FR 47366),

we responded to comments we received on EHRs and noted that CMS planned

to

[[Page 24182]]

continue participating in the American Health Information Community

(which has now sunset and is replaced by the National eHealth

Collaborative) and other entities to explore processes through which an

EHR could speed the collection of data and minimize the resources

necessary for quality reporting.

Recently, we initiated work directed toward enabling EHR submission

of quality measures through EHR standards development and adoption. We

are working under an inter-agency agreement between CMS and the Office

of the National Coordinator for Healthcare Information Technology (ONC)

to identify and harmonize standards for the EHR-based submission of

Emergency Department Throughput measures, Stroke measures, and Venous

Thromboembolism measures. These measures have received NQF endorsement

and are potential measures for future inclusion in the RHQDAPU program.

Pursuant to this agreement, the Healthcare Information Technology

Standards Panel (HITSP) has been tasked with harmonizing the EHR data

element standards for the measure sets. The work for these three

measure sets began in September 2008 and is due to be completed in a

little more than 1 year. It is expected that interoperable standards

will be developed and fully vetted by October 2009. When HITSP posts

the standards, we anticipate that EHR vendors will be able to code

their EHR systems with the new specifications and begin collecting this

data electronically. We expect that these standards will be provided to

its Certification Commission for Healthcare Information Technology

(CCHIT) for inclusion in the criteria for certification of inpatient

EHRs.

b. EHR Testing of Quality Measures Submission

As we have previously stated, we are interested in the reporting of

quality measures using EHRs, and we continue to encourage hospitals to

adopt and use EHRs that conform to industry standards. We believe that

the testing of EHR submission is an important and necessary step to

establish the ability of EHRs to report clinical quality measures and

the capacity of CMS to receive such data.

Through CMS' interagency agreement with ONC previously described,

the interoperable standards for EHR-based submission of the Emergency

Department (ED) Throughput, Stroke, and Venous Thromboembolism (VTE)

measures are scheduled to be finalized in late 2009 and will be

available for review and testing. We anticipate testing the components

required for the submission of clinical quality data extracted from

EHRs for these measures, and are exploring different mechanisms and

formats that will aid the submission process, as well as ensure that

the summary measure results extracted from the EHRs are reliable. When

the interoperable for EHR-based submission standards become available,

EHR vendors will be able to employ them in EHR systems and begin

testing how they facilitate the electronic collection of these data. We

intend to follow similar processes and procedures to those we are using

for the PQRI EHR testing being conducted as described in the CY 2009

Medicare Physician Fee Schedule final rule with comment period (73 FR

69828 through 69830).

We anticipate moving forward with testing CMS' technical ability to

accept data from EHRs for the ED, Stroke, and VTE measures as early as

July 1, 2010. Pursuant to the Paperwork Reduction Act, prior to the

beginning of testing EHR-based data submission, we will publish a

Federal Register notice seeking public comments on the process we

intend to follow to select EHR vendors/hospitals and the methodology we

plan to use for testing EHR-based data submissions.

The test measures described above are not currently required under

the RHQDAPU program. As long as that remains the case, EHR test data

that is received for these measures will not be used to make RHQDAPU

program payment decisions. In addition, the posting of the electronic

specifications for any particular measure should not be interpreted as

a signal that we intend to select the measure for inclusion in the

RHQDAPU program measure set.

We intend to select several EHR vendors/hospitals to develop and

test EHR clinical quality data submission. EHR vendors/hospitals that

wish to participate in the development and testing process will be able

to self-nominate by sending a letter of interest to: ``RHQDAPU Program

IT Testing Nomination'' Centers for Medicare and Medicaid Services,

Office of Clinical Standards and Quality, Quality Measurement and

Health Assessment Group, 7500 Security Boulevard, Mail Stop S3-02-01,

Baltimore, MD 21244-8532. The letter must be received by CMS by 6 p.m.,

E.S.T. on December 31, 2009. Vendors/hospitals will be selected based

on the following criteria: (1) They are able to submit clinical EHR

data using interoperability standards such as Cross Document Sharing

(XDS), Cross Community Access (XCA), Clinical Data Architecture (CDA),

and Health Level 7 Version 3 to a CMS-designated clinical data

repository; and (2) they have established or have applied for a

QualityNet account. More information regarding these capabilities will

be made available on the Hospital Quality Initiative section of the CMS

Web site at: www.cms.hhs.gov/HospitalQualityInits/. Preference may be

given to EHR vendors/hospitals that utilize EHRs that are currently

certified by the CCHIT, use the National Health Information Network

(NHIN), and/or utilize Health Information Technology Standards Panel

(HITSP)/Integrating the Healthcare Environment (IHE) standards.

EHR vendors/hospitals that would like to test the submission of

inpatient EHR data to the CMS-designated clinical data repository

should update their EHR products or otherwise ensure that those

products can capture and submit the necessary data elements identified

for an EHR-based submission once the standardized format has been

determined. We suggest that these entities begin submitting EHR data

promptly after CMS announces that the clinical data repository is ready

to accept such data so that problems that may complicate or preclude a

successful quality measure data submission can be corrected.

We welcome comments on this discussion of EHR-based data submission

testing.

c. HITECH Act EHR Provisions

On February 17, 2009, the President signed into law the ARRA,

Public Law 111-5. The HITECH Act (Title IV of Division B of the ARRA,

together with Title XIII of Division A of the ARRA), authorizes payment

incentives under Medicare for the adoption and use of certified EHR

technology beginning in FY 2011. Hospitals are eligible for these

payment incentives if they meet the following three requirements:

meaningful use of certified EHR technology; electronic exchange of

health information; and reporting on measures using certified EHR

technology (provided the Secretary has the capacity to receive such

information electronically). With respect to this requirement, under

section 1886(n)(3)(A)(ii) of the Act, as added by section 4102 of the

HITECH Act, the Secretary shall select measures, including clinical

quality measures, that hospitals must provide to CMS in order to be

eligible for the EHR incentive payments. With respect to the clinical

quality measures, section 1886(n)(3)(B)(i) of the Act requires the

Secretary to give preference to those clinical quality measures that

have been selected for the RHQDAPU program

[[Page 24183]]

under section 1886(b)(3)(B)(viii) of the Act or that have been endorsed

by the entity with a contract with the Secretary under section 1890(a)

of the Act. Any measures must be proposed for public comment prior to

their selection, except in the case of measures previously selected for

the RHQDAPU program under section 1886(b)(3)(B)(viii) of the Act.

Thus, the RHQDAPU program and the HITECH Act have important areas

of overlap and synergy with respect to the reporting of quality

measures using EHRs. We believe the financial incentives under the

HITECH Act for the adoption and meaningful use of certified EHR

technology by hospitals will encourage the adoption and use of

certified EHRs for the reporting of clinical quality measures under the

RHQDAPU program. Further, these efforts to test the submission of

quality data through EHRs may provide a foundation for establishing the

capacity of hospitals to send, and for CMS to receive, quality measures

via hospital EHRs for future RHQDAPU program measures. We again note

that the provisions in this proposed rule do not implicate or implement

any HITECH statutory provisions. Those provisions will be implemented

in a future rulemaking.

B. Sole Community Hospitals (SCHs) and Medicare-Dependent, Small Rural

Hospitals (MDHs): Budget Neutrality Adjustment Factors for FY 2002-

Based Hospital-Specific Rate for MDHs (Sec. 412.79(j))

1. Background

Under the IPPS, special payment protections are provided to a sole

community hospital (SCH). Section 1886(d)(5)(D)(iii) of the Act defines

an SCH as a hospital that, by reason of factors such as isolated

location, weather conditions, travel conditions, or absence of other

like hospitals (as determined by the Secretary) is the sole source of

inpatient hospital services reasonably available to Medicare

beneficiaries. The regulations that set forth the criteria that a

hospital must meet to be classified as an SCH are located at 42 CFR

412.92. Section 1886(d)(5)(D)(iii)(III) of the Act and the regulations

at Sec. 412.109 also provide that certain essential access community

hospitals (EACHs) will be treated as an SCH for payment purposes under

the IPPS.

Under the IPPS, separate special payment protections also are

provided to a Medicare-dependent, small rural hospital (MDH). Section

1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is

located in a rural area, has not more than 100 beds, is not an SCH, and

has a high percentage of Medicare discharges (not less than 60 percent

of its inpatient days or discharges in its 1987 cost reporting year or

in two of its most recent three settled Medicare cost reporting years).

The regulations that set forth the criteria that a hospital must meet

to be classified as an MDH are located at 42 CFR 412.108.

Although SCHs and MDHs are paid under special payment

methodologies, they are still paid under section 1886(d) of the Act.

Like all IPPS hospitals paid under section 1886(d) of the Act, SCHs and

MDHs are paid for their discharges based on the DRG weights calculated

under section 1886(d)(4) of the Act.

For SCHs, effective with hospital cost reporting periods beginning

prior to January 1, 2009, section 1886(d)(5)(D)(i) of the Act (as

amended by section 6003(e) of Pub. L. 101-239 (OBRA 1989)) and section

1886(b)(3)(I) of the Act (as added by section 405 of Public Law 106-113

(BBRA 1999) and further amended by section 213 of Public Law 106-554

(BIPA 2000) provide that SCHs are paid based on whichever of four

statutorily specified rates (listed below) yields the greatest

aggregate payment to the hospital for the cost reporting period. For

cost reporting periods beginning on or after January 1, 2009, section

122 of Public Law 110-275 (MIPPA 2008) further amended the Act to

specify that SCHs will be paid based on a FY 2006 hospital-specific

rate (that is, based on their updated costs per discharge from their

12-month cost reporting period beginning during Federal fiscal year

2006), if this results in the greatest payment to the SCH. Therefore,

SCHs are paid based on whichever of the following rates yields the

greatest aggregate payment to the hospital for the cost reporting

period:

The Federal rate applicable to the hospital;

The updated hospital-specific rate based on FY 1982 costs

per discharge;

The updated hospital-specific rate based on FY 1987 costs

per discharge;

The updated hospital-specific rate based on FY 1996 costs

per discharge; or

The updated hospital-specific rate based on FY 2006 costs

per discharge.

For purposes of payment to SCHs for which the FY 1996 hospital-

specific rate yields the greatest aggregate payment, payments for

discharges during FYs 2001, 2002, and 2003 were based on a blend of the

FY 1996 hospital-specific rate and the greater of the Federal rate or

the updated FY 1982 or FY 1987 hospital-specific rate. For discharges

during FY 2004 and subsequent fiscal years, payments based on the FY

1996 hospital-specific rate are based on 100 percent of the updated FY

1996 hospital-specific rate.

Through and including FY 2006, under section 1886(d)(5)(G) of the

Act, MDHs are paid based on the Federal rate or, if higher, the Federal

rate plus 50 percent of the amount by which the Federal rate is

exceeded by the updated hospital-specific rates based on FY 1982 or FY

1987 costs per discharge, whichever of these hospital-specific rates is

higher. Section 5003(b) of Public Law 109-171 (DRA 2005) amended

section 1886(d)(5)(G) of the Act to provide that, for discharges

occurring on or after October 1, 2006, MDHs are paid based on the

Federal rate or, if higher, the Federal rate plus 75 percent of the

amount by which the Federal rate is exceeded by the updated hospital-

specific rate based on FY 1982, FY 1987, or FY 2002 costs per

discharge, whichever of these hospital-specific rates is the highest.

Unlike SCHs, MDHs do not have the option to use their FY 1996 hospital-

specific rate.

For each cost reporting period, the fiscal intermediary or MAC

determines which of the payment options will yield the highest

aggregate payment. Interim payments are automatically made at the

highest rate using the best data available at the time the fiscal

intermediary or MAC makes the determination. However, it may not be

possible for the fiscal intermediary or MAC to determine in advance

precisely which of the rates will yield the highest aggregate payment

by year's end. In many instances, it is not possible to forecast the

outlier payments, or the amount of the DSH adjustment or the IME

adjustment, all of which are applicable only to payments based on the

Federal rate and not to payments based on the hospital-specific rate.

The fiscal intermediary or MAC makes a final adjustment at the close of

the cost reporting period after it determines precisely which of the

payment rates would yield the highest aggregate payment to the

hospital.

If a hospital disagrees with the fiscal intermediary's or the MAC's

determination regarding the final amount of program payment to which it

is entitled, it has the right to appeal the fiscal intermediary's or

the MAC's decision in accordance with the procedures set forth in 42

CFR Part 405, Subpart R, which govern provider payment determinations

and appeals.

2. FY 2002-Based Hospital-Specific Rate

Acute care hospitals, including MDHs and SCHs, are paid under the

IPPS. As mentioned earlier, under the special

[[Page 24184]]

payment methodologies for MDHs and SCHs, Medicare payments per

discharge are made based on DRG weights, just like all other acute care

hospitals paid under the IPPS. (We note that the MS-DRGs are currently

used under the IPPS, effective beginning in FY 2008.) As discussed

above, although the payment formulas for MDHs and SCHs differ slightly,

it is common to both types of hospitals that they may be paid based on

an updated hospital-specific rate determined from their costs per

discharge in a specified base year.

Section 1886(d)(4)(C)(iii) of the Act requires that aggregate IPPS

payments be projected to neither increase nor decrease as a result of

the annual changes to the DRG classifications and weighting factors.

Beginning in FY 1994, in applying the current year's budget neutrality

adjustment factor to both the standard Federal rate and hospital

specific rates, we do not remove the prior years' budget neutrality

adjustment factors when applying the current year budget neutrality

adjustment factor to assure that estimated aggregate payments after the

DRG changes are equal to estimated aggregate payments prior to the

changes (48 FR 46345). As we explained, if we were to remove the prior

year adjustment(s), we would not satisfy this condition. As we have

previously explained (for example, in the FY 2006 IPPS final rule (70

FR 47429)), all section 1886(d) hospitals, including hospitals that are

paid based on a hospital-specific rate, are subject to a DRG budget

neutrality adjustment factor. As is the case for all other IPPS

hospitals, these hospitals are paid based on DRG classification and

weighting factors that must be considered when we determine whether

aggregate IPPS payments are projected to increase or decrease as a

result of the annual changes to the DRG classifications and weighting

factors.

In order to comply with the statutory requirement that the DRG

changes be budget neutral, we compute a budget neutrality adjustment

factor based on a comparison of estimated aggregate payments using the

current year's relative weights and factors to aggregate payments using

the prior year's relative weights and factors. This budget neutrality

adjustment factor is then applied to the standardized per discharge

payment amounts (that is, the Federal rates and the hospital-specific

rates). Cumulative budget neutrality factors, beginning with the

adjustment factor for FY 1993, apply to all rebased hospital-specific

rate amounts derived from base years later than FY 1993. As discussed

in the FY 2001 IPPS proposed rule (55 FR 19466), we normalize DRG

weights by an adjustment factor in order to ensure that the average

case weight after recalibration is equal to the average case weight

prior to recalibration. While this adjustment is intended to ensure

that recalibration does not affect total payments to hospitals under

section 1886(d) of the Act, our analysis has indicated that the

normalization adjustment does not achieve budget neutrality with

respect to aggregate payments to hospitals under section 1886(d) of the

Act. Thus, in order to comply with the requirement of section

1886(d)(4)(C)(iii) of the Act that the DRG reclassification changes and

recalibration of the relative weights be budget neutral, we also

compute a budget neutrality adjustment factor that applies to both the

standardized amounts and the hospital-specific rates. This budget

neutrality adjustment ensures that the recalibration process does not

inadvertently increase total payments to hospitals. If we were to

remove this budget neutrality adjustment factor for years prior to the

base year, we believe the normalized DRG weights applied to the

hospital-specific amounts would be artificially high, thus resulting in

higher aggregate payments than permitted under the statute.

Section 1886(b)(3)(I) of the Act (as added by section 405 of Pub.

L. 106-113 (BBRA 1999) and further amended by section 213 of Public Law

106-554 (BIPA 2000)) contains a provision for SCHs to rebase their

hospital-specific rate using the hospital's FY 1996 cost per discharge

data. Specifically, beginning in FY 2001, SCHs can use their allowable

FY 1996 operating costs for inpatient hospital services as the basis

for their hospital-specific rate rather than only their FY 1982 or FY

1987 costs, if using FY 1996 costs would result in higher payments.

Effective for cost reporting periods beginning on or after January 1,

2009, SCHs will be paid based on their hospital-specific rate using FY

2006 costs, if this rate yields higher payments (as provided for under

section 122 of Pub. L. 110-275 (MIPPA 2008)). For the reasons explained

above, the instructions for implementing both the FY 1996 and FY 2006

SCH rebasing provisions direct the fiscal intermediary or MAC to apply

cumulative budget neutrality adjustment factors to account for DRG

changes since FY 1993 in determining an SCH's hospital-specific rate

based on either FY 1996 or FY 2006 cost data. (The FY 1996 SCH rebasing

provision was implemented in Transmittal A-00-66 (Change Request 1331)

dated September 18, 2000, and the FY 2006 SCH rebasing provision was

implemented in a Joint Signature Memorandum (JSM/TDL-09052), dated

November 17, 2008.)

As stated previously, section 5003(b) of Public Law 109-171 (DRA

2005) allows MDHs to use the hospital's FY 2002 costs per discharge

(that is, the FY 2002 updated hospital-specific rate) for discharges

occurring on or after October 1, 2006, if that results in a higher

payment. To implement this provision, CMS issued Transmittal 1067

(Change Request 5276 dated September 25, 2006) with instructions to

fiscal intermediaries to determine and update the FY 2002 hospital-

specific rate for qualifying MDHs. To calculate an MDH's FY 2002

hospital-specific rate and update it to FY 2007, the instructions

directed fiscal intermediaries to apply cumulative budget adjustment

factors for FYs 2003 through 2007. However, the instructions did not

include the cumulative budget neutrality adjustment factor to account

for changes in the DRGs from FYs 1993 through 2002. Consequently, any

MDH that has been paid based on its FY 2002 hospital-specific rate

since FY 2007 was paid based on a hospital-specific rate that was

computed inconsistent with CMS' stated policy of applying a cumulative

budget neutrality adjustment factor to account for DRG changes as a

result of annual updates. As a result, effective beginning in FY 2007,

any MDH that was paid based on its FY 2002 hospital-specific rate

(calculated in accordance with the instructions provided in Transmittal

1067) has been paid based on a hospital-specific rate that failed to

include a cumulative budget neutrality adjustment factor to account for

DRG changes from FYs 1993 through 2002 (a cumulative budget neutrality

adjustment factor of 0.982557 (or about -1.74 percent)), in addition to

the cumulative budget neutrality adjustment factors applied for FYs

2003 through 2007 that have already been applied as specified in the

implementing instructions. In order to conduct a meaningful comparison

between payments under the Federal rate, which is adjusted by the

cumulative budget neutrality factor, and payments based on the

hospital-specific rate, consistent with our established policy of

applying a cumulative budget neutrality adjustment factor to account

for DRG changes since FY 1993, for discharges beginning on or after

October 1, 2009, we will include the cumulative budget neutrality

adjustment factors for the DRG changes from FYs 1993 through 2002 in

addition to the cumulative

[[Page 24185]]

budget neutrality adjustment factors for FYs 2003 forward. The

cumulative budget neutrality adjustment factor of 0.982557 is

calculated as the product of the following budget neutrality adjustment

factors to account for DRG changes from FYs 1993 through 2002: 0.999851

for FY 1993; 0.999003 for FY 1994; 0.998050 for FY 1995; 0.999306 for

FY 1996; 0.998703 for FY 1997; 0.997731 for FY 1998; 0.998978 for FY

1999; 0.997808 for FY 2000; 0.997174 for FY 2001; and 0.995821 for FY

2002.

We considered applying a factor of 0.982557 to any MDH's FY 2002

hospital-specific rate to account for the cumulative budget neutrality

adjustment for DRG changes from FYs 1993 through 2002, either effective

for discharges occurring on or after October 1, 2006 (the initial

effective date of the FY 2002 rebasing) or, alternatively, effective

upon the issuance of the correction. However, consistent with the

prospective nature of the rates under the IPPS, we are applying the

adjustment on a prospective basis only, effective for discharges

occurring on or after October 1, 2009 (FY 2010). This effective date

would give affected MDHs sufficient notice of the change to their

hospital-specific rate. We estimate that approximately 50 MDHs would be

affected by the application of the cumulative budget neutrality

adjustment for DRG changes from FYs 1993 through 2002. Based on the

current cumulative budget neutrality adjustment factor of 0.982557 to

account for DRG changes from FYs 1993 through 2002, we estimate that,

in some instances, application of the cumulative budget neutrality

adjustment factor would lower the hospital-specific rate to the point

that the Federal rate would result in higher payments.

C. Rural Referral Centers (RRCs) (Sec. 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the

regulations at Sec. 412.96 set forth the criteria that a hospital must

meet in order to qualify under the IPPS as an RRC. For discharges

occurring before October 1, 1994, RRCs received the benefit of payment

based on the other urban standardized amount rather than the rural

standardized amount (as discussed in the FY 1993 IPPS final rule (59 FR

45404 through 45409). Although the other urban and rural standardized

amounts are the same for discharges occurring on or after October 1,

1994, RRCs continue to receive special treatment under both the DSH

payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108-173 raised the DSH adjustment for

RRCs such that they are not subject to the 12-percent cap on DSH

payments that is applicable to other rural hospitals. RRCs are also not

subject to the proximity criteria when applying for geographic

reclassification. In addition, they do not have to meet the requirement

that a hospital's average hourly wage must exceed the average hourly

wage of the labor market area where the hospital is located by a

certain percentage.

Section 4202(b) of Public Law 105-33 states, in part, ``[a]ny

hospital classified as an RRC by the Secretary \* \* \* for fiscal year

1991 shall be classified as such an RRC for fiscal year 1998 and each

subsequent year.'' In the August 29, 1997 IPPS final rule with comment

period (62 FR 45999), CMS reinstated RRC status for all hospitals that

lost the status due to triennial review or MGCRB reclassification.

However, CMS did not reinstate the status of hospitals that lost RRC

status because they were now urban for all purposes because of the OMB

designation of their geographic area as urban. However, subsequently,

in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that

we were revisiting that decision. Specifically, we stated that we would

permit hospitals that previously qualified as an RRC and lost their

status due to OMB redesignation of the county in which they are located

from rural to urban to be reinstated as an RRC. Otherwise, a hospital

seeking RRC status must satisfy all of the other applicable criteria.

We used the definitions of ``urban'' and ``rural'' specified in Subpart

D of 42 CFR Part 412. One of the criteria under which a hospital may

qualify as an RRC is to have 275 or more beds available for use (Sec.

412.96(b)(1)(ii)). A rural hospital that does not meet the bed size

requirement can qualify as an RRC if the hospital meets two mandatory

prerequisites (a minimum CMI and a minimum number of discharges), and

at least one of three optional criteria (relating to specialty

composition of medical staff, source of inpatients, or referral

volume). (We refer readers to Sec. 412.96(c)(1) through (c)(5) and the

September 30, 1988 Federal Register (53 FR 38513).) With respect to the

two mandatory prerequisites, a hospital may be classified as an RRC

if--

The hospital's CMI is at least equal to the lower of the

median CMI for urban hospitals in its census region, excluding

hospitals with approved teaching programs, or the median CMI for all

urban hospitals nationally; and

The hospital's number of discharges is at least 5,000 per

year, or, if fewer, the median number of discharges for urban hospitals

in the census region in which the hospital is located. (The number of

discharges criterion for an osteopathic hospital is at least 3,000

discharges per year, as specified in section 1886(d)(5)(C)(i) of the

Act.)

1. Case-Mix Index

Section 412.96(c)(1) provides that CMS establish updated national

and regional CMI values in each year's annual notice of prospective

payment rates for purposes of determining RRC status. The methodology

we used to determine the national and regional CMI values is set forth

in the regulations at Sec. 412.96(c)(1)(ii). The proposed national

median CMI value for FY 2010 includes data from all urban hospitals

nationwide, and the proposed regional values for FY 2010 are the median

CMI values of urban hospitals within each census region, excluding

those hospitals with approved teaching programs (that is, those

hospitals that train residents in an approved GME program as provided

in Sec. 413.75). These proposed values are based on discharges

occurring during FY 2008 (October 1, 2007 through September 30, 2008),

and include bills posted to CMS' records through December 2008.

We are proposing that, in addition to meeting other criteria, if

rural hospitals with fewer than 275 beds are to qualify for initial RRC

status for cost reporting periods beginning on or after October 1,

2009, they must have a CMI value for FY 2008 that is at least--

1.4667; or

The median CMI value (not transfer-adjusted) for urban

hospitals (excluding hospitals with approved teaching programs as

identified in Sec. 413.75) calculated by CMS for the census region in

which the hospital is located.

The proposed median CMI values by region are set forth in the

following table:

------------------------------------------------------------------------

Case-mix

Region index value

------------------------------------------------------------------------

1. New England (CT, ME, MA, NH, RI, VT).................... 1.2609

2. Middle Atlantic (PA, NJ, NY)............................ 1.2993

3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)..... 1.4159

4. East North Central (IL, IN, MI, OH, WI)................. 1.4013

5. East South Central (AL, KY, MS, TN)..................... 1.3377

6. West North Central (IA, KS, MN, MO, NE, ND, SD)......... 1.4010

7. West South Central (AR, LA, OK, TX)..................... 1.4667

8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)............... 1.5233

[[Page 24186]]

9. Pacific (AK, CA, HI, OR, WA)............................ 1.4390

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The preceding numbers will be revised in the FY 2010 IPPS final

rule to the extent required to reflect the updated FY 2008 MedPAR file,

which will contain data from additional bills received through March

2009.

Hospitals seeking to qualify as RRCs or those wishing to know how

their CMI value compares to the criteria should obtain hospital-

specific CMI values (not transfer-adjusted) from their fiscal

intermediary or MAC. Data are available on the Provider Statistical and

Reimbursement (PS&R) System. In keeping with our policy on discharges,

these CMI values are computed based on all Medicare patient discharges

subject to the IPPS MS-DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national

and regional numbers of discharges in each year's annual notice of

prospective payment rates for purposes of determining RRC status. As

specified in section 1886(d)(5)(C)(ii) of the Act, the national

standard is set at 5,000 discharges. We are proposing to update the

regional standards based on discharges for urban hospitals' cost

reporting periods that began during FY 2007 (that is, October 1, 2006

through September 30, 2007), which were the latest cost report data

available at the time this proposed rule was developed.

Therefore, we are proposing that, in addition to meeting other

criteria, a hospital, if it is to qualify for initial RRC status for

cost reporting periods beginning on or after October 1, 2009, must have

as the number of discharges for its cost reporting period that began

during FY 2007 a figure that is at least--

5,000 (3,000 for an osteopathic hospital); or

The median number of discharges for urban hospitals in the

census region in which the hospital is located, as indicated in the

following table.

------------------------------------------------------------------------

Number of

Region discharges

------------------------------------------------------------------------

1. New England (CT, ME, MA, NH, RI, VT).................... 8,329

2. Middle Atlantic (PA, NJ, NY)............................ 10,655

3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)..... 10,038

4. East North Central (IL, IN, MI, OH, WI)................. 9,262

5. East South Central (AL, KY, MS, TN)..................... 6,311

6. West North Central (IA, KS, MN, MO, NE, ND, SD)......... 8,764

7. West South Central (AR, LA, OK, TX)..................... 6,222

8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)............... 10,452

9. Pacific (AK, CA, HI, OR, WA)............................ 8,763

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These numbers will be revised in the FY 2010 IPPS final rule based

on the latest available cost report data.

We note that the median number of discharges for hospitals in each

census region is greater than the national standard of 5,000

discharges. Therefore, 5,000 discharges is the minimum criterion for

all hospitals.

We reiterate that, if an osteopathic hospital is to qualify for RRC

status for cost reporting periods beginning on or after October 1,

2009, the hospital would be required to have at least 3,000 discharges

for its cost reporting period that began during FY 2007.

D. Indirect Medical Education (IME) Adjustment (Sec. 412.105)

1. Background

Section 1886(d)(5)(B) of the Act provides for an additional payment

amount under the IPPS for hospitals that have residents in an approved

graduate medical education (GME) program in order to reflect the higher

indirect patient care costs of teaching hospitals relative to

nonteaching hospitals. The regulations regarding the calculation of

this additional payment, known as the indirect medical education (IME)

adjustment, are located at Sec. 412.105.

Public Law 105-33 (BBA 1987) established a limit on the number of

allopathic and osteopathic residents that a hospital may include in its

full-time equivalent (FTE) resident count for direct GME and IME

payment purposes. Under section 1886(h)(4)(F) of the Act, for cost

reporting periods beginning on or after October 1, 1997, a hospital's

unweighted FTE count of residents for purposes of direct GME may not

exceed the hospital's unweighted FTE count for its most recent cost

reporting period ending on or before December 31, 1996. Under section

1886(d)(5)(B)(v) of the Act, a similar limit on the FTE resident count

for IME purposes is effective for discharges occurring on or after

October 1, 1997.

2. IME Adjustment Factor for FY 2010

The IME adjustment to the MS-DRG payment is based in part on the

applicable IME adjustment factor. The IME adjustment factor is

calculated by using a hospital's ratio of residents to beds, which is

represented as r, and a formula multiplier, which is represented as c,

in the following equation: c x [{1 + r{time} \.405\ - 1]. The formula

is traditionally described in terms of a certain percentage increase in

payment for every 10-percent increase in the resident-to-bed ratio.

Section 502(a) of Public Law 108-173 modified the formula

multiplier (c) to be used in the calculation of the IME adjustment.

Prior to the enactment of Public Law 108-173, the formula multiplier

was fixed at 1.35 for discharges occurring during FY 2003 and

thereafter. In the FY 2005 IPPS final rule, we announced the schedule

of formula multipliers to be used in the calculation of the IME

adjustment and incorporated the schedule in our regulations at Sec.

412.105(d)(3)(viii) through (d)(3)(xii). Section 502(a) modifies the

formula multiplier beginning midway through FY 2004 and provides for a

new schedule of formula multipliers for FYs 2005 and thereafter as

follows:

For discharges occurring on or after April 1, 2004, and

before October 1, 2004, the formula multiplier is 1.47.

For discharges occurring during FY 2005, the formula

multiplier is 1.42.

For discharges occurring during FY 2006, the formula

multiplier is 1.37.

For discharges occurring during FY 2007, the formula

multiplier is 1.32.

For discharges occurring during FY 2008 and fiscal years

thereafter, the formula multiplier is 1.35.

Accordingly, for discharges occurring during FY 2010, the formula

multiplier is 1.35. We estimate that application of this formula

multiplier for the FY 2010 IME adjustment will result in an increase in

IPPS payment of 5.5 percent for every approximately 10-percent increase

in the hospital's resident-to-bed ratio.

3. IME-Related Proposed Changes in Other Sections of This Proposed Rule

We refer readers to section V.E.2. and 4. of the preamble of this

proposed rule for a discussion of proposed changes to the policies for

counting beds and patient days in relation to the calculations for the

IME adjustment at Sec. 412.105(b) and the DSH payment adjustment at

Sec. 412.106(a)(1)(ii). The regulations relating to the DSH payment

adjustment at Sec. 412.106(a)(1)(i) cross-reference the IME regulation

at Sec. 412.105(b), which specifies how the number of beds in a

hospital is determined for purposes of calculating a teaching

hospital's IME adjustment. Specifically, we are proposing to change

[[Page 24187]]

our policies with respect to counting bed days for patients receiving

observation services.

We also refer readers to section V.G.2. of the preamble of this

proposed rule for a discussion of our proposed clarification of the

definition of a new medical residency training program for purposes of

Medicare direct GME payment. This proposed clarification would also

apply for purposes of IME payment and could affect IME FTE resident cap

adjustments for new medical residency training programs.

E. Payment Adjustment for Medicare Disproportionate Share Hospitals

(DSHs) (Sec. 412.106)

1. Background

Section 1886(d)(5)(F) of the Act provides for additional Medicare

payments to subsection (d) hospitals that serve a significant

disproportionate number of low-income patients. The Act specifies two

methods by which a hospital may qualify for the Medicare

disproportionate share hospital (DSH) adjustment. Under the first

method, hospitals that are located in an urban area and have 100 or

more beds may receive a Medicare DSH payment adjustment if the hospital

can demonstrate that, during its cost reporting period, more than 30

percent of its net inpatient care revenues are derived from State and

local government payments for care furnished to needy patients with low

incomes. This method is commonly referred to as the ``Pickle method.''

The second method for qualifying for the DSH adjustment, which is the

most common, is based on a complex statutory formula under which the

DSH payment adjustment is based on the hospital's geographic

designation, the number of beds in the hospital, and the level of the

hospital's disproportionate patient percentage (DPP). A hospital's DPP

is the sum of two fractions: the ``Medicare fraction'' and the

``Medicaid fraction.'' The Medicare fraction is computed by dividing

the number of the hospital's inpatient days that are furnished to

patients who were entitled to both Medicare Part A (including patients

who are enrolled in a Medicare Advantage (Part C) plan) and

Supplemental Security Income (SSI) benefits by the hospital's total

number of patient days furnished to patients entitled to benefits under

Medicare Part A (including patients who are enrolled in a Medicare

Advantage (Part C) plan). The Medicaid fraction is computed by dividing

the hospital's number of inpatient days furnished to patients who, for

such days, were eligible for Medicaid, but were not entitled to

benefits under Medicare Part A, by the hospital's total number of

inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the DSH

statutory references (under section 1886(d)(5)(F) of the Act) to

``days'' apply only to inpatient days. Regulations located at 42 CFR

412.106 govern the Medicare DSH payment adjustment and specify how the

DPP is calculated as well as how beds and patient days are counted in

determining the Medicare DSH payment adjustment. Under Sec.

412.106(a)(1)(i), the number of beds for the Medicare DSH payment

adjustment is determined in accordance with bed counting rules for the

IME adjustment under Sec. 412.105(b).

In section V.E.4. of this preamble, we are combining our discussion

of proposed changes to the policies for counting beds in relation to

the calculations for the IME adjustment at Sec. 412.105(b) and the DSH

payment adjustment at Sec. 412.106(a)(1)(ii) because the underlying

concepts are similar and we believe they should generally be

interpreted in a consistent manner for both purposes. Specifically, we

are proposing to change our policies with respect to counting patient

days and bed days for patients receiving observation services.

2. Proposed Policy Change Relating to the Inclusion of Labor and

Delivery Patient Days in the Medicare DSH Calculation

a. Background

As discussed in the FY 2004 IPPS final rule (68 FR 45419 through

45420), prior to December 1991, Medicare's policy on counting days for

purposes of allocating costs on the cost report and for purposes of the

DSH payment adjustment for maternity patients was to count an inpatient

day for an admitted maternity patient in a labor and delivery room at

the census-taking hour. This pre-December 1991 policy is consistent

with current Medicare policy for counting days for admitted patients in

any other ancillary department at the census-taking hour. However,

based on decisions in a number of Federal Courts of Appeal, including

the United States Court of Appeals for the District of Columbia

Circuit, relating to Medicare's policy for allocating costs, the policy

regarding the counting of inpatient days for maternity patients was

revised to reflect our current policy for purposes of both cost

allocation and the DSH calculation.

Under the existing regulations at Sec. 412.106(a)(1)(ii)(B),

patient days associated with beds used for ancillary labor and delivery

are excluded from the Medicare DSH calculation. This policy, in part,

is based on cost allocation rules (that is, rules for counting days for

admitted patients in ancillary and routine cost centers for purposes of

allocating costs on the Medicare cost report). In particular, section

2205.2 of the Provider Reimbursement Manual (PRM) provides the

following: ``a maternity patient in the labor/delivery room ancillary

area at midnight is included in the census of the inpatient routine

(general or intensive) care area only if the patient has occupied an

inpatient routine bed at some time since admission. No days of

inpatient routine care are counted for a maternity inpatient who is

discharged (or dies) without ever occupying an inpatient routine bed.

However, once a maternity patient has occupied an inpatient routine

bed, at each subsequent census the patient is included in the census of

the inpatient routine care area to which assigned even if the patient

is located in an ancillary area (labor/delivery room or another

ancillary area) at midnight. In some cases, a maternity patient may

occupy an inpatient bed only on the day of discharge, where the day of

discharge differs from the day of admission. For purposes of

apportioning the cost of inpatient routine care, this single day of

routine care is counted as the day of admission (to routine care) and

discharge and, therefore, is counted as one day of inpatient routine

care.''

In applying the rules discussed above, if, for example, a Medicaid

patient is in the labor room at the census-taking hour and has not yet

occupied a routine inpatient bed, the day would not be counted as an

inpatient day in the numerator or the denominator of the Medicaid

fraction of the Medicare DPP. If, instead, the same patient were in the

labor room at the census-taking hour, but had first occupied a routine

inpatient bed, the day would be counted as an inpatient patient day in

both the numerator and the denominator of the Medicaid fraction of the

Medicare DPP for purposes of the DSH payment adjustment (and for

apportioning the cost of routine care on the Medicare cost report).

We further clarified this policy in the FY 2004 IPPS final rule (68

FR 45419 through 45420), given that hospitals had increasingly begun

redesigning their maternity areas from separate labor and delivery

rooms and postpartum rooms to single multipurpose labor, delivery, and

postpartum (LDP) rooms. In order to appropriately track the days and

costs associated with LDP rooms under our existing Medicare DSH policy,

we stated

[[Page 24188]]

that it was necessary to apportion them between the labor and delivery

cost center, which is an ancillary cost center, and the routine adults

and pediatrics cost center (68 FR 45420). This is done by determining

the proportion of a patient's stay in the LDP room that is associated

with the patient receiving ancillary services (labor and delivery), as

opposed to routine adult and pediatric services (postpartum).

Therefore, under the current policy, days associated with labor and

delivery services furnished to patients who did not occupy a routine

bed prior to occupying an ancillary labor and delivery bed before the

census-taking hour are not included as inpatient days for purposes of

the DSH calculation. This policy is applicable whether the hospital

maintains separate labor and delivery rooms and postpartum rooms, or

whether it maintains ``maternity suites'' in which labor, delivery, and

postpartum services all occur in the same bed. However, in the latter

case, patient days are counted proportionally based on the proportion

of (routine/ancillary) services furnished. (We refer readers to the

example provided in the FY 2004 IPPS final rule (68 FR 45420) that

describes how routine and ancillary days are allocated under this

policy.)

b. Proposed Policy Change

Upon further examination of our existing policy on counting patient

days, we no longer believe that it is appropriate to apply the cost

allocation rules for purposes of counting labor and delivery patient

days in the Medicare DSH calculation. That is, we believe that even if

a particular labor and delivery patient day is not included in the

inpatient routine care census-taking for purposes of apportioning

routine costs, it may still reasonably be considered to be an inpatient

day for purposes of determining the DPP, provided that the unit or ward

in which the labor and delivery bed is located is generally providing

services that are payable under the IPPS. In general, we believe that

labor and delivery patient days (regardless of whether they are

associated with patients who occupied a routine bed prior to occupying

an ancillary labor and delivery bed) are generally payable under the

IPPS. Therefore, we believe that such patient days should be included

in the DPP as inpatient days once the patient has been admitted to the

hospital an as inpatient. Accordingly, for cost reporting periods

beginning on or after October 1, 2009, we are proposing to change our

existing policy regarding patient days to include, in the DPP

calculation, patient days associated with maternity patients who were

admitted as inpatients and were receiving ancillary labor and delivery

services at the time the inpatient routine census is taken, regardless

of whether the patient occupied a routine bed prior to occupying a bed

in a distinct ancillary labor and delivery room and regardless of

whether the patient occupied a routine bed prior to occupying an

ancillary labor and delivery bed and regardless of whether the patient

occupies a ``maternity suite'' in which labor, delivery, recovery, and

postpartum care all take place in the same room. This proposed policy

would be consistent with our existing policy under section 2205 of the

PRM regarding counting patient days associated with other ancillary

areas (such as surgery and postanesthesia).

We note that we are not proposing to change our policy on patient

days for labor and delivery patients who are not admitted to the

hospital as inpatients. For example, if a woman presents at a hospital

for labor and delivery services, but is determined by medical staff to

be in false labor and is sent home without ever being admitted to the

hospital as an inpatient, any days associated with such services

furnished by the hospital would not be included in the DPP for purposes

of the Medicare DSH calculation. That is, because the patient would be

considered an outpatient, the day (or days) associated with the

hospital visit would not be counted for purposes of the Medicare DSH

calculation because such days would not be considered inpatient days.

In addition, this proposed policy does not affect existing policies

relating to the allocation of costs for Medicare cost reporting

purposes or for determining the number of available beds under Sec.

412.105(b)(4) or Sec. 412.106(a)(1)(i). In other words, our hospital

instructions in the PRM for those purposes remain unchanged and

unaffected by this proposed policy.

3. Proposed Policy Change Relating to Calculation of Inpatient Days in

the Medicaid Fraction in the Medicare DSH Calculation

a. Background

As stated under section V.E.1. of this preamble, a hospital can

qualify for the Medicare DSH payment adjustment based on its Medicare

DPP, which is equal to the sum of the percentage of total Medicare

inpatient days attributable to patients entitled to both Medicare Part

A (including patients enrolled in Medicare Advantage (Part C)) and SSI

and the percentage of total inpatient days attributable to patients

eligible for Medicaid, but not entitled for Medicare Part A.

[GRAPHIC] [TIFF OMITTED] TP22MY09.013

Our existing policy of aggregating days for the Medicare fraction

of the DSH calculation is to count days by the date of discharge. This

policy, which is specified in the regulations at Sec.

412.106(b)(2)(i)(A), applies to how days are counted in both the

numerator and denominator of the Medicare fraction.

Under the existing Medicare DSH payment adjustment policy, a

hospital is required to report its Medicaid inpatient days (that is,

the ``numerator'' of the Medicaid fraction) in the cost reporting

period in which the patient was discharged. However, despite our

existing policy to count the days in the numerator of the Medicaid

fraction based on the date of discharge, we believe that there may have

been confusion about the existing policy that may have led hospitals to

vary in the methodology they use to aggregate days in the numerator of

the Medicaid fraction for patients who were eligible for Medicaid. In

many cases, we have found that hospitals are reporting these days to

their fiscal intermediary or MAC based on the method by which their

respective State Medicaid agencies have chosen to collect and report

Medicaid-eligible days to the hospital. We understand that State

Medicaid agencies differ in how they collect and report Medicaid-

eligible days. As a result, hospitals may be counting Medicaid-eligible

days in the numerator of the Medicaid fraction of the DPP based on one

of several possible methodologies, rather than consistently counting

days based on the date of discharge, as required under the existing

policy. The various methodologies being used by State Medicaid agencies

include date of discharge, date of admission, date of

[[Page 24189]]

Medicaid payment, and dates of service. With the exception of the

methodology that accumulates days in the numerator of the Medicaid

fraction by the date of Medicaid payment, we believe that any of these

methodologies could appropriately capture all inpatient days in which

an individual was Medicaid-eligible for a hospital for the purpose of

counting days in the numerator of the Medicaid fraction used in the

DPP. We do not believe that the date of Medicaid payment is appropriate

because our policy is to include inpatient days for which the patient

was eligible for Medicaid, regardless of whether Medicaid paid for the

days. Therefore, we believe that the date of Medicaid payment

methodology may not capture all of the days that a hospital would be

allowed to include in the numerator of its Medicaid fraction. With

respect to the other possible alternatives to counting days in the

numerator of the Medicaid fraction, we believe that it becomes

problematic when hospitals change the methodology they use to count

days in the numerator of the Medicaid fraction from one cost reporting

period to the next. Such changes in the methodology of counting days

may result in ``double counting'' of the same patient days in more than

one cost reporting period for a hospital.

b. Proposed Policy Change

To address the issue of hospitals reporting days in the numerator

for the Medicaid fraction of the DPP in the Medicare DSH calculation

based on data they receive from their respective State Medicaid agency

and the fact that the State Medicaid agency may report such days based

on one of several different methodologies, we are proposing to revise

our existing policy by adding a new paragraph (iv) to Sec.

412.106(b)(4) to allow hospitals to report days in the numerator of the

Medicaid fraction of the DPP based on one of three methodologies.

Specifically, we are proposing that, effective for cost reporting

periods beginning on or after October 1, 2009, a hospital may report

Medicaid-eligible days in the numerator of the Medicaid fraction of the

DPP of a cost reporting period based on date of admission, date of

discharge, or dates of service. However, under the proposed revised

policy, a hospital would be required to notify CMS (through the fiscal

intermediary or MAC) in writing if the hospital chooses to change its

methodology of counting days in the numerator of the Medicaid fraction

of the DPP. The written notification would have to be submitted at

least 30 days prior to the beginning of the cost reporting period to

which the requested change would apply. The written notification must

specify the changed methodology the hospital wishes to use and the cost

reporting period to which the requested change would apply. A hospital

would only be able to make such a change effective on the first day of

the beginning of a cost reporting period and the change would have to

be effective for the entire cost reporting period; that is, a hospital

would not be permitted to change its methodology in the middle of a

cost reporting period. This change would also be effective for all

subsequent cost reporting periods unless the hospital submits a

subsequent notification to change its methodology for a future cost

reporting period. We note that we would expect that a hospital would

rarely decide to change the methodology it uses to count days in the

numerator of the Medicaid fraction of the DPP and that such a change

would be prompted out of necessity (for example, the State Medicaid

agency changes the methodology it uses to provide patient Medicaid

eligibility information to hospitals). In addition, we are proposing

that if a hospital changes its methodology for counting days in the

numerator of the Medicaid fraction, CMS, or the fiscal intermediary or

MAC, would have the authority to adjust the inpatient days reported by

the hospital in a cost reporting period to prevent ``double counting''

of days in the numerator of the Medicaid fraction of the DPP of the

Medicare DSH calculation reported in another cost reporting period.

4. Proposed Policy Change Relating to the Exclusion of Observation Beds

and Patient Days From the Medicare DSH Calculation

a. Background

Observation services are defined in the Medicare Benefit Policy

Manual (Publication No. 100-02, Chapter 6, section 20.6A) as a ``well-

defined set of specific, clinically appropriate services, which include

ongoing short-term treatment, assessment, and reassessment before a

decision can be made regarding whether patients will require further

treatment.'' Observation services are furnished by a hospital and

include the use of a bed and periodic monitoring by a hospital's

nursing or other staff in order to evaluate an outpatient's condition

and/or to determine the need for a possible admission to the hospital

as an inpatient. As discussed in section 20.6A of the Medicare Benefit

Policy Manual, when a physician orders that a patient be placed under

observation care but has not formally admitted him or her as an

inpatient, the patient initially is treated as an outpatient.

Consequently, the costs incurred for patients receiving observation

services are not generally recognized under the IPPS as part of the

inpatient operating costs of the hospital. In some circumstances,

observation services, although furnished to outpatients, are paid as

part of an MS-DRG under the IPPS. In particular, section 1886(d) of the

Act sets forth the payment system, based on prospectively determined

rates, for the operating costs of inpatient hospital services, which

are defined under section 1886(a)(4) of the Act to include ``the costs

of all services for which payment may be made under this title that are

provided by the hospital (or by an entity wholly owned or operated by

the hospital) to the patient during the 3 days immediately preceding

the date of the patient's admission if such services are diagnostic

services (including clinical diagnostic laboratory tests) or are other

services related to the admission (as defined by the Secretary).'' As

further explained in section 40.3 of Chapter 3 of the Medicare Claims

Processing Manual (Publication 100-04), if a hospital outpatient

receives diagnostic preadmission services that are related to a

patient's hospital admission such that there is an exact match between

the principal diagnosis for both the hospital outpatient claim and the

inpatient stay, there is no payment for the diagnostic preadmission

services under the hospital OPPS. Rather, these preadmission outpatient

services are rolled into the particular MS-DRG and paid under the IPPS.

Our policy prior to October 1, 2003, as discussed in the FY 2004

IPPS final rule (68 FR 45418), had been to exclude all observation days

from the available bed and the patient day counts. CMS clarified that

if a hospital provides observation services in beds that are generally

used to provide hospital inpatient services, the days that those beds

are used for observation services are to be excluded from the bed day

count (even if the patient is ultimately admitted as an acute

inpatient).

In the FY 2004 IPPS proposed rule (68 FR 27205 through 27206), we

also proposed to amend our policy with respect to observation days for

patients who are ultimately admitted for inpatient acute care.

Specifically, we are proposing that if a patient is admitted as an

acute inpatient subsequent to receiving outpatient observation

services, the days associated with the observation services would be

included in the available bed and patient day counts. We did not

finalize this policy

[[Page 24190]]

until the FY 2005 IPPS final rule (69 FR 49096 through 49098) when we

revised our regulations at Sec. 412.105(b)(4) and Sec.

412.106(a)(1)(ii) to specify that observation days are to be excluded

from the counts of both available beds and patient days, unless a

patient who receives outpatient observation services is ultimately

admitted for acute inpatient care, in which case the bed days and

patient days would be included in those counts. In implementing this

policy, we revised Worksheet S-3, Part I of the Medicare hospital cost

report by subscripting columns 5 and 6 to create columns 5.01 and 5.02,

and 6.01 and 6.02, to allow for separate reporting of observation days

for patients who are subsequently admitted as inpatients and a separate

line for observation days for patients not admitted. This policy change

applied to all cost reporting periods beginning on or after October 1,

2004.

b. Proposed Policy Change

As we previously indicated, a patient who is receiving observation

services is a hospital outpatient, and the costs associated with those

services are paid under the OPPS in most circumstances. If, however, a

patient receives observation services from a hospital within 3 days of

an inpatient admission and the outpatient observation care that he or

she receives is related to the admission such that there is an exact

match between the principal diagnosis for both the hospital outpatient

claim and the inpatient stay, a payment is not made to the hospital

under the OPPS, as explained in section 40.3-C of Chapter 3 of the

Medicare Claims Processing Manual. According to section 40.3-C of the

Medicare Claims Processing Manual, these preadmission outpatient

diagnostic and nondiagnostic services are ``deemed to be inpatient

services, and included in the inpatient payment, unless there is no

Part A coverage.'' By this we mean that such preadmission services are

considered operating costs of hospital inpatient services for payment

purposes only, as described in section 1886(a)(4) of the Act. That is

to say that payment for these preadmission services, including

observation services furnished to hospital outpatients who are later

admitted as inpatients, is included within the per case inpatient

payment if the services meet the statutory criteria described in

section 1886(a)(4) of the Act, but they are still services furnished to

patients who are outpatients of the hospital at the time those services

are furnished. We note that although these preadmission services may be

considered operating costs for hospital inpatient services for payment

purposes, such services are not furnished to an inpatient because these

services are furnished prior to the patient being formally admitted

and, therefore, the associated day is not considered to be an inpatient

day. Thus, even if payment for these preadmission services is included

in the inpatient payment, the admission date for the inpatient stay

begins when the patient is formally admitted. Because observation

services are services furnished to outpatients of the hospital, we are

proposing that the patient days during which observation services are

furnished are not included in the DSH calculation, regardless of

whether the patients under observation are later admitted. We believe

that patient days during which observation services are furnished, like

the days during which all other preadmission diagnostic and

nondiagnostic services are furnished, are not inpatient days and,

therefore, we are proposing to exclude such patient days from the DPP

of the Medicare DSH calculation.

In accordance with section 1812(a) of the Act, for a patient day to

be considered part of a beneficiary's spell of illness, the patient

must have had ``inpatient hospital services furnished to him during

such spell.'' In addition, section 1861(a) of the Act defines a ``spell

of illness'' as beginning on the first day on which such ``individual

is furnished inpatient hospital services.'' Section 1861(b) of the Act

defines ``inpatient hospital services'' as ``services furnished to an

inpatient of the hospital.'' Thus, with respect to a spell of illness,

even if observation services are eventually bundled into the inpatient

payment, the patient is not admitted as an inpatient while he or she

remains under observation and the days under observation are not

considered to be inpatient days that count toward a beneficiary's spell

of illness. In addition, with respect to the 3-day inpatient stay

requirement for patients to secure Medicare coverage of SNF benefits,

section 20.1 of Chapter 8 of the Medicare Benefit Policy Manual

(Publication No. 100-02) states: ``Time spent in observation status or

in the emergency room prior to (or in lieu of) an inpatient admission

to the hospital does not count toward the 3-day qualifying inpatient

hospital stay, as a person who appears at a hospital's emergency room

seeking examination or treatment or is placed on observation has not

been admitted to the hospital as an inpatient; instead, the person

receives outpatient services. For purposes of the SNF benefit's

qualifying hospital stay requirement, inpatient status commences with

the calendar day of hospital admission.'' Other Medicare policies do

not consider observation days to be inpatient days because observation

services are outpatient services furnished to outpatients of the

hospital. While other Medicare policies do not necessarily dictate how

we treat patient days for DSH payment purposes, we believe it is

important that patient days be treated consistently among the various

Medicare policies. We believe that because observation days are not

considered inpatient days for a beneficiary's spell of illness or for

qualifying for SNF benefits, this policy provides additional support

for our proposal to no longer include any observation day as an

inpatient day in the calculation of the DPP of the Medicare DSH

calculation, nor should the associated observation bed days be included

in determining the number of available inpatient beds used for purposes

of determining a hospital's IME and DSH payment adjustments.

As we indicated above, the DSH regulations at Sec. 412.106 explain

how the DPP is calculated. Specifically, the DPP is based on the

hospital's patient days where patient days apply only to inpatient

days. Because a patient under observation in the hospital is considered

to be an outpatient of the hospital and receives services prior to

being admitted as an inpatient, we believe that observation days, even

for a patient who is subsequently admitted, should not be considered

inpatient days. Accordingly, we are proposing to revise the regulations

at Sec. 412.106(a)(1)(ii) to exclude patient days associated with beds

used for outpatient observation services, even if the patient is later

admitted as an inpatient. We are proposing to exclude all observation

patient days from the DPP of the Medicare DSH calculation. This

proposal would be effective for cost reporting periods beginning on or

after October 1, 2009.

For the same reasons, we also are proposing to eliminate from bed

counting observation bed days for patients who are subsequently

admitted as inpatients for purposes of both the DSH payment adjustment

and the IME payment adjustment. The rules for counting hospital beds

for the purposes of the IME adjustment are codified in the IME

regulations at Sec. 412.105(b), which is cross-referenced in Sec.

412.106(a)(1)(i) for purposes of the DSH payment adjustment. We believe

it is important to apply a consistent definition for counting bed days

for both the IME and DSH payment adjustments. Therefore, we are

proposing to revise Sec. 412.105(b)(4) to state that observation

[[Page 24191]]

days are excluded from the counts of available beds, regardless of

whether or not the patient under observation is ultimately admitted for

acute inpatient care.

As we stated earlier, when we implemented the policy to include

observation days for admitted patients for DSH payment adjustment

purposes for FY 2005, we revised the Medicare hospital cost report to

include columns for hospitals to report their observation days for

patients admitted as inpatients and observation days for patients not

admitted. Under the proposal in this proposed rule, hospitals would no

longer be required to distinguish on the cost report between

observation bed days and patient days for patients who are ultimately

admitted and observation bed days and patient days for patients who are

not admitted because none of these bed days and patient days would be

included in the DSH payment adjustment. We are proposing that,

effective for cost reporting periods beginning on or after October 1,

2009, hospitals would be required to report their total observation bed

days so that the total observation days can be deducted from the bed

day count for IME and DSH payment adjustment purposes.

In summary, we are proposing to exclude observation patient days

for admitted patients from the patient day count in Sec.

412.106(a)(1)(ii) (for DSH) and the bed day count at Sec. 412.105(b)

(for IME), as a cross-reference at Sec. 412.106(a)(1)(i) (for DSH),

because observation services are defined as outpatient services

furnished to outpatients of the hospital, regardless of whether or not

the patient under observation is subsequently admitted.

F. Technical Correction to Regulations on Payments for Anesthesia

Services Furnished by Hospital or CAH Employed Nonphysician

Anesthetists or Obtained Under Arrangements (Sec. 412.113)

Section 412.113(c) of the regulations contain our rules governing

payments for anesthesia services furnished by a hospital or CAH by

qualified nonphysician anesthetists employed by the hospital or CAH or

obtained under arrangements. We have discovered that, under paragraph

(c)(2)(i)(B) of Sec. 412.113, there is an incorrect cross-reference to

``Sec. 410.66'' for the definition of a qualified nonphysician

anesthetist. The correct cross-reference for the definition of a

qualified nonphysician anesthetist is ``Sec. 410.69''. We are

proposing to correct the cross-reference in Sec. 412.113(c)(2)(i)(B)

to refer to ``Sec. 410.69''.

G. Payments for Direct Graduate Medical Education (GME) (Sec. Sec.

413.75 and 413.79)

1. Background

Under section 1886(a)(4) of the Act, costs of approved educational

activities are excluded from the operating costs of hospital inpatient

services. Section 1886(h) of the Act, as implemented in regulations at

Sec. 413.75 through Sec. 413.83, establishes a methodology for

determining payments to hospitals for the direct costs of approved GME

programs. Section 1886(h)(2) of the Act sets forth a methodology for

the determination of a hospital-specific, base-period per resident

amount (PRA) that is calculated by dividing a hospital's allowable

direct costs of GME for a base period by its number of residents in the

base period. The base period is, for most hospitals, the hospital's

cost reporting period beginning in FY 1984 (that is, the period between

October 1, 1983, through September 30, 1984). Medicare direct GME

payments are calculated by multiplying the PRA times the weighted

number of full-time equivalent (FTE) residents working in all areas of

the hospital complex (and nonhospital sites, when applicable), and the

hospital's Medicare share of total inpatient days. The base year PRA is

updated annually for inflation.

Section 1886(h)(4)(F) of the Act established a limit on the number

of allopathic and osteopathic FTE residents that a hospital may include

in its FTE resident count for purposes of calculating direct GME

payments. For most hospitals, the limit, or cap, is the unweighted

number of allopathic and osteopathic FTE residents training in the

hospital's most recent cost reporting period ending on or before

December 31, 1996.

2. Clarification of Definition of New Medical Residency Training

Program

For purposes of determining direct GME and IME payments, the

Medicare statute establishes a cap on the number of allopathic and

osteopathic FTE residents a hospital may count, which, for most

hospitals, is based on the number of allopathic and osteopathic FTE

residents the hospital was training in its most recent cost reporting

period ending on or before December 31, 1996. Section 1886(h)(4)(H)(i)

of the Act requires the Secretary to prescribe rules for the

application of the FTE resident cap in the case of medical residency

programs that are established on or after January 1, 1995. This

statutory provision is also made applicable for purposes of the IME

adjustment under the IPPS through section 1886(d)(5)(B)(viii) of the

Act. The provision specifies that such rules must be consistent with

the principles of the statutory provisions regarding the establishment

of the FTE resident caps and regarding application of a 3-year rolling

average count of FTE residents. The statute also requires the Secretary

to give special consideration in such rules to facilities that meet the

needs of underserved rural areas. In accordance with the statute, we

issued regulations to permit adjustments to the FTE resident caps,

under certain circumstances, for hospitals that establish new medical

residency training programs on or after January 1, 1995. Section

413.79(e)(1) of the regulations state that if a hospital had no

allopathic or osteopathic residents in the base year, the hospital may

receive an adjustment to its FTE resident cap (which would be zero) if

it establishes one or more new medical residency training programs, but

only for new programs established within 3 academic years after

residents begin training in the first program. (Rural hospitals may

receive FTE cap adjustments for newly established programs at any time

under the regulations at Sec. 413.79(e)(1)(iii). Under Sec.

413.79(e)(2), hospitals that had allopathic or osteopathic residents in

the base year were only permitted to receive an adjustment for new

programs established on or after January 1, 1995, and before August 5,

1997. Section 413.79(l) defines a new medical residency training

program as ``a medical residency that receives initial accreditation by

the appropriate accrediting body or begins training residents on or

after January 1, 1995.'' These regulations concerning cap adjustments

for newly established medical residency training programs also apply

for IME purposes as stated at Sec. 412.105(f)(1)(vii).

It has come to our attention that there has been some

misinterpretation or misunderstanding of these regulations among some

hospitals and Medicare contractors despite previous discussions of the

topic in the Federal Register. Specifically, some hospitals or

contractors took the regulations to mean that, as long as the relevant

accrediting body (either the Accreditation Council on Graduate Medical

Education (ACGME) for allopathic programs or the American Osteopathic

Association (AOA) for osteopathic programs) grants an ``initial''

accreditation or reaccredits a program as ``new,'' the hospital may

receive an FTE cap adjustment for that program, regardless of whether

that program may have been accredited

[[Page 24192]]

previously at another hospital. In other words, some hospitals and

contractors appear to have read our regulations to mean that the

Secretary would defer, in all circumstances, to the relevant

accrediting body's identification of a particular accreditation as a

``new'' or ``initial'' accreditation of a medical residency training

program.

In the FY 1998 IPPS final rule that established Sec. 413.79(l) of

the regulations, we discussed both the meaning of this regulation and

the rationale for establishing it:

``For purposes of this provision, a `program' will be considered

newly established if it is accredited for the first time, including

provisional accreditation on or after January 1, 1995, by the

accrediting body. Although the Secretary of the Department of Health

and Human Services has broad authority to prescribe rules for counting

residents in new programs, the Conference Report for Public Law 105-33

[House Conference Report No. 105-217, pp. 821-822] indicates concern

that the aggregate number of FTE residents should not increase over

current levels.'' (62 FR 46006)

Similarly, in the FY 2000 IPPS final rule (64 FR 41519), we

responded to a public comment suggesting that CMS include within the

definition of ``new residency program'' a residency program that may

have been in existence at other clinical sites in the past. We replied

that ``the language `begins training residents on or after January 1,

1995' [in the regulation at Sec. 413.79(l)] means that the program may

have been accredited by the appropriate accrediting body prior to

January 1, 1995, but did not begin training in the program until on or

after January 1, 1995. The language does not mean that it is the first

time a particular hospital began training residents in a program on or

after January 1, 1995, but that program was in existence at another

hospital prior to January 1, 1995, as the commenter suggests.''

(Emphasis added.)

Accordingly, as we have suggested in discussions in our previous

rules, rather than relying solely on the accrediting body's

characterization of whether a program is new, we continue to believe it

is appropriate that CMS require a hospital to evaluate whether a

particular program is a newly established one for Medicare GME purposes

by considering whether a program was initially accredited ``for the

first time,'' and is not a program that existed previously at another

hospital. In evaluating whether a program is truly new, as opposed to

an existing program that is relocated to a new site, it is important to

consider not only the characterization by the accrediting body, but

also supporting factors such as (but not limited to) whether there are

new program directors and/or new teaching staff, and/or whether there

are only new residents training in the program(s) at the different

site. In determining whether a particular program is a newly

established one, it may also be necessary to consider factors such as

the relationship between hospitals (for example, common ownership or a

shared medical school or teaching relationship) and the degree to which

the hospital with the original program continues to operate its own

program in the same specialty. (Although this discussion of new

programs is framed in the context of a hospital operating a program, we

note that many programs are operated or sponsored by schools of

medicine or other nonhospital entities. This section is intended to

address all GME programs that were previously accredited at one

operating entity, and that entity ceases to operate the program, but

the program is then opened and operated at another entity and is

accredited as a new program at the second entity. Such a program would

not be treated as new at the second entity.) In any case, we believe it

is appropriate to be deliberate in the determinations regarding FTE

resident cap adjustments relating to residents in new programs. The

statute clearly requires that our rules regarding adjustments to

hospitals' FTE resident caps for newly established programs must adhere

to the principles of the statutory provision limiting the count of FTE

residents for direct GME and IME payments to the count for the most

recent cost reporting period ending on or before December 31, 1996. In

addition, as we indicated in our final rule establishing FTE cap

adjustments for ``new programs,'' the Conference Report for the BBA

explicitly indicates that the aggregate number of FTE residents should

be held to the ``current'' levels at the time the BBA was enacted

(House Conference Report No. 105-217, pp. 821-822).

If we were to find that a program at one hospital is a newly

established program after it was relocated from another hospital, the

result would be that an FTE resident cap adjustment would be granted

based on the same program at two different hospitals. Furthermore, as

long as both hospitals continue to operate, the FTE resident cap slots

that were vacated from the program at the first hospital could

potentially be filled with residents from that hospital's other

residency training programs. We do not believe such an increase in the

aggregate number of FTE residents and the potential duplication of the

FTE resident cap adjustment would be consistent with the statutory

mandate to adhere to the principles of the base-year FTE resident caps

when devising rules to account for newly established medical residency

training programs. Therefore, we are proposing to clarify our policy

that a new medical residency program is one that receives initial

accreditation for the first time, as opposed to reaccreditation of a

program that existed previously at the same or another hospital.

Furthermore, we believe it is appropriate and necessary that CMS expect

a hospital that wishes to claim an adjustment to its direct GME and IME

FTE caps due to a new medical residency program to first evaluate

whether the program is ``new'' for Medicare purposes, rather than to

rely exclusively on the characterization of a particular program by the

relevant accrediting body.

3. Participation of New Teaching Hospitals in Medicare GME Affiliation

Groups

Sections 1886(h)(4)(F) and 1886(d)(5)(B)(v) of the Act establish

limits on the number of allopathic and osteopathic residents that

hospitals may count for purposes of calculating direct GME payments and

the IME adjustment, respectively. Accordingly, effective October 1,

1997, we established hospital-specific direct GME and IME FTE resident

caps. Furthermore, under the authority granted by section

1886(h)(4)(H)(ii) of the Act, the Secretary issued rules to allow

institutions that are members of the same affiliated group to elect to

apply their direct GME and IME FTE resident caps on an aggregate basis.

Accordingly, as specified in the regulations at Sec. Sec. 413.79(f)

and 412.105(f)(1)(vi), hospitals that are part of the same Medicare GME

affiliated group are permitted to apply their direct GME and IME FTE

resident caps on an aggregate basis, and to temporarily adjust each

hospital's caps to reflect the rotation of residents among affiliated

hospitals during an academic year. Under Sec. 413.75(b), a Medicare

GME affiliated group can be formed by two or more hospitals if they are

under common ownership, or if they are jointly listed as program

sponsors or major participating institutions in the same program.

Furthermore, the existing regulations at Sec. 413.79(f)(1) specify

that each hospital in a Medicare GME affiliated group must submit a

Medicare GME affiliation agreement (as defined under Sec. 413.75(b))

to the CMS fiscal

[[Page 24193]]

intermediary or MAC servicing the hospital and send a copy to CMS'

Central Office no later than July 1 of the residency program year

during which the Medicare GME affiliation agreement will be in effect.

For example, in order for a hospital to receive a temporary adjustment

to its FTE resident caps to reflect participation in a Medicare GME

affiliated group for the academic year beginning July 1, 2009, through

June 30, 2010, each hospital in the affiliated group is required to

submit a Medicare GME affiliation agreement to the fiscal intermediary

or MAC servicing the hospital and to CMS' Central Office no later than

July 1, 2009.

It has recently come to CMS' attention that flexibility in the

submission deadline for Medicare GME affiliation agreements due to an

unanticipated need is warranted in situations where a hospital opens

after July 1 and begins training residents for the first time, after

July 1 of an academic year. That is, the new hospital, since it did not

train residents in the FTE cap base year, would have FTE resident caps

of zero. Currently, if a new hospital begins training residents from

another hospital's existing program, the new hospital would not be able

to receive a temporary FTE resident cap adjustment through

participation in a Medicare GME affiliated group because the existing

regulations do not provide flexibility for a hospital that begins

training residents after the start of an academic year to enter into

and submit a Medicare GME affiliation agreement after the July 1

submission deadline. That is, a new hospital that opens after July 1

would not be able to enter into a Medicare GME affiliation agreement

because the hospital did not exist before the submission deadline. We

understand that the new hospital is likely to incur GME costs during

the first year of training residents, and we believe it is reasonable

to permit the new hospital that receives a new Medicare provider

agreement and begins training residents for the first time after July 1

of an academic year to receive an adjustment to its FTE resident caps

for IME and direct GME payments through participation in a Medicare GME

affiliated group during its first year of training residents, even if

the hospital completes and submits the Medicare GME affiliation

agreement to CMS after July 1 of the academic year. Accordingly, we are

proposing to amend Sec. 413.79(f) by revising paragraph (f)(1) and

adding a new paragraph (f)(6) (the existing paragraph (f)(6) would be

redesignated as paragraph (f)(7)). The proposed new paragraph (f)(6)

would provide that a hospital that is new after July 1 and that begins

training residents for the first time prior to the following July 1

would be permitted to receive a temporary adjustment to its FTE

resident caps to reflect its participation in an existing Medicare GME

affiliated group if the new hospital submits a Medicare GME affiliation

agreement prior to the end of the first cost reporting period during

which the hospital begins training residents. For this purpose, a new

hospital is one for which a new Medicare provider agreement takes

effect in accordance with Sec. 489.13. We are proposing to require

that the Medicare GME affiliation agreement specify the effective

period for the agreement, which in any case would begin no earlier than

the date the affiliation agreement is submitted to CMS. Furthermore, we

are proposing that each of the other hospitals participating in the

Medicare GME affiliated group with the new hospital would be required

to submit an amended Medicare GME affiliation agreement that reflects

the participation of the new hospital to the CMS contractor servicing

the hospital and send a copy to the CMS Central Office no later than

June 30 of the residency program year during which the Medicare GME

affiliation agreement will be in effect.

4. Technical Corrections to Regulations

We have discovered that in the existing Sec. 413.79(k), under the

provision on residents training in rural track programs, paragraph

(k)(7) incorrectly appears as regulation text after paragraph (l) of

Sec. 413.79. To correct this error, we are proposing to move paragraph

(l) so that it appears as the last paragraph of the section after

paragraph (k)(7).

In addition, the regulations at Sec. 413.75(b), paragraph (1),

define an ``approved medical residency program'' as a program that is

``approved by one of the national organizations listed in Sec.

415.152''. Under Sec. 415.152, in the definition of an ``approved

graduate medical education (GME) program'', we reference a residency

program approved by the ``Committee on Hospitals of the Bureau of

Professional Education of the American Osteopathic Association'' (AOA).

It has come to our attention that the structure of the AOA has changed

and that we should merely refer to a residency program approved by the

AOA. Therefore, we are proposing to make a technical change to

paragraph (1) of the definition of an ``approved graduate medical

education (GME) program'' under Sec. 415.152, to remove the phrase

``the Committee on Hospitals of the Bureau of Professional Education

of''.

H. Hospital Emergency Services Under EMTALA (Sec. 489.24)

1. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Act impose

specific obligations on certain Medicare-participating hospitals and

CAHs. (Throughout this section of this proposed rule, when we reference

the obligation of a ``hospital'' under these sections of the Act and in

our regulations, we mean to include CAHs as well.) These obligations

concern an individual who comes to a hospital emergency department and

requests examination or treatment for a medical condition, and apply to

all individuals, regardless of whether they are beneficiaries of any

program under the Act.

The statutory provisions cited above are frequently referred to as

the Emergency Medical Treatment and Labor Act (EMTALA), also known as

the patient antidumping statute. Section 9121 of the Consolidated

Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law 99-272,

incorporated the responsibilities of Medicare hospitals in emergency

cases into the Social Security Act. Congress incorporated these

antidumping provisions within the Act as a part of the hospital's

provider agreement to ensure that any individual with an emergency

medical condition is not denied essential lifesaving services. Under

section 1866(a)(1)(I)(i) of the Act, a hospital that fails to fulfill

its EMTALA obligations under these provisions may be subject to

termination of its Medicare provider agreement, which would result in

loss to the hospital of all Medicare and Medicaid payments.

Section 1867 of the Act sets forth requirements for medical

screening examinations for individuals who come to the hospital and

request examination or treatment for a medical condition. The section

further provides that if a hospital finds that such an individual has

an emergency medical condition, it is obligated to provide that

individual with either necessary stabilizing treatment or with an

appropriate transfer to another medical facility.

The regulations implementing section 1867 of the Act are found at

42 CFR 489.24. The regulations at 42 CFR 489.20(l), (m), (q), and (r)

also refer to certain EMTALA requirements outlined in section 1866 of

the Act. The Interpretive Guidelines concerning

[[Page 24194]]

EMTALA are found at Appendix V of the CMS State Operations Manual.

2. Proposed Changes Relating to Applicability of Sanctions Under EMTALA

Section 1135 of the Act authorizes the Secretary to temporarily

waive or modify the application of several requirements of titles

XVIII, XIX, or XXI of the Act (the Medicare, Medicaid, and State

Children's Health Insurance Program provisions), and their implementing

regulations in an emergency area during an emergency period. Section

1135(g)(1) of the Act defines an ``emergency area'' as the geographical

area in which there exists an emergency or disaster declared by the

President pursuant to the National Emergencies Act or the Robert T.

Stafford Disaster Relief and Emergency Assistance Act (subsection A)

and a public health emergency declared by the Secretary pursuant to

section 247d of Title 42 of the United States Code. Section 1135(g)(1)

of the Act also defines an ``emergency period'' as the period during

which such a disaster or emergency exists. Section 1135(b) of the Act

lists the categories of otherwise applicable statutory and regulatory

requirements that may be waived or modified. Included among these are

the waiver of sanctions under EMTALA for, in subparagraph (b)(3)(A), a

transfer of an individual who has not been stabilized (if the transfer

arises out of the circumstances of the emergency) in violation of the

EMTALA requirements governing transfer of an individual whose emergency

medical condition has not been stabilized (section 1867(c) of the Act)

and, in subparagraph (b)(3)(B), the direction or relocation of an

individual to receive medical screening in an alternate location,

pursuant to an appropriate State emergency preparedness plan. Section

1135(b) of the Act further states that, except for certain emergencies

involving pandemic infectious disease (described in further detail

below), a waiver or modification provided for under section 1135(b)(3)

of the Act shall be limited to a 72-hour period beginning upon

implementation of a hospital disaster protocol.

Section 302(b) of the Pandemic and All-Hazards Preparedness Act,

Public Law 109-417, made two specific changes that affect EMTALA

implementation in instances where the Secretary has invoked the section

1135 waiver authority in an emergency area during an emergency period.

Section 302(b)(1)(A) of Public Law 109-417 amended section

1135(b)(3)(B) of the Act to state that sanctions for the direction or

relocation of an individual for screening may be waived where, in the

case of a public health emergency that involves a pandemic infectious

disease, that direction or relocation occurs pursuant to a State

pandemic preparedness plan, or to an appropriate State emergency

preparedness plan. In addition, sections 302(b)(1)(B) and (b)(1)(C) of

Public Law 109-417 amended section 1135(b) of the Act to further state

that ``if a public health emergency involves a pandemic infectious

disease (such as pandemic influenza), the duration of a waiver or

modification for such emergency shall be determined in accordance with

section 1135(e) of the Act as such subsection applies to public health

emergencies.''

In the FY 2008 IPPS final rule with comment period (72 FR 47413),

we amended the regulations at Sec. 489.24(a)(2) (which refers to the

nonapplicability of certain EMTALA provisions in an emergency area

during an emergency period) to incorporate the changes made to section

1135 of the Act by the Pandemic and All-Hazards Preparedness Act. We

amended the regulations to specify that, under a section 1135 waiver,

the sanctions that do not apply are either those for the inappropriate

transfer of an individual who has not been stabilized or those for the

direction or relocation of an individual to receive medical screening

at an alternate location. We also added a second sentence to paragraph

(a)(2) to state that a waiver of these sanctions for EMTALA violations

is limited to a 72-hour period beginning upon the implementation of a

hospital disaster protocol, except that if a public health emergency

involves a pandemic infectious disease (such as pandemic influenza),

the duration of the waiver will be determined in accordance with

section 1135(e) of the Act as it applies to public health emergencies.

In the FY 2009 IPPS final rule (73 FR 28667), we made a technical

change to the regulations at Sec. 489.24(a)(2) by adding section 1135

language we had inadvertently left out when we made changes to the

regulations at Sec. 489.24(a)(2) in the FY 2008 IPPS final rule with

comment period. Specifically, we added the phrases ``pursuant to an

appropriate State emergency preparedness plan or, in the case of a

public health emergency that includes a pandemic infectious disease,

pursuant to a State pandemic preparedness plan'' and ``during an

emergency period,'' to make the regulatory language consistent with the

statutory text. Existing Sec. 489.24(a)(2) states that ``Sanctions

under this section for an inappropriate transfer during a national

emergency or for the direction or relocation of an individual to

receive medical screening at an alternate location pursuant to an

appropriate State emergency preparedness plan or, in the case of a

public health emergency that involves a pandemic infectious disease,

pursuant to a State pandemic preparedness plan do not apply to a

hospital with a dedicated emergency department located in an emergency

area during an emergency period, as specified in section 1135(g)(1) of

the Act. A waiver of these sanctions is limited to a 72-hour period

beginning upon the implementation of a hospital disaster protocol,

except that, if a public health emergency involves a pandemic

infectious disease (such as pandemic influenza), the waiver will

continue in effect until the termination of the applicable declaration

of a public health emergency, as provided for by section 1135(e)(1)(B)

of the Act.''

After further review of the revised regulatory language as compared

to the statutory language at section 1135 of the Act, we believe that

further revisions to the language of Sec. 489.24(a)(2) are necessary

to make the language conform more closely to the language of section

1135 of the Act and better reflect how the section 1135 authority has

been used in practice. Specifically, we believe that the regulatory

language should be revised to be more consistent with the language in

the statute to state that EMTALA sanctions for an inappropriate

transfer may be waived only if the inappropriate transfer arises out of

the circumstances of the emergency. We are further proposing to amend

the regulations to provide that the sanctions waived for both an

inappropriate transfer and the redirection or relocation of an

individual to receive a medical screening examination at an alternate

location are only applicable if the hospital does not discriminate on

the basis of an individual's source of payment or ability to pay. These

additional requirements (which are underlined) are currently not

included in the regulations text at Sec. 489.24(a)(2). To ensure that

the language of the regulations is fully consistent with the statutory

language at section 1135 of the Act, we believe the regulations need to

be clarified to include these provisions.

In addition, we believe the existing regulations do not adequately

reflect the Secretary's authority under section 1135 of the Act to

waive or modify requirements for a single health care provider, a class

of health care providers, or a geographic subset of health care

providers located within an

[[Page 24195]]

emergency area during an emergency period. The language at section

1135(b) of the Act states:

``To the extent necessary to accomplish the purpose specified in

subsection (a), the Secretary is authorized, subject to the provisions

of this section, to temporarily waive or modify the application of,

with respect to health care items and services furnished by a health

care provider (or classes of health care providers) in any emergency

area (or portion of such an area) during any portion of an emergency

period, the requirements of titles XVIII, XIX, or XXI, or any

regulation thereunder (and the requirements of this title other than

this section, and regulations thereunder, insofar as they relate to

such titles), pertaining to--'' (emphases added).

Thus, it is clear from the emphasized text that waivers under the

section 1135 authority may be tailored and applied to one or more

hospitals in the emergency area (or portion thereof) during some or all

of the emergency period, as necessary. However, the existing

regulations may inadvertently imply, contrary to the flexibility

clearly contemplated in the statute, that all hospitals in all portions

of an emergency area during an entire emergency period automatically

receive a waiver of EMTALA sanctions. We are proposing revisions to the

regulation text to clarify this issue.

We also are proposing to revise the regulations to further clarify

that the Secretary has the authority to implement a section 1135 waiver

as necessary to ensure that the purpose of section 1135(a) of the Act

can be achieved. That is, the Secretary is authorized to apply a

section 1135 waiver, for example, to one or more hospitals in the

emergency area (or portion thereof) during some or all of the emergency

period, as necessary. The Secretary may delegate implementation of a

waiver of EMTALA sanctions to CMS (as the Secretary has done in every

instance in which the section 1135 waiver authority has been invoked

thus far.)

In summary, we are proposing to revise the regulations at Sec.

489.24(a)(2) to state that a waiver of EMTALA sanctions pursuant to an

inappropriate transfer only applies if the transfer arises out of the

circumstances of the emergency. We also are proposing to revise the

regulations to provide that the sanctions waived for an inappropriate

transfer or for the relocation or redirection of an individual to

receive a medical screening examination at an alternate location are

only in effect if the hospital to which the waiver applies does not

discriminate on the source of an individual's payment or ability to

pay. In addition, we are proposing to revise the regulations to state

that the Secretary has the authority to apply the waiver of EMTALA

sanctions to one or more hospitals in a portion of an emergency area or

a portion of an emergency period. The proposed revised Sec.

489.24(a)(2) reads as follows:

``When a waiver has been issued in accordance with section 1135 of

the Act that includes a waiver under section 1135(b)(3) of the Act,

sanctions under this section for an inappropriate transfer or for the

direction or relocation of an individual to receive medical screening

at an alternate location do not apply to a hospital with a dedicated

emergency department if the following conditions are met:

(i) If relating to an inappropriate transfer, the transfer arises

out of the circumstances of the emergency.

(ii) If relating to the direction or relocation of an individual to

receive medical screening at an alternate location, the direction or

relocation is pursuant to an appropriate State emergency preparedness

plan or, in the case of a public health emergency that involves a

pandemic infectious disease, pursuant to a State pandemic preparedness

plan.

(iii) The hospital does not discriminate on the basis of an

individual's source of payment or ability to pay.

(iv) The hospital is located in an emergency area during an

emergency period, as those terms are defined in section 1135(g)(1) of

the Act.

(v) There is a determination that a waiver of sanctions is

necessary.

A waiver of these sanctions is limited to a 72-hour period

beginning upon the implementation of a hospital disaster protocol,

except that, if a public health emergency involves a pandemic

infectious disease (such as pandemic influenza), the waiver will

continue in effect until the termination of the applicable declaration

of a public health emergency, as provided under section 1135(e)(1)(B)

of the Act.''

I. Rural Community Hospital Demonstration Program

In accordance with the requirements of section 410A(a) of Public

Law 108-173, the Secretary has established a 5-year demonstration

program (beginning with selected hospitals' first cost reporting period

beginning on or after October 1, 2004) to test the feasibility and

advisability of establishing ``rural community hospitals'' for Medicare

payment purposes for covered inpatient hospital services furnished to

Medicare beneficiaries. A rural community hospital, as defined in

section 410A(f)(1), is a hospital that--

Is located in a rural area (as defined in section

1886(d)(2)(D) of the Act) or is treated as being located in a rural

area under section 1886(d)(8)(E) of the Act;

Has fewer than 51 beds (excluding beds in a distinct part

psychiatric or rehabilitation unit) as reported in its most recent cost

report;

Provides 24-hour emergency care services; and

Is not designated or eligible for designation as a CAH.

Section 410A(a)(4) of Public Law 108-173 states that no more than

15 such hospitals may participate in the demonstration program.

As we indicated in the FY 2005 IPPS final rule (69 FR 49078), in

accordance with sections 410A(a)(2) and (a)(4) of Public Law 108-173

and using 2002 data from the U.S. Census Bureau, we identified 10

States with the lowest population density from which to select

hospitals: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North

Dakota, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau

Statistical Abstract of the United States: 2003). Thirteen rural

community hospitals located within these States are currently

participating in the demonstration program. (Of the 13 hospitals that

participated in the first 2 years of the demonstration program, 4

hospitals located in Nebraska became CAHs and withdrew from the

program.) In a notice published in the Federal Register on February 6,

2008 (73 FR 6971 through 6973), we announced a solicitation for up to

six additional hospitals to participate in the demonstration program.

The February 6, 2008 notice specified the eligibility requirements for

the demonstration program. Four additional hospitals were selected to

participate under this solicitation. These four additional hospitals

began under the demonstration payment methodology with the hospital's

first cost reporting period starting on or after July 1, 2008. The end

date of participation for these hospitals is September 30, 2010.

Under the demonstration program, participating hospitals are paid

the reasonable costs of providing covered inpatient hospital services

(other than services furnished by a psychiatric or rehabilitation unit

of a hospital that is a distinct part), applicable for discharges

occurring in the first cost reporting period beginning on or after the

October 1, 2004 implementation date of the demonstration program (or

the July 1, 2008 date for the newly selected hospitals). Payments to

the

[[Page 24196]]

participating hospitals will be the lesser amount of the reasonable

cost or a target amount in subsequent cost reporting periods. The

target amount in the second cost reporting period is defined as the

reasonable costs of providing covered inpatient hospital services in

the first cost reporting period, increased by the inpatient prospective

payment update factor (as defined in section 1886(b)(3)(B) of the Act)

for that particular cost reporting period. The target amount in

subsequent cost reporting periods is defined as the preceding cost

reporting period's target amount, increased by the inpatient

prospective payment update factor (as defined in section 1886(b)(3)(B)

of the Act) for that particular cost reporting period.

Covered inpatient hospital services are inpatient hospital services

(defined in section 1861(b) of the Act), and include extended care

services furnished under an agreement under section 1883 of the Act.

Section 410A of Public Law 108-173 requires that, ``in conducting

the demonstration program under this section, the Secretary shall

ensure that the aggregate payments made by the Secretary do not exceed

the amount which the Secretary would have paid if the demonstration

program under this section was not implemented.'' Generally, when CMS

implements a demonstration program on a budget neutral basis, the

demonstration program is budget neutral in its own terms; in other

words, the aggregate payments to the participating hospitals do not

exceed the amount that would be paid to those same hospitals in the

absence of the demonstration program. This form of budget neutrality is

viable when, by changing payments or aligning incentives to improve

overall efficiency, or both, a demonstration program may reduce the use

of some services or eliminate the need for others, resulting in reduced

expenditures for the demonstration program's participants. These

reduced expenditures offset increased payments elsewhere under the

demonstration program, thus ensuring that the demonstration program as

a whole is budget neutral or yields savings. However, the small scale

of this demonstration program, in conjunction with the payment

methodology, makes it extremely unlikely that this demonstration

program could be viable under the usual form of budget neutrality.

Specifically, cost-based payments to participating small rural

hospitals are likely to increase Medicare outlays without producing any

offsetting reduction in Medicare expenditures elsewhere. Therefore, a

rural community hospital's participation in this demonstration program

is unlikely to yield benefits to the participant if budget neutrality

were to be implemented by reducing other payments for these hospitals.

In this proposed rule, we are proposing two measures to achieve

budget neutrality for the demonstration program for FY 2010, which,

when combined, would lead to an adjustment in the national inpatient

PPS rates. We are proposing to adjust the national inpatient PPS rates

by an amount sufficient to account for the added costs of this

demonstration program. We are proposing to apply budget neutrality

across the payment system as a whole rather than merely across the

participants in this demonstration program. As we discussed in the FY

2005, FY 2006, FY 2007, FY 2008, and FY 2009 IPPS final rules (69 FR

49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; and 73 FR 48670), we

believe that the language of the statutory budget neutrality

requirements permits the agency to implement the budget neutrality

provision in this manner.

First, we are estimating the cost of the demonstration program for

FY 2010 for the 13 currently participating hospitals. The estimate of

the portion of the budget neutrality adjustment that accounts for the

costs of the demonstration for FY 2010 for 9 of the 13 currently

participating hospitals (that is, the 9 hospitals that have

participated in the demonstration since its inception and that continue

to participate in the demonstration) is based on data from their first

and second year cost reports--that is, cost reporting periods beginning

in CY 2005 and CY 2006. We are proposing to use these cost reports

because they are the most recent complete cost reports and, thus, we

believe they enable us to estimate FY 2010 costs as accurately as

possible. In addition, we estimate the cost of the demonstration for FY

2010 for the 4 hospitals that joined the demonstration in 2008 based on

data for their cost reporting periods beginning October 1, 2005,

through July 1, 2006 (that is, cost reporting periods that include CY

2006). Cost reports for these periods were included along with the

hospitals' applications for the demonstration program. When we add

together the estimated costs of the demonstration for FY 2010 for the 9

hospitals that have participated in the demonstration since its

inception and the 4 new hospitals selected in 2008, the total estimated

cost is $14,613,632. This estimated amount reflects the difference

between the participating hospitals' estimated costs under the

methodology set forth in Public Law 108-173 and the estimated amount

the hospitals would have been paid under the IPPS.

Second, because the cost reports of all hospitals participating in

the demonstration in its first year (that is FY 2005) have been

finalized, we are able to determine how much the cost of the

demonstration program exceeded the amount that was offset by the budget

neutrality adjustment for FY 2005. For all 13 hospitals that

participated in the demonstration in FY 2005, the amount is $7,179,461.

The total proposed budget neutrality offset amount to be applied

for the demonstration for FY 2010 is the sum of these two amounts, or

$21,793,093. We discuss the payment rate adjustment that is required to

ensure the budget neutrality of the demonstration program for FY 2010

in section II.A.4. of the Addendum to this proposed rule. We are

proposing that the budget neutrality offset amount may be different in

the FY 2010 IPPS final rule to the extent we have more recent data.

J. Technical Correction to Regulations Relating to Calculation of the

Federal Rate Under the IPPS

Section 412.63 of the regulations specifies the procedures for

determining the standardized amounts for inpatient operating costs for

Federal fiscal years 1984 through 2004. These standardized amounts

included a ``large urban area'' standardized amount for large urban

hospitals and an ``other area'' standardized amount for hospitals

located in other areas. In the FY 1989 IPPS final rule, we established

Sec. 412.63(c)(5). Consistent with section 1886(d)(3)(C)(ii) of the

Act, Sec. 412.63(c)(5) states that, for FYs 1987 through 2004, CMS

calculated the average standardized amounts by excluding an estimate

for IME payments. Accordingly, beginning in FY 1989, we updated the

standardized amounts using an IME adjustment factor that excludes an

estimate of IME payments. For a complete discussion on this adjustment

factor for IME, we refer readers to the FY 1989 IPPS final rule (53 FR

38538 through 38539).

Section 1886(d)(3)(A)(iv) of the Act, as amended by section 401(a)

of Public Law 108-173, requires that, beginning with FY 2004 and

thereafter, we compute the standardized amount for all hospitals in any

area equal to the standardized amount for the previous fiscal year for

large urban hospitals, updated by the applicable percentage update

under section 1886(b)(3)(B)(i) of the Act. In other words, beginning in

FY 2004, we no longer computed a ``large urban area'' standardized

amount and a

[[Page 24197]]

separate ``other area'' standardized amount. As a result of this

statutory change, we established new regulations at Sec. 412.64 to

specify the computation of the single standardized amount for FY 2005

and subsequent fiscal years (69 FR 49077). With the exception of

removing a separate standardized amount for non-large urban hospitals,

the regulation text at Sec. 412.64 virtually mirrors the regulation

text at Sec. 412.63. For FY 2005 and subsequent fiscal years, we

excluded an estimate for IME payments from the calculation of the

standardized amount in accordance with section 1886(d)(3)(A)(iv) of the

Act. However, we inadvertently omitted from Sec. 412.64 the language

under paragraph (c)(5) of Sec. 412.63 that implements the exclusion of

an estimate for IME payments from the calculation of the standardized

amount in accordance with section 1886(d)(3)(A)(iv) of the Act.

Therefore, we are proposing to revise Sec. 412.64(c) to include this

language so that Sec. 412.64(c) reflects the statutory requirement

under section 1886(d)(3)(A)(iv) of the Act that calculation of the

standardized amount excludes IME payments.

VI. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the

capital-related costs of inpatient acute hospital services ``in

accordance with a prospective payment system established by the

Secretary.'' Under the statute, the Secretary has broad authority in

establishing and implementing the IPPS for acute care hospital

inpatient capital-related costs. We initially implemented the IPPS for

capital-related costs in the Federal fiscal year (FY) 1992 IPPS final

rule (56 FR 43358), in which we established a 10-year transition period

to change the payment methodology for Medicare hospital inpatient

capital-related costs from a reasonable cost-based methodology to a

prospective methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period

established to phase in the IPPS for hospital inpatient capital-related

costs. For cost reporting periods beginning in FY 2002, capital IPPS

payments are based solely on the Federal rate for almost all acute care

hospitals (other than hospitals receiving certain exception payments

and certain new hospitals). (We refer readers to the FY 2002 IPPS final

rule (66 FR 39910 through 39914) for additional information on the

methodology used to determine capital IPPS payments to hospitals both

during and after the transition period.) The basic methodology for

determining capital prospective payments using the Federal rate is set

forth in Sec. 412.312 of the regulations. For the purpose of

calculating payments for each discharge, currently the standard Federal

rate is adjusted as follows:

(Standard Federal Rate) x (DRG Weight) x (Geographic Adjustment

Factor (GAF)) x (COLA for hospitals located in Alaska and Hawaii) x (1

+ Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if

applicable).

As discussed in the FY 2008 IPPS final rule with comment period (72

FR 47393 through 47401), based on our analysis of data on hospital

inpatient Medicare capital margins that we obtained through our

monitoring and comprehensive review of the adequacy of IPPS payments

for capital-related costs, we made changes in the payment structure

under the capital IPPS beginning with FY 2008. (We also provided an

extended capital IPPS margin analysis discussion in the FY 2009 IPPS

final rule (73 FR 48671 through 48675).) Specifically, in the FY 2008

IPPS final rule with comment period, we made two changes to the

structure of payments under the capital IPPS: (1) We discontinued the

3.0 percent additional payment that had been provided to hospitals

located in large urban areas at Sec. 412.316(b) for FYs 2008 and

beyond, (72 FR 47400 and 47412); and (2) we established a phase-out of

the capital teaching adjustment (that is, the capital IME adjustment

factor) at Sec. 412.322 over a 3-year period beginning in FY 2008 (72

FR 47401 and 47412).

Under the established 3-year phase-out of the capital teaching

adjustment, we maintained the adjustment for FY 2008 in order to give

teaching hospitals an opportunity to plan and make adjustments in

correlation to the change. For the second year of the transition (FY

2009), we revised the regulations at Sec. 412.322 by adding paragraph

(c), which currently specifies that, for discharges occurring during FY

2009, the formula for determining the amount of the capital IPPS

teaching adjustment is half of the amount provided under the previous

formula (at Sec. 412.322(b)). Furthermore, for the last year of the

transition (FY 2010) and subsequent years, we added paragraph (d) to

Sec. 412.322, which specifies that, for discharges occurring during FY

2010 and after, hospitals will no longer receive an adjustment for

teaching activity under the capital IPPS.

Section 4301(b)(1) of the American Recovery and Reinvestment Act of

2009 (ARRA), Public Law 111-5, enacted on February 17, 2009, directed

the Secretary to not apply the 50-percent reduction in the capital IPPS

teaching adjustment for FY 2009, thereby restoring the full capital IME

adjustment for FY 2009. However, section 4301(b)(2) of Public Law 111-5

specifies that the law will not affect the phase-out of the capital

IPPS teaching adjustment for FY 2010 and subsequent fiscal years. The

provisions of Public Law 111-5 related to the capital IPPS teaching

adjustment are further discussed in section VI.E.2. of the preamble of

this proposed rule.

B. Exception Payments

The regulations at Sec. 412.348(f) provide that a hospital may

request an additional payment if the hospital incurs unanticipated

capital expenditures in excess of $5 million due to extraordinary

circumstances beyond the hospital's control. This policy was originally

established for hospitals during the 10-year transition period, but as

we discussed in the FY 2003 IPPS final rule (67 FR 50102), we revised

the regulations at Sec. 412.312 to specify that payments for

extraordinary circumstances are also made for cost reporting periods

after the transition period (that is, cost reporting periods beginning

on or after October 1, 2001). Additional information on the exception

payment for extraordinary circumstances in Sec. 412.348(f) can be

found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

During the transition period, under Sec. Sec. 412.348(b) through

(e), eligible hospitals could receive regular exception payments. These

exception payments guaranteed a hospital a minimum payment percentage

of its Medicare allowable capital-related costs depending on the class

of the hospital (Sec. 412.348(c)), but were available only during the

10-year transition period. After the end of the transition period,

eligible hospitals can no longer receive this exception payment.

However, even after the transition period, eligible hospitals receive

additional payments under the special exceptions provisions at Sec.

412.348(g), which guarantees all eligible hospitals a minimum payment

of 70 percent of its Medicare allowable capital-related costs provided

that special exceptions payments do not exceed 10 percent of total

capital IPPS payments. Special exceptions payments may be made only for

the 10 years from the cost reporting year in which the hospital

completes its qualifying project, and the hospital must have completed

the project no later than the hospital's cost reporting period

[[Page 24198]]

beginning before October 1, 2001. Thus, an eligible hospital may

receive special exceptions payments for up to 10 years beyond the end

of the capital IPPS transition period. Hospitals eligible for special

exceptions payments are required to submit documentation to the fiscal

intermediary or MAC indicating the completion date of their project.

(For more detailed information regarding the special exceptions policy

under Sec. 412.348(g), we refer readers to the FY 2002 IPPS final rule

(66 FR 39911 through 39914) and the FY 2003 IPPS final rule (67 FR

50102).)

C. New Hospitals

Under the IPPS for capital-related costs, Sec. 412.300(b) of the

regulations defines a new hospital as a hospital that has operated

(under current or previous ownership) for less than 2 years. For

example, the following hospitals are not considered new hospitals: (1)

A hospital that builds new or replacement facilities at the same or

another location, even if coincidental with a change of ownership, a

change in management, or a lease arrangement; (2) a hospital that

closes and subsequently reopens; (3) a hospital that has been in

operation for more than 2 years but has participated in the Medicare

program for less than 2 years; and (4) a hospital that changes its

status from a hospital that is excluded from the IPPS to a hospital

that is subject to the capital IPPS. For more detailed information, we

refer readers to the FY 1992 IPPS final rule (56 FR 43418). During the

10-year transition period, a new hospital was exempt from the capital

IPPS for its first 2 years of operation and was paid 85 percent of its

reasonable costs during that period. Originally, this provision was

effective only through the transition period and, therefore, ended with

cost reporting periods beginning in FY 2002. Because, as discussed in

the FY 2003 IPPS final rule (67 FR 50101), we believe that special

protection to new hospitals is also appropriate even after the

transition period, we revised the regulations at Sec. 412.304(c)(2) to

provide that, for cost reporting periods beginning on or after October

1, 2002, a new hospital (defined under Sec. 412.300(b)) is paid 85

percent of its Medicare allowable capital-related costs through its

first 2 years of operation, unless the new hospital elects to receive

full prospective payment based on 100 percent of the Federal rate. (We

refer readers to the FY 2003 IPPS final rule (67 FR 50101 through

50102) for a detailed discussion of the special payment provisions for

new hospitals under the capital IPPS after the 10-year transition

period.)

D. Hospitals Located in Puerto Rico

Section 412.374 of the regulations provides for the use of a

blended payment amount for prospective payments for capital-related

costs to hospitals located in Puerto Rico. Accordingly, under the

capital IPPS, we compute a separate payment rate specific to Puerto

Rico hospitals using the same methodology used to compute the national

Federal rate for capital-related costs. In general, hospitals located

in Puerto Rico are paid a blend of the applicable capital IPPS Puerto

Rico rate and the applicable capital IPPS Federal rate.

Prior to FY 1998, hospitals in Puerto Rico were paid a blended

capital IPPS rate that consisted of 75 percent of the capital IPPS

Puerto Rico specific rate and 25 percent of the capital IPPS Federal

rate. However, effective October 1, 1997 (FY 1998), in conjunction with

the change to the operating IPPS blend percentage for hospitals located

in Puerto Rico required by section 4406 of Public Law 105-33, we

revised the methodology for computing capital IPPS payments to

hospitals in Puerto Rico to be based on a blend of 50 percent of the

capital IPPS Puerto Rico rate and 50 percent of the capital IPPS

Federal rate. Similarly, in conjunction with the change in operating

IPPS payments to hospitals located in Puerto Rico for FY 2005 required

by section 504 of Public Law 108-173, we again revised the methodology

for computing capital IPPS payments to hospitals located in Puerto Rico

to be based on a blend of 25 percent of the capital IPPS Puerto Rico

rate and 75 percent of the capital IPPS Federal rate effective for

discharges occurring on or after October 1, 2004.

E. Proposed Changes

1. Proposed FY 2010 MS-DRG Documentation and Coding Adjustment

a. Background on the Prospective MS-DRG Documentation and Coding

Adjustments for FY 2008 and FY 2009

In the FY 2008 IPPS final rule with comment period (72 FR 47175

through 47186), we adopted the MS-DRG patient classification system for

the IPPS, effective October 1, 2007, to better recognize patients'

severity of illness in Medicare payment rates. Adoption of the MS-DRGs

resulted in the expansion of the number of DRGs from 538 in FY 2007 to

745 in FY 2008 (currently 746, including one additional MS-DRG created

in FY 2009). By increasing the number of DRGs and more fully taking

into account patients' severity of illness in Medicare payment rates,

the MS-DRGs encourage hospitals to change their documentation and

coding of patient diagnoses. In that same final rule with comment

period (72 FR 47183), we indicated that we believe the adoption of the

MS-DRGs had the potential to lead to increases in aggregate payments

without a corresponding increase in actual patient severity of illness

due to the incentives for changes in documentation and coding.

Accordingly, we established adjustments to both the national operating

standardized amount and the national capital Federal rate to eliminate

the estimated effect of changes in documentation and coding resulting

from the adoption of the MS-DRGs that do not reflect real changes in

case-mix. Specifically, we established prospective documentation and

coding adjustments of -1.2 percent for FY 2008, -1.8 percent for FY

2009, and -1.8 percent for FY 2010. However, to comply with section

7(a) of Public Law 110-90, enacted on September 29, 2007, in a final

rule published in the Federal Register on November 27, 2007 (72 FR

66886 through 66888), we modified the documentation and coding

adjustment for FY 2008 to -0.6 percent, and consequently revised the FY

2008 IPPS operating and capital payment rates, factors, and thresholds

accordingly, with these revisions effective October 1, 2007.

For FY 2009, section 7(a) of Public Law 110-90 required a

documentation and coding adjustment of -0.9 percent instead of the -1.8

percent adjustment established in the FY 2008 IPPS final rule with

comment period. As discussed in the FY 2008 IPPS final rule with

comment period (72 FR 48447 and 48733 through 48774), we applied a

documentation and coding adjustment of -0.9 percent to the FY 2009 IPPS

national standardized amounts and the capital Federal rate. The

documentation and coding adjustments established in the FY 2009 IPPS

final rule, as amended by Pub. L. 110-90, are cumulative. As a result,

the -0.9 percent documentation and coding adjustment in FY 2009 was in

addition to the -0.6 percent adjustment in FY 2008, yielding a combined

effect of -1.5 percent. (For additional details on the development and

implementation of the documentation and coding adjustments for FY 2008

and FY 2009, we refer readers to section II.D. of this preamble and the

following rules published in the Federal Register August 22, 2007 (72

FR 47175 through 47186 and 47431 through 47432); November 27, 2007 (72

FR 66886 through 66888); and August 19, 2008 (73 FR 48447 through 48450

and 48773 through 48775).)

[[Page 24199]]

b. Proposed Prospective MS-DRG Documentation and Coding Adjustment to

the National Capital Federal Rate for FY 2010 and Subsequent Years

Consistent with the prospective adjustment to the national average

operating IPPS standardized amounts (discussed in section II.D. of this

preamble), under the capital IPPS we also continue to believe that it

is appropriate to make adjustments to the capital IPPS rates to

eliminate the effect of any documentation and coding changes as a

result of the implementation of the MS-DRGs. These adjustments are

intended to ensure that future annual aggregate IPPS payments are the

same as payments that otherwise would have been made had the

prospective adjustments for documentation and coding applied in FY 2008

and FY 2009 accurately reflected the change due to documentation and

coding that occurred in those years. As noted above in section VI.A. of

this preamble, under section 1886(g) of the Act, the Secretary has

broad authority in establishing and implementing the IPPS for acute

care hospital inpatient capital-related costs (that is, the capital

IPPS). We have consistently stated since the initial implementation of

the MS-DRG system that we do not believe it is appropriate for Medicare

expenditures under the capital IPPS to increase due to MS-DRG related

changes in documentation and coding. Accordingly, we believe that it is

appropriate under the Secretary's broad authority under section 1886(g)

of the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act

and section 7(b) of Public Law 110-90, to make adjustments to the

capital Federal rate to eliminate the full effect of the documentation

and coding changes resulting from the adoption of the MS-DRGs. We

believe that this is appropriate because, in absence of such

adjustments, the effect of the documentation and coding changes

resulting from the adoption of the MS-DRGs results in inappropriately

high capital IPPS payments because that portion of the increase in

aggregate payments is not due to an increase patient severity (and

costs).

We have performed a thorough retrospective evaluation of the most

recent available claims data, and the results of this evaluation were

used by our actuaries to determine any necessary payment adjustments

beyond the cumulative -1.5 percent adjustment applied in determining

the FY 2009 capital Federal rate to ensure budget neutrality for the

implementation of MS-DRGs. Specifically, as discussed in greater detail

in section II.D.4. of the preamble of this proposed rule, we performed

a retrospective evaluation of the FY 2008 claims data updated through

December 2008. Based on this evaluation, our actuaries have determined

that the implementation of the MS-DRG system resulted in a 2.5 percent

change in case-mix due to documentation and coding that did not reflect

real changes in case-mix for discharges occurring during FY 2008. (As

noted above, our analysis plan is described in greater detail in

section II.D.4. of this preamble. As also noted in that section, the FY

2008 MedPAR files are available to the public to allow independent

analysis of the documentation and coding effect, and we are seeking

public comment on our methodology and analysis.)

The estimated 2.5 percent change in FY 2008 case-mix due to

documentation and coding changes that did not reflect real changes in

case-mix for discharges occurring during FY 2008 exceeds the -0.6

percent prospective documentation and coding adjustment applied to the

FY 2008 capital Federal rate (as established in the final rule

published in the Federal Register on November 27, 2007 (72 FR 66886

through 66888)) by 1.9 percentage points (2.5 percent minus 0.6

percent). Therefore, in this proposed rule, under the Secretary's broad

authority under section 1886(g) of the Act, in conjunction with section

1886(d)(3)(A)(vi) of the Act and section 7(b) of Public Law 110-90, we

are proposing to reduce the capital Federal rate in FY 2010 by -1.9

percent to account for the amount by which the 2.5 percent change in FY

2008 exceeds the established -0.6 percent adjustment. Furthermore,

consistent with our proposal under the operating IPPS, we are proposing

to leave that proposed -1.9 percent adjustment in place for subsequent

fiscal years to account for the effect in FY 2010 and subsequent years

of the amount by which the 2.5 percent change in FY 2008 exceeds the

established -0.6 percent adjustment.

We also examined the differences in case-mix between the FY 2008

claims data in which cases were grouped through the FY 2008 GROUPER

(Version 25.0) and the FY 2009 GROUPER (Version 26.0). As discussed in

section II.D.5. of this preamble, this was to help inform our analysis

of the potential for increase in the documentation and coding effect in

FY 2009. In FY 2008, we were transitioning to the fully implemented MS-

DRG relative weights and the fully implemented cost-based weights. We

found that the use of the transition weights mitigated the FY 2008

documentation and coding effect on expenditures. Specifically, our

analysis shows that, even assuming no additional changes in

documentation and coding in FY 2009, the use of the FY 2009 MS-DRG

relative weights (which no longer were based on a blend of the MS-DRGs

and the CMS DRGs) results in an additional 0.7 percent documentation

and coding effect in FY 2009. Based on these analyses and other

factors, our actuaries continue to estimate that the cumulative overall

effect of documentation and coding changes under the MS-DRG system will

be 4.8 percent. Our actuaries also estimate that these changes will be

substantially complete by the end of FY 2009. Therefore, our current

estimate of the MS-DRG documentation and coding effect is 2.3 percent

for discharges occurring during FY 2009. Consistent with the proposal

for the national operating standardized amounts presented in section

II.D.4. of this preamble, we will address any differences between the

increase in FY 2009 case-mix due to documentation and coding that did

not reflect real changes in case-mix for discharges occurring during FY

2009 and the -0.9 percent prospective documentation and coding

adjustment applied to the FY 2009 capital Federal rate (as established

in the FY 2009 IPPS final rule (73 FR 48773 through 48774) in the FY

2011 rulemkaing cycle after an evaluation of the extent of the overall

national average changes in case-mix for FY 2009 based on a

retrospective evaluation of all FY 2009 claims data.

As we stated in section II.D. of this preamble, we are seeking

public comment on the proposed -1.9 percent prospective adjustments to

address the effect of documentation and coding changes unrelated to

changes in real case-mix in FY 2008. In addition, as we discussed in

section II.D. of the preamble of this proposed rule, we are seeking

public comment on addressing in the FY 2011 rulemaking cycle any

differences between the increase in FY 2009 case-mix due to

documentation and coding changes that do not reflect real changes in

case-mix for discharges occurring during FY 2009 and the -0.9 percent

prospective documentation and coding adjustment applied in determining

the FY 2009 capital Federal rate established in the FY 2009 IPPS final

rule.

In summary, in this proposed rule, we are proposing to adjust the

FY 2010 capital Federal rate by a cumulative prospective reduction of

3.4 percent to account for increased Medicare expenditures resulting

from the changes

[[Page 24200]]

in documentation and coding practices with the adoption of the MS-DRGs.

In addition, we are proposing to leave that adjustment in place for

subsequent fiscal years to account for the effect in FY 2010 and

subsequent years in order to ensure that changes in documentation and

coding resulting from adoption of the MS-DRGs do not lead to an

increase in aggregate payments not reflective of an increase in real

case-mix. (In sections II.D.3. and 6. of this preamble, we discuss

section 7(b)(1)(B) of Pub. L. 110-90 and the requirement to make an

additional adjustment to the standardized amounts (referred to as

recoupment or repayment adjustments in FYs 2010 through 2012 required

by Pub. L. 110-90). We note that we are not proposing to apply section

7(b)(1)(B) of Pub. L. 110-90 to the capital Federal rate.) The

application of this proposed MS-DRG documentation and coding adjustment

in the determination of the proposed FY 2010 capital Federal rate is

shown in section III.A.5. of the Addendum of this proposed rule.

c. Proposed Documentation and Coding Adjustment to the Puerto Rico-

Specific Capital Rate

Under Sec. 412.74, Puerto Rico hospitals are currently paid based

on 75 percent of the national capital Federal rate and 25 percent of

the Puerto Rico-specific capital rate. In the FY 2009 IPPS final rule

(73 FR 48775), consistent with our development of the FY 2009 Puerto

Rico-specific operating standardized amount, we did not apply the

additional -0.9 percent documentation and coding adjustment (or the

cumulative -1.5 percent adjustment) to the FY 2009 Puerto Rico-specific

capital rate. However, we discussed that the statute gives broad

authority to the Secretary under section 1886(g) of the Act, with

respect to the development of and adjustments to a capital PPS, and

therefore we would not be outside the authority of section 1886(g) of

the Act in applying the documentation and coding adjustment to the

Puerto Rico-specific portion of the capital payment rate. As we

explained in that same final rule, to date we had not yet applied a

documentation and coding adjustment to the Puerto Rico-specific capital

rate because we have historically made changes to the capital IPPS

consistent with those changes made to the operating IPPS. We also

stated that we may propose to apply such an adjustment to the Puerto

Rico capital rates in the future.

As discussed in section II.D.10. of this preamble, when we

performed a retrospective evaluation of the FY 2008 claims data of

hospitals located in Puerto Rico using the same methodology discussed

above, we found that the change in case-mix due to documentation and

coding that did not reflect real changes in case-mix for discharges

occurring during FY 2008 from hospitals located in Puerto Rico is

approximately 1.1 percent. Given this case-mix increase due to changes

in documentation and coding under the MS-DRGs, consistent with our

proposal to adjust the FY 2010 capital Federal rate presented above and

consistent with our proposed adjustment to the FY 2010 Puerto Rico-

specific standardized amount discussed in section II.D.10.of this

preamble, in this proposed rule, under the Secretary's broad authority

under section 1886(g) of the Act, we are proposing to adjust the Puerto

Rico-specific capital rate by -1.1 percent in FY 2010 for the FY 2008

increase in case-mix due to changes in documentation and coding under

the MS-DRGs. In addition, consistent with our other proposals

concerning prospective MS-DRG documentation and coding adjustments to

the capital Federal rate and operating IPPS standardized amounts

presented in this proposed rule, we are proposing to leave that

proposed -1.1 percent adjustment in place for subsequent fiscal years

in order to ensure that changes in documentation and coding resulting

from the adoption of the MS-DRGs do not lead to an increase in

aggregate payments not reflective of an increase in real case-mix. The

proposed 1.1 percent adjustment would be applied to the capital Puerto

Rico-specific rate that accounts for 25 percent of payments to

hospitals located in Puerto Rico, with the remaining 75 percent based

on the national capital Federal rate, which we are proposing to adjust

as described above. Consequently, the proposed overall reduction to the

FY 2010 payment rates for hospitals located in Puerto Rico to account

for documentation and coding changes would be slightly less than the

reduction for IPPS hospitals paid based on 100 percent of the national

capital Federal rate. As noted above, the Puerto Rico-specific capital

rate was not adjusted for the effects of documentation and coding

changes in FY 2008 or FY 2009 as were the FY 2008 and FY 2009 national

capital Federal rates.

Similar to the analysis performed for all IPPS hospitals noted

above, we also examined FY 2008 claims data from hospitals located in

Puerto Rico to help inform analysis of the potential for increase in

the documentation and coding effect in FY 2009. As discussed in greater

detail in section II.D.10. of this preamble, based on this analysis,

our actuaries estimate that the cumulative overall effect of

documentation and coding changes under the MS-DRG system in FY 2009 for

hospitals located in Puerto Rico will be 1.3 percent (1.1 percent plus

an additional 0.2 percent). Consistent with the proposal for the

operating Puerto Rico-specific standardized amounts presented in

section II.D.10. of this preamble, we will address any increase in FY

2009 case-mix due to documentation and coding that did not reflect real

changes in case-mix for discharges occurring during FY 2009 in the FY

2011 rulemaking cycle.

As stated in section II.D.10. of this preamble, we are seeking

public comment on the proposed -1.1 percent prospective adjustment to

the Puerto Rico-specific IPPS rates in FY 2010 for the FY 2008

documentation and coding effect, including the methodology for

determining these adjustments. In addition, we are seeking public

comment on addressing in the FY 2011 rulemaking cycle any increase in

FY 2009 case-mix due to documentation and coding changes that did not

reflect real changes in case-mix for discharges occurring during FY

2009.

2. Revision to the FY 2009 IME Adjustment Factor

As noted in section VI.A. of this preamble, section 4301(b)(1) of

Public Law 111-5 requires that the phase-out of the capital IPPS

teaching adjustment specified at Sec. 412.322(c) of the regulations

(that is, the 50-percent reduction for FY 2009) shall not be applied,

and the Secretary shall apply Sec. 412.322 without regard to paragraph

(c) of that section. Furthermore, section 4301(b)(2) of the Pub. L.

111-5 specifies that the law has no effect on Sec. 412.322(d), which

eliminates the capital IPPS teaching adjustment for FY 2010 and

thereafter. Therefore, in order to reflect the current statutory

requirements as specified in section 4301(b)(1) of Public Law 111-5, in

this proposed rule, we are proposing to delete Sec. 412.322(c) of the

existing regulations. In the absence of existing Sec. 412.322(c), the

capital IPPS teaching adjustment for FY 2009 will not be reduced by 50

percent but will be as determined under Sec. 412.322(b) (that is, the

full capital IME teaching adjustment). The elimination of the teaching

adjustment for FY 2010, as currently specified at Sec. 412.322(d) of

the regulations, will remain, consistent with section 4301(b)(2) of

Public Law 111-5. We note that we have issued instructions (Change

Request 6444

[[Page 24201]]

dated March 27, 2009) to fiscal intermediaries and MACs to implement

the change to the capital teaching adjustment for FY 2009, as specified

in section 4301(b)(1) of Public Law 111-5. As noted above, in this

proposed rule, we are proposing to revise the existing regulations at

Sec. 412.322 by deleting the language of paragraph (c) and labeling

the paragraph ``Repealed.'' We are soliciting public comments on our

proposed implementation of section 4301(b) of Public Law 111-5

concerning capital IME payments.

3. Other Proposed Changes for FY 2010

The proposed annual update to the capital IPPS national and Puerto

Rico-specific rates, as provided for at Sec. 412.308(c), for FY 2010

is discussed in section III. of the Addendum to this proposed rule.

VII. Proposed Changes for Hospitals Excluded From the IPPS

A. Excluded Hospitals

Historically, hospitals and hospital units excluded from the

prospective payment system received payment for inpatient hospital

services they furnished on the basis of reasonable costs, subject to a

rate-of-increase ceiling. An annual per discharge limit (the target

amount as defined in Sec. 413.40(a)) was set for each hospital or

hospital unit based on the hospital's own cost experience in its base

year. The target amount was multiplied by the Medicare discharges and

applied as an aggregate upper limit (the ceiling as defined in Sec.

413.40(a)) on total inpatient operating costs for a hospital's cost

reporting period. Prior to October 1, 1997, these payment provisions

applied consistently to all categories of excluded providers, which

included rehabilitation hospitals and units (now referred to as IRFs),

psychiatric hospitals and units (now referred to as IPFs), LTCHs,

children's hospitals, and cancer hospitals.

Payment to children's hospitals and cancer hospitals that are

excluded from the IPPS continues to be subject to the rate-of-increase

ceiling based on the hospital's own historical cost experience. (We

note that, in accordance with Sec. 403.752(a) of the regulations,

RNHCIs are also subject to the rate-of-increase limits established

under Sec. 413.40 of the regulations.)

In this FY 2010 proposed rule, we are proposing that the percentage

increase in the rate-of-increase limits for cancer and children's

hospitals and RNHCIs would be the percentage increase in the proposed

FY 2010 IPPS operating market basket. In compliance with section 404 of

the MMA, in this proposed rule, we are proposing to replace the FY

2002-based IPPS operating and capital market baskets with the revised

and rebased FY 2006-based IPPS operating and capital market baskets for

FY 2010. Therefore, consistent with the current law, based on IHS

Global Insight, Inc.'s 2009 first quarter forecast, with historical

data through the 2008 fourth quarter, we are estimating that the FY

2010 update to the IPPS operating market basket will be 2.1 percent

(that is, the current estimate of the market basket rate-of-increase).

Consistent with our historical approach, we calculate the proposed

IPPS operating market basket for FY 2010 using the most recent data

available. However, if more recent data become available for the final

rule, we will use them to calculate the IPPS operating market basket

for FY 2010. For cancer and children's hospitals and RNHCIs, the

proposed FY 2010 rate-of-increase percentage that is applied to FY 2009

target amounts in order to calculate the proposed FY 2010 target

amounts is estimated to be 2.1 percent, in accordance with the

applicable regulations in 42 CFR 413.40.

We note that IRFs, IPFs, and LTCHs, which were paid previously

under the reasonable cost methodology, now receive payment under their

own prospective payment systems, in accordance with changes made to the

statute. In general, the prospective payment systems for IRFs, IPFs,

and LTCHs provided transition periods of varying lengths during which

time a portion of the prospective payment was based on cost-based

reimbursement rules under Part 413. (However, certain providers do not

receive a transition period or may elect to bypass the transition

period as applicable under 42 CFR Part 412, Subparts N, O, and P.) We

note that the various transition periods provided for under the IRF

PPS, the IPF PPS, and the LTCH PPS have ended.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We

refer readers to section IV. of the Addendum to this proposed rule for

the proposed specific update changes to the Federal payment rates for

LTCHs under the LTCH PPS for RY 2010. The annual updates for the IRF

PPS and the IPF PPS are issued by the agency in separate Federal

Register documents.

B. Criteria for Satellite Facilities of Hospitals

The regulations at 42 CFR 412.22(e) specify the criteria that a

hospital that occupies space in a building also used by another

hospital or in one or more separate buildings located on the same

campus as buildings used by another hospital (also known as a hospital-

within-hospital (HwH)) must meet in order to be excluded from the IPPS.

Section 412.22(e)(1)(i) specifies that the HwH must have a governing

body that is separate from the governing body of the hospital occupying

space in the same building or on the same campus. The HwH's governing

body must not be under the control of the hospital with which it shares

space in a building or on a campus, nor can it be under the control of

any third entity that controls both hospitals.

It has come to our attention that there is an inadvertent

inconsistency between the governance and control criteria at Sec.

412.22(h)(2)(iii)(A) that satellite facilities must meet in order to be

excluded from the IPPS and the separate governing body criteria at

Sec. 412.22(e)(1)(i) that HwHs must meet in order to be excluded from

the IPPS. Specifically, the separate governing body requirement for

satellite facilities at Sec. 412.22(h)(2)(iii)(A) mistakenly omits

language regarding a third entity. In particular, it fails to indicate

that the governing body of the hospital of which the satellite facility

is a part cannot be under the control of any third entity that controls

both the hospital of which the satellite facility is a part and the

hospital with which the satellite facility is co-located.

As explained in past rulemaking, we believe satellite facilities

are similar enough to HwHs to warrant application of more closely

related criteria to both types of facilities (67 FR 49982 and 50105

through 50106). Specifically, satellite facilities are like HwHs in

that the satellite facilities are also physically located in acute care

hospitals that are paid for inpatient services they furnish under the

acute care IPPS. Moreover, both satellite facilities and HwHs provide

hospital inpatient services that are generally paid for at higher rates

than would apply if the facilities were treated by Medicare as part of

the acute care hospitals. In view of these facts, we continue to

believe that it is important to establish clear criteria for ensuring

that a satellite facility is not merely a unit of the acute care

hospital with which it is co-located, but rather is organizationally

and functionally separate from the hospital. Therefore, we believe the

separate governing body requirements for satellite facilities should

include requirements that are similar to those we included at Sec.

412.22(e)(1)(i) for HwHs; that is, that the governing body of the

hospital of which the satellite facility is a part cannot be under the

control of any third entity that controls both the hospital of

[[Page 24202]]

which the satellite facility is a part and the hospital with which the

satellite facility is co-located. Accordingly, we are proposing to

amend the criteria for satellite facilities at Sec.

412.22(h)(2)(iii)(A) by adding language under paragraph (1) to state

that, except as provided in proposed paragraph (h)(2)(iii)(A)(2), the

governing body of the hospital of which the satellite facility is a

part cannot be under the control of any third entity that controls both

the hospital of which the satellite facility is a part and the hospital

with which the satellite facility is co-located. We are proposing that

the revised criteria would be effective with cost reporting periods

beginning on or after October 1, 2009.

In addition, we are proposing to add a ``grandfathering'' provision

to the regulations at Sec. 412.22(h)(2)(iii)(A)(2). Currently, an

IPPS-excluded hospital with a satellite facility that has its governing

body under the control of a third entity that controls the hospital of

which the satellite facility is a part and the hospital with which the

satellite facility is co-located can retain its IPPS-excluded status.

An IPPS-excluded hospital that currently has a satellite facility

already has its organizational structure and financial systems in

place. To require now that a hospital that currently has a satellite

facility must meet the proposed new separate governance criteria with

respect to that satellite facility could create undue financial and

organizational difficulties. This could further result in the closure

of the satellite facility and the discontinuation of services because

of the inability of the hospital and its satellite facility to meet the

proposed new separate governance criteria. Therefore, we are proposing

that if a hospital and its satellite facility were excluded from the

IPPS under the provision of Sec. 412.22(h) for the most recent cost

reporting period beginning before October 1, 2009, the hospital would

be required to meet the proposed new separate governance criteria at

Sec. 412.22(h)(2)(iii)(A)(1) with respect to that satellite facility

in order to retain its IPPS-excluded status (proposed Sec.

412.22(h)(2)(iii)(A)(2)).

However, because the proposed new separate governance criteria

would be effective for cost reporting periods beginning on or after

October 1, 2009, a hospital that establishes an additional satellite

facility in a cost reporting period beginning on or after October 1,

2009, will have knowledge of the requirements that must be met in order

to retain its IPPS-excluded status prior to establishing the additional

satellite facility, and it will be able to plan accordingly.

Furthermore, no organizational or financial relationship would already

be in place with respect to the additional satellite facility. Thus,

there would not be a need for the hospital and its additional satellite

facility to be grandfathered. This situation is distinguishable from a

hospital with a satellite facility established in the most recent cost

reporting period beginning prior to October 1, 2009, as discussed

above.

Therefore, we are proposing that if a hospital and its satellite

facility were excluded from the IPPS under the provision of Sec.

412.22(h) for the most recent cost reporting period prior to October 1,

2009, and the hospital establishes an additional satellite facility in

a cost reporting priod beginning on or after October 1, 2009, the

hospital would not be required to meet the proposed new separate

governance criteria at Sec. 412.22(h)(2)(iii)(A)(1), with respect to

the additional satellite facility, in order to be excluded from the

IPPS. (We note that the hospital and the new additional satellite

facility also would be required to meet the other applicable

requirements in Sec. 412.22(h), consistent with our longstanding

policies.)

We give the following example of how the proposed regulations at

Sec. 412.22(h)(2)(iii)(A)(2) and (h)(2)(iii)(A)(3) would work.

Hospital A established a satellite facility (s-B) at Hospital B in a

cost reporting period beginning prior to October 1, 2009, under the

applicable criteria for hospitals and satellite facilities at Sec.

412.22(h), and therefore, the hospital and that satellite facility were

excluded from the IPPS in the most recent cost reporting period

beginning prior to October 1, 2009. If Hospital A establishes an

additional satellite facility (s-C) at Hospital C in a cost reporting

period beginning on or after October 1, 2009, Hospital A and its

satellite facility at Hospital C must meet the applicable hospital and

satellite facility criteria at Sec. 412.22(h), including the proposed

new separate governance criteria at paragraph (h)(2)(iii)(A)(1), in

order to be excluded from the IPPS. Thus, the governing body of

Hospital A cannot be under the control of any third entity that

controls both Hospital A and Hospital C. However, Hospital A and s-B

must continue to meet the other applicable criteria in Sec. 412.22(h)

to be excluded from the IPPS.

C. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare

Rural Hospital Flexibility Programs (MRHFPs) under which individual

States may designate certain facilities as critical access hospitals

(CAHs). Facilities that are so designated and meet the CAH conditions

of participation under 42 CFR Part 485, Subpart F, will be certified as

CAHs by CMS. Regulations governing payments to CAHs for services to

Medicare beneficiaries are located in 42 CFR Part 413.

2. Payment for Clinical Diagnostic Laboratory Tests Furnished by CAHs

Section 1834(g)(1) of the Act states that payment for outpatient

services furnished by a CAH will be made at 101 percent of the

reasonable costs to the CAH in providing those services, except for

those CAHs that elect the optional reimbursement method outlined at

section 1834(g)(2) of the Act. We refer to payment under the elective

methodology described in section 1834(g)(2) of the Act as the

``optional method.'' (We discuss proposed changes to the CAH optional

method of payment regulations below in section VII.C.3. of this

preamble.) Section 1834(g)(4) of the Act provides that there is no

beneficiary cost-sharing for ``clinical diagnostic laboratory services

furnished as an outpatient critical access hospital service.''

Section 148 of Public Law 110-275 (MIPPA) amended section

1834(g)(4) of the Act, effective for services furnished on or after

July 1, 2009. Specifically, section 148(a)(1) of Public Law 110-275

changed the heading of section 1834(g)(4) of the Act to read

``Treatment of Clinical Diagnostic Laboratory Services.'' Section

148(a)(2) of Public Law 110-275 amended section 1834(g)(4) of the Act

by adding, in relevant part, that ``\* \* \* clinical diagnostic

laboratory services furnished by a critical access hospital shall be

treated as being furnished as part of outpatient critical access

services without regard to whether the individual with respect to whom

such services are furnished is physically present in the critical

access hospital, or in a skilled nursing facility or a clinic

(including a rural health clinic) that is operated by a critical access

hospital, at the time the specimen is collected.''

Regulations implementing section 1834(g) of the Act are set forth

at Sec. 413.70. Currently, the regulations at Sec. 413.70(b)(2)(iii)

state that payment to a CAH for clinical diagnostic laboratory services

is made at 101 percent of reasonable cost ``only if the individuals

[for whom the tests are performed] are outpatients of the CAH, as

defined in Sec. 410.2 \* \* \* and are physically present in the CAH, at

the time the specimens are collected.'' Clinical diagnostic

[[Page 24203]]

laboratory tests performed for individuals who are not physically

present in the CAH when the specimen is collected are paid on the basis

of the Clinical Laboratory Fee Schedule (CLFS) in accordance with the

provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Act.

In this proposed rule, we are proposing to amend the regulations at

Sec. 413.70(b) in order to implement the changes made by section

148(a)(2) of Public Law 110-275. Section 148(a)(2) of Public Law 110-

275 mandates that, effective for services furnished on or after July 1,

2009, individuals are no longer required to be physically present in

the CAH at the time the specimen is collected in order for the CAH to

receive payment based on reasonable cost for furnishing outpatient

clinical diagnostic laboratory tests. Specifically, we believe the use

of the phrase ``without regard to whether the individual with respect

to whom such services are furnished is physically present in the

critical access hospital'' means that as long as the tests are

performed for individuals who are CAH outpatients as defined in Sec.

410.2, payment based on reasonable cost must be made regardless of

where the specimen is collected, even if the patient is not physically

present in the CAH at the time the specimen is collected. Accordingly,

we are proposing to implement section 148(a)(2) by revising the

existing regulations to reflect our interpretation of the statutory

change.

We are proposing to amend the regulations at Sec. 413.70(b) by

deleting existing Sec. 413.70(b)(2)(iii) and adding a new Sec.

413.70(b)(7) to state that in order for a CAH to be paid for outpatient

clinical diagnostic laboratory tests, a CAH outpatient is no longer

required to be physically present in the CAH at the time the specimen

is collected. However, if the individual is not physically present in

the CAH at the time the specimen is collected, the individual must

continue to be an outpatient of the CAH, as defined at Sec. 410.2. We

consider an individual to be an outpatient of the CAH if the individual

is receiving services directly from the CAH. This requirement is

consistent with our definition of a CAH outpatient at Sec. 410.2,

which states that outpatient ``means a person who has not been admitted

as an inpatient but who is registered on the hospital or CAH records as

an outpatient and receives services (rather than supplies alone)

directly from the hospital or CAH.'' Consistent with section 1834(g)(4)

of the Act, we are proposing, to amend the regulations to provide that,

in order to be receiving services directly from the CAH, either the

individual must be receiving outpatient services in the CAH on the same

day the specimen is collected, or the specimen must be collected by an

employee of the CAH. Accordingly, where the individual is an outpatient

of the CAH as defined above, the individual would not be required to be

physically present in the CAH at the time the specimen is collected.

In addition, we do not believe that the enactment of section 148 of

Public Law 110-275 has any effect on the applicability of the

requirements at section 1862(a)(18) of the Act and the implementing

regulations at Sec. 411.15(p), which set forth requirements for

payment of services furnished to SNF patients. Accordingly, we are

proposing that, in cases where Medicare rules otherwise require

consolidated billing or bundling of payments (for example, for services

furnished to SNF patients during a Medicare Part A covered stay), the

CAH laboratory payment provision would only provide for separate

payment to the CAH once consolidated billing no longer applies. Where

consolidated billing is required by Medicare rules, a separate payment

for bundled services furnished by another provider, including a CAH, is

prohibited. For example, for purposes of payment to a CAH for

performing a clinical laboratory test on a specimen collected from a

SNF patient, the proposed new CAH payment rules would apply only once

the consolidated billing rules for SNF payments no longer apply.

Coverage under Medicare Part A for services furnished to a SNF patient

is limited to 100 days in a benefit period. During that period, the

collection of a specimen by a CAH employee in the SNF and the CAH's

performance of a laboratory test on the specimen would be bundled into

the SNF payment. Once the SNF patient has exhausted his or her Medicare

Part A SNF days (that is, after 100 days), payment for the specimen

collection by a CAH employee and the test performance by the CAH would

no longer be bundled into the SNF payment and the CAH could receive a

reasonable cost-based payment for the collection of a specimen by a CAH

employee and the performance of the laboratory test by the CAH.

In summary, we are proposing that a CAH may receive reasonable

cost-based payment for outpatient clinical diagnostic laboratory tests

furnished to an individual who is an outpatient of the CAH (and

therefore receiving services directly from the CAH) even if the

individual with respect to whom the laboratory services are furnished

is not physically present in the CAH at the time the specimen is

collected. In order for the individual to be determined to be receiving

services directly from the CAH, we are proposing that the individual

must either have received outpatient services in the CAH on the same

day the specimen is collected or the specimen must be collected by an

employee of the CAH. In either case, the individual would not need to

be physically present in the CAH at the time the specimen is collected.

We also note that if the individual is physically present in the CAH or

a facility that is provider-based to the CAH when the specimen is

collected, the CAH would also receive a reasonable cost-based payment.

In this case, the specimen would not need to be collected by an

employee of the CAH. (We refer readers to section VII.D. of this

preamble for further discussion of CAH provider-based facilities.)

Section 148 of Public Law 110-275 applies to all services furnished

on or after July 1, 2009. Accordingly, we intend to issue guidance that

will instruct Medicare contractors on the implementation of this

statutory provision effective July 1, 2009. We expect the instructions

in the guidance will parallel the proposed changes to the regulations

described above. However, we will consider all public comments received

in response to this proposal and make any necessary and appropriate

modifications before finalizing revisions to our regulations. We also

believe it will be important to develop a modifier that could assist

CMS in tracking laboratory services paid to CAHs under this provision.

When a modifier is developed, we will issue guidance regarding its use.

3. CAH Optional Method of Payment for Outpatient Services

Section 1834(g) of the Act establishes the payment rules for

outpatient services furnished by a CAH. Section 403(d) of Public Law

106-113 (BBRA) amended section 1834(g) of the Act to provide for two

methods of payment for outpatient services furnished by a CAH.

Specifically, section 1834(g)(1) of the Act, as amended by Public Law

106-113, provided that the amount of payment for outpatient services

furnished by a CAH was equal to the reasonable cost of providing such

services, unless the CAH made an election, under section 1834(g)(2) of

the Act, to receive amounts that were equal to the reasonable cost of

the CAH for facility services plus, with respect to the professional

services, the amount otherwise paid for professional services under

Medicare, less the applicable Medicare deductible and coinsurance

[[Page 24204]]

amount. The election made under section 1834(g)(2) of the Act is

sometimes referred to as ``Method II.'' Throughout this section of this

preamble, we refer to this election as the ``optional method.''

Section 202 of Public Law 106-554 (BIPA) amended section

1834(g)(2)(B) of the Act to increase the payment for professional

services under the optional method to 115 percent of the amount

otherwise paid for professional services under Medicare. In addition,

section 405(a)(1) of Public Law 108-173 (MMA) amended section

1834(g)(l) of the Act by inserting the phrase ``equal to 101 percent

of'' before the phrase ``the reasonable costs''. However, section

405(a)(1) of Public Law 108-173 did not amend the phrase ``reasonable

costs'' under the optional method at section 1834(g)(2)(A) of the Act.

Accordingly, section 1834(g) of the Act currently provides for two

methods of payment for outpatient CAH services. Under the first method,

as specified at section 1834(g)(1) of the Act, a CAH will be paid 101

percent of reasonable costs, unless it elects to be paid under the

methodology specified at section 1834(g)(2) of the Act. Under the

method specified at section 1834(g)(1) of the Act, facility services

are paid at 101 percent of reasonable costs to the CAH through the

Medicare fiscal intermediary or the Medicare Part A/B MAC, while

payments for physician and other professional services are made to the

physician under the Medicare Physician Fee Schedule (MPFS) through the

Medicare carriers. However, under section 1834(g)(2) of the Act (the

optional method), a CAH submits bills for both the facility and the

professional services to its Medicare fiscal intermediary or its

Medicare Part A/B MAC. If a CAH chooses this optional method for

outpatient services, the physician or other practitioner must reassign

his or her billing rights to the CAH to bill the Medicare program for

those services. In accordance with section 1834(g)(2)(A) of the Act,

under this optional method, the CAH receives reasonable cost payment

for its facility costs and, with respect to the professional services,

115 percent of the amount otherwise paid for professional services

under Medicare.

Regulations implementing section 1834(g) of the Act are set forth

at Sec. 413.70(b). Section 413.70(b) states that, unless a CAH elects

the optional method, payment for outpatient CAH services is 101 percent

of the reasonable costs of the CAH in providing CAH services to its

outpatients. However, existing Sec. 413.70(b)(3)(ii)(A) states that a

CAH may elect, under the optional method, to be paid at 101 percent of

the reasonable costs for facility services. As a result, we believe

that the existing regulation is not consistent with the plain reading

of section 1834(g)(2) of the Act, which provides for payment under the

optional method of reasonable cost for facility services.

In order to ensure that the regulations are consistent with the

plain reading of section 1834(g)(2)(A) of the Act, we are proposing to

revise Sec. 413.70(b)(3)(ii)(A) to state that CAHs that elect the

optional method will receive payment based on reasonable cost for

outpatient facility services. The proposed change would not affect

payment for the professional component as set forth under Sec.

413.70(b)(3)(ii)(B).

D. Provider-Based Status of Facilities and Organizations: Proposed

Policy Changes

1. Background

Since the beginning of the Medicare program, some providers, which

we refer to as ``main providers'', have functioned as a single entity

while owning and operating multiple provider-based departments,

locations, and facilities that were treated as part of the main

provider for Medicare purposes. Therefore, we have maintained that

having clear criteria for provider-based status is important because by

failing to properly distinguish between a provider-based facility and a

freestanding facility, we risk additional program payments and

increased beneficiary coinsurance liability with no commensurate

benefit to the Medicare program or its beneficiaries. In addition, we

jeopardize the delivery of safe and appropriate health care services to

beneficiaries.

The Medicare policies regarding provider-based status of facilities

and organizations are set forth at 42 CFR 413.65. The regulations at

Sec. 413.65 have been revised and updated on numerous occasions since

they were originally issued on April 7, 2000 (65 FR 18504). We note

that the implementation of the April 7, 2000 regulations was delayed by

Public Law 106-554 (BIPA) for many providers. Public Law 106-554 also

made changes in the criteria for determining provider-based status,

which we implemented in a final rule published in the Federal Register

on November 30, 2001 (66 FR 59956). The most recent revisions of Sec.

413.65 were included in the FY 2006 IPPS final rule (70 FR 47457

through 47461 and 47487 through 47488) when we updated the rules with

respect to the facilities for which provider-based determinations will

not be made and clarified some of the provider-based definitions and

requirements.

Currently, Sec. 413.65(a) specifies the facilities and

organizations for which provider-based status may be sought and lists

those facilities for which determinations of provider-based status for

Medicare payment purposes are not made. Section 413.65(b) describes the

procedures for making provider-based determinations, and Sec.

413.65(c) explains the requirements for reporting material changes in

relationships between main providers and provider-based facilities and

organizations. In Sec. 413.65(d), we specify all of the requirements

that any facility or organization for which provider-based status is

sought must meet, whether located on or off the campus of a potential

main provider. Section 413.65(e) specifies additional requirements

applicable to off-campus facilities or organizations. These

requirements include: operation under the ownership and control of the

main provider; administration and supervision; and location. Sections

413.65(f) through (o) set forth the policies regarding provider-based

status for joint ventures, obligations of hospital outpatient

departments and hospital-based entities, management contracts,

furnishing of all services under arrangement, inappropriate treatment

of a facility or organization as provider-based, temporary treatment as

provider-based, correction of errors, status of Indian Health Service

and Tribal facilities and organizations, FQHCs and ``look alikes,'' and

effective dates of provider-based status.

2. Proposed Changes to the Scope of the Provider-Based Status

Regulations for CAHs

(a) CAH-Based Clinical Diagnostic Laboratory Facilities

The provider-based status rules generally apply to situations where

there is a financial incentive for a facility or organization to claim

affiliation with a main provider. The provider-based status rules

establish criteria for a facility or organization to demonstrate that

it is integrated with the main provider for payment purposes. However,

the regulation at Sec. 413.65(a)(1)(ii) lists specific types of

facilities and organizations for which CMS will not make provider-based

determinations. Included on this list of facilities exempt from

provider-based determinations are facilities that furnish only clinical

diagnostic laboratory services (Sec. 413.65(a)(1)(ii)(G)).

As we have stated in previously issued rules (that is, the FY 2006

IPPS final rule (70 FR 47457)), the list at

[[Page 24205]]

Sec. 413.65(a)(1)(ii) was created after we had concluded that

``provider-based determinations should not be made for these facilities

because the outcome of the determination (that is, whether a facility,

unit, or department is found to be freestanding or provider-based)

would not affect the methodology used to make Medicare or Medicaid

payment, the scope of benefits available to a Medicare beneficiary in

or at the facility, or the deductible or coinsurance liability of a

Medicare beneficiary in or at the facility.'' We note that we excluded

a facility that furnishes only clinical diagnostic laboratory services

in Sec. 413.65(a)(1)(ii)(G) from the list in Sec. 413.65(a)(1)(ii)

because these facilities are generally paid under the Clinical

Laboratory Fee Schedule (CLFS), regardless of the setting in which the

services are furnished. Consequently, we believed that whether a

clinical diagnostic laboratory was freestanding or provider-based would

not affect the amount of Medicare payment.

However, upon further review of existing Sec. 413.65(a)(1)(ii), we

believe that a clinical diagnostic laboratory, when operated as part of

a CAH, generates a higher Medicare payment than when operating as a

freestanding facility. When a clinical diagnostic laboratory is part of

a CAH, the services furnished by the laboratory are generally paid at

101 percent of reasonable cost. Otherwise, clinical diagnostic

laboratory services provided by a freestanding diagnostic laboratory

are paid under the CLFS. Currently, because the services of a clinical

diagnostic laboratory of a CAH are paid at a higher rate by virtue of

being provided by a CAH department, we believe they should be subject

to the rules under the provider-based status regulations at Sec.

413.65.

Therefore, we are proposing to exclude a clinical diagnostic

laboratory facility that operates as part of a CAH from the list of

facilities for which we do not make provider-based determinations. That

is, we are proposing to revise the regulations to require facilities

furnishing only clinical diagnostic laboratory tests that operate as

part of a CAH to meet the applicable provider-based criteria in Sec.

413.65 in order for the CAH to receive payments for the services

furnished at those facilities at 101 percent of reasonable cost.

Specifically, we are proposing to revise the language of Sec.

413.65(a)(1)(ii)(G) to state that CMS will not make a determination of

provider-based status for payment purposes as to whether the following

facilities are provider-based: ``Independent diagnostic testing

facilities that furnish only services paid under a fee schedule, such

as facilities that furnish only screening mammography services,

facilities that furnish only clinical diagnostic laboratory tests,

other than those clinical diagnostic laboratory facilities operating as

parts of CAHs, or facilities that furnish only some combination of

these services'' (emphasis added). In addition, we would specify that

``Clinical diagnostic laboratories operating as parts of CAHs must meet

the applicable provider-based requirements.''

In proposing this change to the provider-based status rules, we

recognize that there may be confusion between this proposal that a

clinical diagnostic laboratory facility that is part of a CAH must meet

provider-based rules in order to receive the higher reasonable cost-

based payment and the proposal discussed in section VII.C.2. of this

preamble to implement section 148 of Public Law 110-275. In section

VII.C.2. of this preamble, we are proposing to revise the regulations

at Sec. 413.70 to specify that CAHs can bill for outpatient clinical

diagnostic laboratory services furnished to patients who are

outpatients of the CAH, regardless of whether they are physically

present in the CAH at the time the specimen is collected. In the

proposed revision of Sec. 413.70, we are proposing that, in order for

a CAH to bill 101 percent of reasonable costs for outpatient clinical

diagnostic laboratory services furnished to an individual, the

individual must be an outpatient of the CAH, as defined at Sec. 410.2,

and be receiving services directly from the CAH. That is, either the

individual must be receiving outpatient services in the CAH on the same

day that the specimen is collected or the specimen must be collected by

an employee of the CAH. Under the proposed changes to the provider-

based status rules under Sec. 413.65 in this section of this proposed

rule, if a CAH chooses to own or operate a clinical diagnostic

laboratory facility, the facility must meet the provider-based status

requirements under Sec. 413.65 in order for the facility to be

considered part of the CAH and in order for the CAH to be eligible to

be paid based on 101 percent of reasonable cost for the clinical

diagnostic laboratory services furnished by the laboratory facility.

According to our proposal in section VII.C.2. of this preamble, a CAH

would have the option to bill for outpatient clinical diagnostic

laboratory services at 101 percent of reasonable cost for patients

receiving services in nonprovider-based facilities or locations as long

as the patients are outpatients of the CAH as defined above and either

the specimen is collected by an employee of the CAH or the individual

is receiving outpatient services in the CAH on the same day that the

specimen is collected. In addition, under our provider-based status

proposal, a CAH can also bill for clinical diagnostic laboratory

services at 101 percent of reasonable costs for patients who are

furnished services in a clinical diagnostic laboratory facility that is

owned and operated by the CAH as long as the clinical diagnostic

laboratory facility meets the provider-based status requirements at

Sec. 413.65.

In summary, we believe that clinical diagnostic laboratory

facilities could generate an increase in Medicare payments when they

are part of a CAH compared to when they are freestanding or when they

are part of a hospital. Therefore, we are proposing that these

facilities, which are currently exempt from provider-based

determinations, must meet the applicable provider-based status

requirements at Sec. 413.65 when they are part of a CAH in order for

the CAH to receive payment for their clinical diagnostic laboratory

services based on reasonable cost. It is important to note that, in

addition to meeting the provider-based status requirements at Sec.

413.65, these provider-based facilities would also have to meet other

requirements for provider-based facilities operated by CAHs, including

distance requirements under Sec. 485.610(e). Generally, the

regulations at Sec. 485.610(e) also provide that an off-campus

provider-based department, remote location, or distinct part

psychiatric or rehabilitation unit of a CAH that was created or

acquired on or after January 1, 2008, cannot be within 35 miles of a

hospital or another CAH if the CAH is to continue meeting the location

requirements under Sec. 485.610(e).

b. CAH-Based Ambulance Services

The existing regulations at Sec. 413.70(b)(5) provide that

ambulance services are paid at reasonable cost if the services are

furnished by a CAH or by an entity owned and operated by a CAH, but

only if the CAH or entity is the only supplier or provider of ambulance

service within a 35-mile drive of the CAH or entity. We are soliciting

public comments regarding whether an ambulance service that is owned

and operated by a CAH, and is eligible to receive reasonable cost-based

payment should be required to meet the provider-based status rules. It

is important to consider that the regulation at Sec. 413.70(b)(5)

already specifies proximity criteria that CAH-owned and operated

ambulance services must meet

[[Page 24206]]

in order to be paid at reasonable cost. However, these proximity

requirements are used to ensure that CAH-owned and operated ambulance

services do not receive higher payments in relation to a competing

ambulance service that is not owned and operated by a CAH. It can be

argued that CAH-owned and operated ambulance suppliers or providers

should also be required to meet the provider-based status requirements

to demonstrate that the ambulance services are integrated with the CAH

because the CAH ambulance services are paid at a higher Medicare

payment level when they are owned and operated by a CAH compared to

when they are freestanding.

3. Technical Correction to Regulations

Section 413.65(a)(1)(ii)(H) of the regulations specifies, among the

facilities for which CMS does not make provider-based determinations

for payment purposes, ``Facilities, other than those operating as parts

of CAHs, furnishing only physical, occupational, or speech therapy to

ambulatory patients, for as long as the $1,500 annual cap on coverage

of physical, occupational, or speech therapy, as described in section

1833(g)(2) of the Act, remains suspended by the action of the

subsequent legislation.'' We are proposing two basic changes to the

language of Sec. 413.65(a)(1)(ii)(H). First, we are proposing to

delete the phrase ``$1,500 annual cap'' and replace it with the generic

phrase ``annual financial cap amount''. We are proposing this change

because we need to update our regulations to reflect that the $1,500

annual financial cap is no longer applicable and has been replaced with

the cap amount described in section 1833(g)(2)(B) of the Act.

Specifically, the $1,500 cap amount described in section 1833(g)(2)(A)

of the Act was limited to 3 years (1999 through 2001). For years after

2001, in general, the amount of the annual cap on payment of physical,

occupational, or speech therapy is the amount specified in the

preceding year increased by the percentage increase in the Medicare

economic index for the current year (section 1833(g)(2)(B) of the Act).

However, we note that the annual cap amount did not apply to expenses

incurred with respect to such therapy services during various years as

set forth in the statute.

Second, we are proposing to replace the phrase ``for as long as''

with the phrase ``throughout any period during which'' and to replace

the phrase ``remains suspended by the action of subsequent

legislation'' with the phrase ``is suspended by legislation''. We are

proposing this change because Sec. 413.65(a)(1)(ii)(H), as currently

written, may incorrectly suggest that the annual financial cap amounts

on the therapy services described in sections 1833(g)(1) and 1833(g)(3)

of the Act continue to be suspended. Although the financial caps on

such services were suspended when the provision was added originally,

they ceased to be suspended for a portion of 2003 and then beginning

January 1, 2006. We believe the proposed change would eliminate any

confusion about whether the therapy caps were or were not currently

suspended as well as accomplish our goal of exempting facilities, other

than those operating as parts of CAHs, that furnish only physical,

occupational, or speech therapy to ambulatory patients from complying

with the provider-based status requirements any time the annual

financial cap amount as described in section 1883(g)(2) of the Act is

suspended by legislation. In conclusion, we maintain that we would not

make provider-based determinations for non-CAH operated facilities

furnishing only physical, occupational, or speech therapy to ambulatory

patients when the therapy cap is suspended.

VIII. Proposed Changes to the Long-Term Care Hospital Prospective

Payment System (LTCH PPS) for RY 2010

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's

Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA)

(Pub. L. 106-113) as amended by section 307(b) of the Medicare,

Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

(BIPA) (Pub. L. 106-554) provides for payment for both the operating

and capital-related costs of hospital inpatient stays in long-term care

hospitals (LTCHs) under Medicare Part A based on prospectively set

rates. The Medicare prospective payment system (PPS) for LTCHs applies

to hospitals that are described in section 1886(d)(1)(B)(iv) of the

Social Security Act (the Act), effective for cost reporting periods

beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines a LTCH as ``a

hospital which has an average inpatient length of stay (as determined

by the Secretary) of greater than 25 days.'' Section

1886(d)(1)(B)(iv)(II) of the Act also provides an alternative

definition of LTCHs: Specifically, a hospital that first received

payment under section 1886(d) of the Act in 1986 and has an average

inpatient length of stay (LOS) (as determined by the Secretary of

Health and Human Services (the Secretary)) of greater than 20 days and

has 80 percent or more of its annual Medicare inpatient discharges with

a principal diagnosis that reflects a finding of neoplastic disease in

the 12-month cost reporting period ending in FY 1997.

Section 123 of the BBRA requires the PPS for LTCHs to be a ``per

discharge'' system with a diagnosis-related group (DRG) based patient

classification system that reflects the differences in patient

resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that

the Secretary shall examine, and may provide for, adjustments to

payments under the LTCH PPS, including adjustments to DRG weights, area

wage adjustments, geographic reclassification, outliers, updates, and a

disproportionate share adjustment.

In the August 30, 2002 Federal Register, we issued a final rule

that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR

55954). This system currently uses information from LTCH patient

records to classify patients into distinct MS-long-term care diagnosis-

related groups (MS-LTC-DRGs) based on clinical characteristics and

expected resource needs. Payments are calculated for each MS-LTC-DRG

and provisions are made for appropriate payment adjustments. Payment

rates under the LTCH PPS are updated annually and published in the

Federal Register.

The LTCH PPS replaced the reasonable cost-based payment system

under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA)

(Pub. L. 97-248) for payments for inpatient services provided by a LTCH

with a cost reporting period beginning on or after October 1, 2002.

(The regulations implementing the TEFRA reasonable cost-based payment

provisions are located at 42 CFR Part 413.) With the implementation of

the PPS for acute care hospitals authorized by the Social Security

Amendments of 1983 (Pub. L. 98-21), which added section 1886(d) to the

Act, certain hospitals, including LTCHs, were excluded from the PPS for

acute care hospitals and were paid their reasonable costs for inpatient

services subject to a per discharge limitation or target amount under

the TEFRA system. For each cost reporting period, a hospital-specific

ceiling on payments was determined by multiplying the hospital's

updated target amount by the number of total current year Medicare

[[Page 24207]]

discharges. (Generally, in section VIII. of this preamble, when we

refer to discharges, the intent is to describe Medicare discharges.)

The August 30, 2002 final rule further details the payment policy under

the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year

transition period. During this 5-year transition period, a LTCH's total

payment under the PPS was based on an increasing percentage of the

Federal rate with a corresponding decrease in the percentage of the

LTCH PPS payment that is based on reasonable cost concepts. However,

effective for cost reporting periods beginning on or after October 1,

2006, total LTCH PPS payments are based on 100 percent of the Federal

rate.

In addition, in the August 30, 2002 final rule, we presented an in-

depth discussion of the LTCH PPS, including the patient classification

system, relative weights, payment rates, additional payments, and the

budget neutrality requirements mandated by section 123 of the BBRA. The

same final rule that established regulations for the LTCH PPS under 42

CFR Part 412, Subpart O also contained LTCH provisions related to

covered inpatient services, limitation on charges to beneficiaries,

medical review requirements, furnishing of inpatient hospital services

directly or under arrangement, and reporting and recordkeeping

requirements. We refer readers to the August 30, 2002 final rule for a

comprehensive discussion of the research and data that supported the

establishment of the LTCH PPS (67 FR 55954).

In the June 6, 2003 Federal Register, we published a final rule

that set forth the FY 2004 annual update of the payment rates for the

Medicare PPS for inpatient hospital services furnished by LTCHs (68 FR

34122). It also changed the annual period for which the payment rates

were to be effective, such that the annual updated rates were effective

from July 1 through June 30 instead of from October 1 through September

30. We refer to the July through June time period as a ``long-term care

hospital rate year'' (LTCH PPS rate year). In addition, we changed the

publication schedule for the annual update to allow for an effective

date of July 1. The payment amounts and factors used to determine the

annual update of the LTCH PPS Federal rate are based on a LTCH PPS rate

year. While the LTCH payment rate updates were to be effective July 1,

the annual update of the DRG classifications and relative weights for

LTCHs continued to be linked to the annual adjustments of the acute

care hospital inpatient DRGs and were effective each October 1.

As discussed in detail in section VIII.A.1. of the May 9, 2008 RY

2009 LTCH PPS final rule (73 FR 26788), we again changed the schedule

for the annual updates of the LTCH PPS Federal payment rates beginning

with RY 2010. We consolidated the rulemaking cycle for the annual

update of the LTCH PPS Federal payment rates and description of the

methodology and data used to calculate these payment rates with the

annual update of the MS-LTC-DRG classifications and associated

weighting factors for LTCHs so that the updates to the rates and the

weights now occur on the same schedule and appear in the same

publication. As a result, the updates to the rates and the weights are

now effective on October 1 (on a Federal fiscal year schedule), and the

annual updates to the LTCH PPS Federal rates will no longer be

published with a July 1 effective date (73 FR 26797 through 26798).

Public Law 110-173 (MMSEA), enacted on December 29, 2007, included

provisions that have various effects on the LTCH PPS. In addition to

amending section 1861 of the Act to add a subsection (ccc) which

provided an additional definition of LTCHs and facility criteria,

Public Law 110-173 also required that no later than 18 months after the

date of enactment of the law, the Secretary conduct a study and submit

a report to Congress that included ``recommendations for such

legislation and administrative actions, including timelines for the

implementation of LTCH patient criteria or other actions, as the

Secretary determines appropriate.'' The payment policy provisions under

Public Law 110-173 also have varying timeframes of applicability.

First, we note that certain provisions of Public Law 110-173 provided

that the Secretary shall not apply, for cost reporting periods

beginning on or after the date of the enactment of Public Law 110-173

(December 29, 2007) for a 3-year period: The extension of payment

adjustments at Sec. 412.534 to ``grandfathered LTCHs'' (a long-term

care hospital identified by the amendment made by section 4417(a) of

Pub. L. 105-33); and the payment adjustment at Sec. 412.536 to

``freestanding'' LTCHs. In addition, Public Law 119-173 provided that

the Secretary shall not apply, for the 3-year period beginning on the

date of enactment of the Act the revision to the short-stay outlier

(SSO) policy that was finalized in the RY 2008 LTCH PPS final rule (72

FR 26904 and 26992) and the one-time adjustment to the payment rates

provided for in Sec. 412.523(d)(3). The statute also provided that the

base rate for RY 2008 be the same as the base rate for RY 2007 (the

revised base rate, however, does not apply to discharges occurring on

or after July 1, 2007, and before April 1, 2008); for a 3-year

moratorium (with specified exceptions) on the establishment of new

LTCHs, LTCH satellites, and on the increase in the number of LTCH beds.

Public Law 110-173 also revised the threshold percentages for certain

co-located LTCHs and LTCH satellites governed under Sec. 412.534.

Finally, Public Law 110-173 provided for an expanded review of medical

necessity for admission and continued stay at LTCHs.

In the RY 2009 LTCH PPS final rule (73 FR 26801 through 26812), we

established the applicable Federal rates for RY 2009 consistent with

section 1886(m)(2) of the Act as amended by Public Law 110-173. We also

revised the regulations at Sec. 412.523(d)(3) to change the

methodology for the one-time budget neutrality adjustment and to comply

with section 114(c)(4) of Public Law 110-173. Other policy revisions

necessitated by the statutory changes of Public Law 110-173 were

addressed in separate rulemaking documents (73 FR 24871 and 73 FR

29699).

Section 4302 of the American Recovery and Reinvestment Act of 2009

(ARRA), Public Law 111-5, enacted on February 17, 2009, included

several amendments to the provisions set forth in section 114 of Public

Law 110-173 (MMSEA). We have issued instructions to the fiscal

intermediaries and MACs interpreting the provisions of section 4302 of

Public Law 111-5 (Change Request 6444). We intend to implement the

provisions of section 4302 of Public Law 111-5 in an interim final rule

with comment period as part of the FY 2010 IPPS and RY 2010 LTCH PPS

final rule. In addition, we intend to finalize the regulatory

provisions implementing section 114 of Public Law 110-173, as

appropriate, in the same final rule.

2. Criteria for Classification as a LTCH

a. Classification as a LTCH

Under the existing regulations at Sec. 412.23(e)(1) and (e)(2)(i),

which implement section 1886(d)(1)(B)(iv)(I) of the Act, to qualify to

be paid under the LTCH PPS, a hospital must have a provider agreement

with Medicare and must have an average Medicare inpatient length of

stay (LOS) of greater than 25 days. Alternatively, Sec.

412.23(e)(2)(ii) states that for cost reporting periods beginning on or

after August 5, 1997, a hospital that was first excluded from the PPS

in 1986 and can

[[Page 24208]]

demonstrate that at least 80 percent of its annual Medicare inpatient

discharges in the 12-month cost reporting period ending in FY 1997 have

a principal diagnosis that reflects a finding of neoplastic disease

must have an average inpatient length of stay for all patients,

including both Medicare and non-Medicare inpatients, of greater than 20

days.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions,

as described in Sec. 412.22(c), and therefore, are not subject to the

LTCH PPS rules:

Veterans' Administration hospitals.

Hospitals that are reimbursed under State cost control

systems approved under 42 CFR Part 403.

Hospitals that are reimbursed in accordance with

demonstration projects authorized under section 402(a) of the Social

Security Amendments of 1967 (Pub. L. 90-248) (42 U.S.C. 1395b-1) or

section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92-

603) (42 U.S.C. 1395b-1 (note)) (Statewide all-payer systems, subject

to the rate-of-increase test at section 1814(b) of the Act).

Nonparticipating hospitals furnishing emergency services

to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth

discussion of beneficiary liability under the LTCH PPS (67 FR 55974

through 55975). In the RY 2005 LTCH PPS final rule (69 FR 25676), we

clarified that the discussion of beneficiary liability in the August

30, 2002 final rule was not meant to establish rates or payments for,

or define Medicare-eligible expenses. Under Sec. 412.507, if the

Medicare payment to the LTCH is the full LTC-DRG payment amount, as

consistent with other established hospital prospective payment systems,

a LTCH may not bill a Medicare beneficiary for more than the deductible

and coinsurance amounts as specified under Sec. 409.82, Sec. 409.83,

and Sec. 409.87 and for items and services as specified under Sec.

489.30(a). However, under the LTCH PPS, Medicare will only pay for days

for which the beneficiary has coverage until the SSO threshold is

exceeded. Therefore, if the Medicare payment was for a SSO case (Sec.

412.529) that was less than the full LTC-DRG payment amount because the

beneficiary had insufficient remaining Medicare days, the LTCH could

also charge the beneficiary for services delivered on those uncovered

days (Sec. 412.507).

4. Administrative Simplification Compliance Act (ASCA) and Health

Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the

Administrative Simplification Compliance Act (ASCA) (Pub. L. 107-105),

and the Health Insurance Portability and Accountability Act of 1996

(HIPAA) (Pub. L. 104-191). Section 3 of the ASCA requires that the

Medicare Program deny payment under Part A or Part B for any expenses

incurred for items or services ``for which a claim is submitted other

than in an electronic form specified by the Secretary.'' Section

1862(h) of the Act (as added by section 3(a) of the ASCA) provides that

the Secretary shall waive such denial in two specific types of cases

and may also waive such denial ``in such unusual cases as the Secretary

finds appropriate'' (68 FR 48805). Section 3 of the ASCA operates in

the context of the HIPAA regulations, which include, among other

provisions, the transactions and code sets standards requirements

codified as 45 CFR parts 160 and 162, subparts A and I through R

(generally known as the Transactions Rule). The Transactions Rule

requires covered entities, including covered health care providers, to

conduct certain electronic healthcare transactions according to the

applicable transactions and code sets standards.

B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group

(MS-LTC-DRG) Classifications and Relative Weights

1. Background

Section 123 of the BBRA requires that the Secretary implement a PPS

for LTCHs (that is, a per discharge system with a diagnosis-related

group (DRG)-based patient classification system reflecting the

differences in patient resources and costs). Section 307(b)(1) of the

BIPA modified the requirements of section 123 of the BBRA by requiring

that the Secretary examine ``the feasibility and the impact of basing

payment under such a system [the long-term care hospital (LTCH) PPS] on

the use of existing (or refined) hospital DRGs that have been modified

to account for different resource use of LTCH patients, as well as the

use of the most recently available hospital discharge data.''

When the LTCH PPS was implemented for cost reporting periods

beginning on or after October 1, 2002, we adopted the same DRG patient

classification system (that is, the CMS DRGs) that was utilized at that

time under the IPPS. As a component of the LTCH PPS, we refer to this

patient classification system as the ``long-term care diagnosis-related

groups (LTC-DRGs).'' As discussed in greater detail below, although the

patient classification system used under both the LTCH PPS and the IPPS

are the same, the relative weights are different. The established

relative weight methodology and data used under the LTCH PPS result in

relative weights under the LTCH PPS that reflect ``the differences in

patient resource use \* \* \*'' of LTCH patients (section 123(a)(1) of the

BBRA (Pub. L. 106-113)).

As part of our efforts to better recognize severity of illness

among patients, in the FY 2008 IPPS final rule with comment period (72

FR 47130), the MS-DRGs and the Medicare severity long-term care

diagnosis-related groups (MS-LTC-DRGs) were adopted under the IPPS and

the LTCH PPS, respectively, effective beginning October 1, 2007 (FY

2008). For a full description of the development and implementation of

the MS-DRGs and MS-LTC-DRGs, we refer readers to the FY 2008 IPPS final

rule with comment period (72 FR 47141 through 47175 and 47277 through

47299). (We note that, in that same final rule, we revised the

regulations at Sec. 412.503 to specify that for LTCH discharges

occurring on or after October 1, 2007, when applying the provisions of

42 CFR Part 412, Subpart O applicable to LTCHs for policy descriptions

and payment calculations, all references to LTC-DRGs would be

considered a reference to MS-LTC-DRGs. For the remainder of this

section, we present the discussion in terms of the current MS-LTC-DRG

patient classification system unless specifically referring to the

previous LTC-DRG patient classification system that was in effect

before October 1, 2007.) We believe the MS-DRGs (and by extension, the

MS-LTC-DRGs) represent a substantial improvement over the previous CMS

DRGs in their ability to differentiate cases based on severity of

illness and resource consumption.

The MS-DRGs adopted in FY 2008 represent an increase in the number

of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). In FY 2009, an

additional MS-DRG was adopted for a total of 746 distinct groupings (73

FR 48497). In addition to improving the DRG system's recognition of

severity of illness, we believe the MS-DRGs are responsive to the

public comments that were made on the FY 2007 IPPS proposed rule with

respect to how we should undertake further DRG reform. The MS-DRGs use

[[Page 24209]]

the CMS DRGs as the starting point for revising the DRG system to

better recognize resource complexity and severity of illness. We have

generally retained all of the refinements and improvements that have

been made to the base DRGs over the years that recognize the

significant advancements in medical technology and changes to medical

practice.

Consistent with section 123 of the BBRA, as amended by section

307(b)(1) of the BIPA, and Sec. 412.515, we use information derived

from LTCH PPS patient records to classify LTCH discharges into distinct

MS-LTC-DRGs based on clinical characteristics and estimated resource

needs. We then assign an appropriate weight to the MS-LTC-DRGs to

account for the difference in resource use by patients exhibiting the

case complexity and multiple medical problems characteristic of LTCHs.

In a departure from the IPPS, and as discussed in greater detail

below in section VIII.B.3.e. of this preamble, we use low-volume MS-

LTC-DRGs (that is, MS-LTC-DRGs with less than 25 LTCH cases) in

determining the MS-LTC-DRG relative weights because LTCHs do not

typically treat the full range of diagnoses as do acute care hospitals.

For purposes of determining the relative weights for the large number

of low-volume MS-LTC-DRGs, we group all of the low-volume MS-LTC-DRGs

into five quintiles based on average charge per discharge. (A detailed

discussion of the application of the Lewin Group ``quintile'' model

that was used to develop the LTC-DRGs appears in the August 30, 2002

LTCH PPS final rule (67 FR 55978).) We also account for adjustments to

payments for SSO cases (that is, cases where the covered LOS at the

LTCH is less than or equal to five-sixths of the geometric ALOS for the

MS-LTC-DRG). Furthermore, we make adjustments to account for

nonmonotonically increasing weights, when necessary. That is,

theoretically, cases under the MS-LTC-DRG system that are more severe

require greater expenditure of medical care resources and will result

in higher average charges such that, in the severity levels within a

base MS-LTC-DRG, the weights should increase monotonically with

severity from the lowest to highest severity level. (We discuss

nonmonotonicity in greater detail and our proposed methodology to

adjust the proposed RY 2010 MS-LTC-DRG relative weights to account for

nonmonotonically increasing relative weights in section VIII.B.3.f.

(Step 6) of this preamble.)

2. Patient Classifications Into MS-LTC-DRGs

a. Background

The MS-DRGs (used under the IPPS) and the MS-LTC-DRGs (used under

the LTCH PPS) are based on the CMS DRG structure. As noted above in

this section, we refer to the DRGs under the LTCH PPS as MS-LTC-DRGs

although they are structurally identical to the DRGs used under the

IPPS.

The MS-DRGs are organized into 25 major diagnostic categories

(MDCs), most of which are based on a particular organ system of the

body; the remainder involve multiple organ systems (such as MDC 22,

Burns). Within most MDCs, cases are then divided into surgical DRGs and

medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy

that orders operating room (O.R.) procedures or groups of O.R.

procedures by resource intensity. The GROUPER software program does not

recognize all ICD-9-CM procedure codes as procedures affecting DRG

assignment. That is, procedures that are not surgical (for example,

EKG), or minor surgical procedures (for example, biopsy of skin and

subcutaneous tissue (code 86.11)) do not affect the MS-LTC-DRG

assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a

predetermined specific rate for each discharge and that payment varies

by the MS-LTC-DRG to which a beneficiary's stay is assigned. Cases are

classified into MS-LTC-DRGs for payment based on the following six data

elements:

Principal diagnosis.

Up to eight additional diagnoses.

Up to six procedures performed.

Age.

Sex.

Discharge status of the patient.

Upon the discharge of the patient from a LTCH, the LTCH must assign

appropriate diagnosis and procedure codes from the most current version

of the International Classification of Diseases, Ninth Revision,

Clinical Modification (ICD-9-CM). HIPAA Transactions and Code Sets

Standards regulations at 45 CFR Parts 160 and 162 require that no later

than October 16, 2003, all covered entities must comply with the

applicable requirements of Subparts A and I through R of Part 162.

Among other requirements, those provisions direct covered entities to

use the ASC X12N 837 Health Care Claim: Institutional, Volumes 1 and 2,

Version 4010, and the applicable standard medical data code sets for

the institutional health care claim or equivalent encounter information

transaction (45 CFR 162.1002 and 45 CFR 162.1102). For additional

information on the ICD-9-CM Coding System, we refer readers to the FY

2008 IPPS final rule with comment period (72 FR 47241 through 47243 and

47277 through 47281). We also refer readers to the detailed discussion

on correct coding practices in the August 30, 2002 LTCH PPS final rule

(67 FR 55981 through 55983). Additional coding instructions and

examples are published in the Coding Clinic for ICD-9-CM, a product of

the American Hospital Association.

To create the MS-DRGs (and by extension, the MS-LTC-DRGs),

individual DRGs were subdivided according to the presence of specific

secondary diagnoses designated as complications or comorbidities (CCs)

into three, two, or one level, depending on the impact of the CCs on

resources used for those cases. Specifically, there are sets of MS-DRGs

that are split into 2 or 3 subgroups based on the presence or absence

of a CC or a major complication and comorbidity (MCC). The original

discussion about the creation of MS-DRGs and their severity levels is

described in detail in the FY 2008 IPPS final rule with comment period

(72 FR 47169). However, to reiterate the development of the CCs and

MCCs, two of our major goals were to create DRGs that would more

accurately reflect the severity of the cases assigned to them and to

create groups that would have sufficient volume so that meaningful and

stable payment weights could be developed. In designating an MS-DRG as

one that will be divided into subgroups based on the presence of a CC

or MCC, we developed a set of criteria to facilitate the decisionmaking

process. The subgroup was required to meet all criteria, which are

described in detail in the FY 2008 IPPS final rule with comment period

(72 FR 47169). As a first step, each of the base MS-DRGs was subdivided

into three subgroups: Non-CC, CC, and MCC. Each subgroup was then

analyzed in relation to the other two subgroups, and the criteria were

applied in the following hierarchical manner.

If a three-way subdivision met the criteria, we divided

the base MS-DRG into three CC subgroups.

If only one type of two-way subdivisions met the criteria,

we subdivided the base MS-DRG into two CC subgroups based on the type

of two-way subdivision that met the criteria.

If both types of two-way subdivisions met the criteria, we

subdivided the base MS-DRG into two CC subgroups based on the type of

two-

[[Page 24210]]

way subdivision with the highest R\2\ (most explanatory power to

explain the difference in average charges).

Otherwise, we did not subdivide the base MS-DRG into CC

subgroups.

For any given base MS-DRG, our evaluation in some cases showed that

a subdivision between a non-CC and a combined CC/MCC subgroup was all

that was warranted (that is, there was not a sufficient difference

between the CC and MCC subgroups to justify separate CC and MCC

subgroups). Conversely, in some cases, even though an MCC subgroup was

warranted, there was not a sufficient difference between the non-CC and

CC subgroups to justify separate subgroups.

Based on this methodology, a base MS-DRG may be subdivided

according to the following three alternatives:

DRGs with three subgroups (MCC, CC, and non-CC).

DRGs with two subgroups consisting of an MCC subgroup but

with the CC and non-CC subgroups combined. These are referred to as

``with MCC'' and ``without MCC.''

DRGs with two subgroups consisting of a non-CC subgroup

but with the CC and MCC subgroups combined. We refer to these two

groups as ``with CC/MCC'' and ``without CC/MCC.''

For example, under the MS-LTC-DRG system, multiple sclerosis and

cerebellar ataxia with MCC is MS-LTC-DRG 58; multiple sclerosis and

cerebellar ataxia with CC is MS-LTC-DRG 59; and multiple sclerosis and

cerebellar ataxia without CC/MCC is MS-LTC-DRG 60. For purposes of

discussion in this section, the term ``base DRG'' is used to refer to

the DRG category that encompasses all levels of severity for that DRG.

For example, when referring to the entire DRG category for multiple

sclerosis and cerebellar ataxia, which includes the above three

severity levels, we would use the term ``base DRG.'' (As noted above in

this section, further information on the development and implementation

of the MS-DRGs and MS-LTC-DRGs can be found in the FY 2008 IPPS final

rule with comment period (72 FR 47138 through 47175 and 47277 through

47299).)

In developing the first MS-DRG GROUPER program (that is, Version

25.0 effective for FY 2008), the diagnoses comprising the CC list were

completely redefined. The revised CC list is primarily comprised of

significant acute disease, acute exacerbations of significant chronic

diseases, advanced or end stage chronic diseases, and chronic diseases

associated with extensive debility. In general, most chronic diseases

were not included on the revised CC list. For a patient with a chronic

disease, a significant acute manifestation of the chronic disease was

required to be present and coded for the patient to be assigned a CC.

In addition to the revision of the CC list, each CC was also

categorized as an MCC or a CC based on relative resource use.

Approximately 12 percent of all diagnoses codes were classified as an

MCC, 24 percent as a CC, and 64 percent as a non-CC. Diagnoses closely

associated with mortality (ventricular fibrillation, cardiac arrest,

shock, and respiratory arrest) were assigned as an MCC if the patient

lived, but as a non-CC if the patient died. The MCC, CC, and non-CC

categorization was used to subdivide the surgical and medical DRGs into

up to three levels, with a case being assigned to the most resource

intensive level (for example, a case with two secondary diagnoses that

are categorized as an MCC and a CC is assigned to the MCC level).

Medicare contractors (that is, fiscal intermediaries and MACs)

enter the clinical and demographic information submitted by LTCHs into

their claims processing systems and subject this information to a

series of automated screening processes called the Medicare Code Editor

(MCE). These screens are designed to identify cases that require

further review before assignment into a MS-LTC-DRG can be made. During

this process, the following types of cases are selected for further

development:

Cases that are improperly coded. (For example, diagnoses

are shown that are inappropriate, given the sex of the patient. Code

68.69 (Other and unspecified radical abdominal hysterectomy) would be

an inappropriate code for a male.)

Cases including surgical procedures not covered under

Medicare. (For example, organ transplant in a nonapproved transplant

center.)

Cases requiring more information. (For example, ICD-9-CM

codes are required to be entered at their highest level of specificity.

There are valid 3-digit, 4-digit, and 5-digit codes. That is, code 262

(Other severe protein-calorie malnutrition) contains all appropriate

digits, but if it is reported with either fewer or more than 3 digits,

the claim will be rejected by the MCE as invalid.)

After screening through the MCE, each claim is classified into the

appropriate MS-LTC-DRG by the Medicare LTCH GROUPER software on the

basis of diagnosis and procedure codes and other demographic

information (age, sex, and discharge status). The GROUPER software used

under the LTCH PPS is the same GROUPER software program used under the

IPPS. Following the MS-LTC-DRG assignment, the Medicare contractor

determines the prospective payment amount by using the Medicare PRICER

program, which accounts for hospital-specific adjustments. Under the

LTCH PPS, we provide an opportunity for LTCHs to review the MS-LTC-DRG

assignments made by the Medicare contractor and to submit additional

information within a specified timeframe as provided in Sec.

412.513(c).

The GROUPER software is used both to classify past cases to measure

relative hospital resource consumption to establish the MS-LTC-DRG

weights and to classify current cases for purposes of determining

payment. The records for all Medicare hospital inpatient discharges are

maintained in the MedPAR file. The data in this file are used to

evaluate possible MS-DRG and MS-LTC-DRG classification changes and to

recalibrate the MS-DRG and MS-LTC-DRG relative weights during our

annual update under both the IPPS (Sec. 412.60(e)) and the LTCH PPS

(Sec. 412.517), respectively.

Although the LTCH PPS RYs 2004 through 2009 annual payment rate

update cycles were effective July 1 through June 30 instead of October

1 through September 30 (with the exception of the 15-month RY 2009

payment rate update cycle, which is effective July 1, 2008 through

September 30, 2009), because the patient classification system utilized

under the LTCH PPS uses the same DRGs as those used under the IPPS for

acute care hospitals, the annual update of the LTC-DRG classifications

and relative weights continued to remain linked to the annual

reclassification and recalibration of the DRGs used under the IPPS.

Therefore, the payment rate update to the MS-LTC-DRG classifications

and relative weights are effective for discharges occurring on or after

October 1 through September 30 of each year (RYs 2004 through 2009),

and we published the annual proposed and final update of the MS-LTC-

DRGs in the same notice as the proposed and final update for the IPPS

(69 FR 34122 through 34125).

In the RY 2009 LTCH PPS final rule, we amended the regulations at

Sec. 412.503 and Sec. 412.535 in order to consolidate the rate year

and fiscal year rulemaking cycles, effective October 1, 2009 (73 FR

26797 through 26798). Specifically, we revised the regulations to shift

the payment rate update from a July 1 through June 30 cycle to an

October 1 through September 30 cycle. We extended the 2009 rate year

period to September 30, 2009, so that RY 2009 is

[[Page 24211]]

15 months; that is, July 1, 2008, through September 30, 2009.

Consequently, after the conclusion of the 15-month RY 2009, both the

annual update of the LTCH PPS payment rates (and the description of the

methodology and data used to calculate these payment rates) and the

annual update of the MS-LTC-DRG classifications and associated

weighting factors for LTCHs will be updated on an October 1 through

September 30 cycle and, thus, be effective on October 1 of each Federal

fiscal year beginning October 1, 2009. Beginning with the RY 2010 LTCH

PPS update, both the annual update of the LTCH PPS payment rate,

including the annual update of the MS-LTC-DRGs, and policy changes will

be presented along with the annual IPPS payment rate and policy changes

in a single combined rulemaking document published in the Federal

Register as is being done in this proposed rule.

Prior to FY 2004, the annual update to the DRGs used under the IPPS

had been based on the annual revisions to the ICD-9-CM codes and was

effective each October 1. As discussed in past LTCH PPS and IPPS

proposed and final rules (most recently in the FY 2009 IPPS final rule

(73 FR 48530)), section 503(a) of Public Law 108-173 amended section

1886(d)(5)(K) of the Act by adding a new clause (vii) which states that

``the Secretary shall provide for the addition of new diagnosis and

procedure codes in [sic] April 1 of each year, but the addition of such

codes shall not require the Secretary to adjust the payment (or

diagnosis-related group classification) \* \* \* until the fiscal year

that begins after such date.'' This requirement improves the

recognition of new technologies under the IPPS by accounting for those

ICD-9-CM codes in the MedPAR claims data earlier than the agency had

accounted for new technology in the past. In implementing the statutory

change, the agency has provided that ICD-9-CM diagnosis and procedure

codes for new medical technology may be created and assigned to

existing DRGs in the middle of the Federal fiscal year, on April 1.

Therefore, there is the possibility that one feature of the GROUPER

software program may be updated twice during a Federal fiscal year

(that is, October 1 and April 1). However, we note that as the

legislation permits, the DRG relative weights in effect for that fiscal

year will continue to be updated only once a year (October 1).

The patient classification system used under the LTCH PPS is the

same patient classification system that is used under the IPPS.

Therefore, the ICD-9-CM codes currently used under both the IPPS and

the LTCH PPS have the potential of being updated twice a year due to

the implementation of section 503(a) of Public Law 108-173 for the IPPS

(as explained above). Because we do not publish a midyear IPPS rule,

any April 1 ICD-9-CM coding update will not be published in the Federal

Register. Rather, consistent with the policy under the IPPS (discussed

in section II.G.7. of the preamble of this proposed rule), we will

assign any new diagnosis or procedure codes to the same DRG in which

its predecessor code was assigned, so that there will be no impact on

the DRG assignments. Any coding updates will be available through the

Web sites provided in section II.G.7. of the preamble of this proposed

rule and through the Coding Clinic for ICD-9-CM. Publishers and

software vendors currently obtain code changes through these sources in

order to update their code books and software system. If new codes are

implemented on April 1, revised code books and software systems,

including the GROUPER software program, will be necessary because the

most current ICD-9-CM codes must be reported. Therefore, for purposes

of the LTCH PPS, because each ICD-9-CM code must be included in the

GROUPER algorithm to classify each case under the correct LTCH PPS, the

GROUPER software program used under the LTCH PPS would need to be

revised to accommodate any new codes.

In implementing section 503(a) of Pub. L. 108-173, there will only

be an April 1 update if new technology diagnosis and procedure code

revisions are requested and approved. We note that any new codes

created for April 1 implementation will be limited to those primarily

needed to describe new technologies and medical services. However, we

reiterate that the process of discussing updates to the ICD-9-CM is an

open process through the ICD-9-CM Coordination and Maintenance

Committee. Requestors will be given the opportunity to present the

merits for a new code and to make a clear and convincing case for the

need to update ICD-9-CM codes for purposes of the IPPS new technology

add-on payment process through an April 1 update (as also discussed in

section II.G.7. of the preamble of this proposed rule).

There were no mid-year codes added to the ICD-9-CM coding system as

a result of the September 24-25, 2008 meeting of the ICD-9-CM

Coordination and Maintenance Committee. The next update to the ICD-9-CM

coding system will occur on October 1, 2009 (FY 2010), and the ICD-9-CM

coding set implemented on October 1, 2009, will continue through

September 30, 2010 (FY 2010). The ICD-9-CM Coordination and Maintenance

Committee met again on March 11-12, 2009. Because this meeting was for

the purpose of informing the public of proposed changes to the ICD-9-CM

code set as well as for requesting comment from the public, no

decisions regarding coding changes were made at this meeting.

Commenters were requested to submit comments by April 3, 2009,

concerning the proposed code revisions discussed at the March 11-12,

2009 meeting. Any new codes or other revisions created as a result of

this meeting are not included in this proposed rule because of the

short turnaround time required for the publication of the proposed

rule. However, new codes and any other revisions will appear in the

final rule in Tables 6A through 6F of the Addendum to that final rule.

Those codes appearing for the first time in the final rule will be

identified with an asterisk leading to the following notation: ``These

codes were discussed at the March 11-12, 2009 ICD-9-CM Coordination and

Maintenance Committee meeting and were not finalized in time to include

in the proposed rule. However, they will be implemented on October 1,

2009.'' The update to the ICD-9-CM coding system that is effective on

October 1, 2009 is discussed in section II.G.7. of the preamble of this

proposed rule.

b. Proposed Changes to the MS-LTC-DRGs for RY 2010

Consistent with our historical practice of using the same patient

classification system under the LTCH PPS as is used under the IPPS, in

this proposed rule, we are proposing to modify and revise the MS-LTC-

DRG classifications effective October 1, 2009, through September 30,

2010 (RY 2010) consistent with the proposed changes to specific MS-DRG

classifications presented above in section II.G. of this proposed rule

(that is, proposed GROUPER Version 27.0). Therefore, the proposed MS-

LTC-DRGs for RY 2010 presented in this proposed rule are the same as

the proposed MS-DRGs that would be used under the IPPS for FY 2010

(that is, GROUPER Version 27.0 as described in section II.G. of the

preamble of this proposed rule). In addition, because the proposed MS-

LTC-DRGs for RY 2010 are the same as the proposed MS-DRGs for FY 2010,

the other proposed changes that would affect MS-DRG (and by extension

MS-LTC-DRG) assignments under the proposed Version 27.0 of the GROUPER

discussed in section II.G. of the preamble of this proposed rule,

including the proposed changes to the

[[Page 24212]]

MCE software and changes to the ICD-9-CM coding system, would also be

applicable under the LTCH PPS for RY 2010.

3. Development of the Proposed RY 2010 MS-LTC-DRG Relative Weights

a. General Overview of the Development of the MS-LTC-DRG Relative

Weights

As we stated in the August 30, 2002 LTCH PPS final rule (67 FR

55984), one of the primary goals for the implementation of the LTCH PPS

is to pay each LTCH an appropriate amount for the efficient delivery of

medical care to Medicare patients. The system must be able to account

adequately for each LTCH's case-mix in order to ensure both fair

distribution of Medicare payments and access to adequate care for those

Medicare patients whose care is more costly. To accomplish these goals,

we have annually adjusted the LTCH PPS standard Federal prospective

payment system rate by the applicable relative weight in determining

payment to LTCHs for each case. (As we have noted above, we adopted the

MS-LTC-DRGs for the LTCH PPS beginning in FY 2008. However, this change

in the patient classification system does not affect the basic

principles of the development of relative weights under a DRG-based

prospective payment system.)

Although the adoption of the MS-LTC-DRGs resulted in some

modifications of existing procedures for assigning weights in cases of

zero volume and/or nonmonotonicity, as discussed in the FY 2008 IPPS

final rule with comment period (72 FR 47289 through 47295) and the FY

2009 IPPS final rule (73 FR 48542 through 48550) and as detailed in the

following sections, the basic methodology for developing the RY 2010

proposed MS-LTC-DRG relative weights in this proposed rule continues to

be determined in accordance with the general methodology established in

the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991).

Under the LTCH PPS, relative weights for each MS-LTC-DRG are a primary

element used to account for the variations in cost per discharge and

resource utilization among the payment groups (Sec. 412.515). To

ensure that Medicare patients classified to each MS-LTC-DRG have access

to an appropriate level of services and to encourage efficiency, we

calculate a relative weight for each MS-LTC-DRG that represents the

resources needed by an average inpatient LTCH case in that MS-LTC-DRG.

For example, cases in an MS-LTC-DRG with a relative weight of 2 will,

on average, cost twice as much to treat as cases in an MS-LTC-DRG with

a weight of 1.

b. Data

In this proposed rule, to calculate the proposed MS-LTC-DRG

relative weights for RY 2010, we are proposing to obtain total Medicare

allowable charges from FY 2008 Medicare LTCH bill data from the

December 2008 update of the MedPAR file, which are the best available

data at this time, and to use the proposed Version 27.0 of the GROUPER

to classify LTCH cases (as discussed above). We also are proposing that

if more recent data become available, we would use those data and the

finalized Version 27.0 of the GROUPER in establishing the RY 2010 MS-

LTC-DRG relative weights in the final rule.

Consistent with our historical methodology, we have excluded the

data from LTCHs that are all-inclusive rate providers and LTCHs that

are reimbursed in accordance with demonstration projects authorized

under section 402(a) of Public Law 90-248 or section 222(a) of Public

Law 92-603. (We refer readers to the FY 2009 IPPS final rule (73 FR

48532).) Therefore, in the development of the proposed RY 2010 MS-LTC-

DRG relative weights in this proposed rule, we have excluded the data

of the 13 all-inclusive rate providers and the 2 LTCHs that are paid in

accordance with demonstration projects that had claims in the FY 2008

MedPAR file.

c. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as

ventilator-dependent patients and rehabilitation and wound care. Some

case types (DRGs) may be treated, to a large extent, in hospitals that

have, from a perspective of charges, relatively high (or low) charges.

This nonrandom distribution of cases with relatively high (or low)

charges in specific MS-LTC-DRGs has the potential to inappropriately

distort the measure of average charges. To account for the fact that

cases may not be randomly distributed across LTCHs, in this proposed

rule, we are proposing to use a hospital-specific relative value (HSRV)

methodology to calculate the proposed MS-LTC-DRG relative weights

instead of the methodology used to determine the MS-DRG relative

weights under the IPPS described in section II.H. of the preamble of

this proposed rule. We believe this method will remove this hospital-

specific source of bias in measuring LTCH average charges.

Specifically, we are reducing the impact of the variation in charges

across providers on any particular proposed MS-LTC-DRG relative weight

by converting each LTCH's charge for a case to a relative value based

on that LTCH's average charge.

Under the HSRV methodology, we standardize charges for each LTCH by

converting its charges for each case to hospital-specific relative

charge values and then adjusting those values for the LTCH's case-mix.

The adjustment for case-mix is needed to rescale the hospital-specific

relative charge values (which, by definition, average 1.0 for each

LTCH). The average relative weight for a LTCH is its case-mix, so it is

reasonable to scale each LTCH's average relative charge value by its

case-mix. In this way, each LTCH's relative charge value is adjusted by

its case-mix to an average that reflects the complexity of the cases it

treats relative to the complexity of the cases treated by all other

LTCHs (the average case-mix of all LTCHs).

In accordance with the methodology established in the August 30,

2002 LTCH PPS final rule (67 FR 55989 through 55991), we continue to

standardize charges for each case by first dividing the adjusted charge

for the case (adjusted for SSOs under Sec. 412.529 as described in

section VIII.B.3.f. (step 3) of the preamble of this proposed rule) by

the average adjusted charge for all cases at the LTCH in which the case

was treated. SSO cases are cases with a length of stay that is less

than or equal to five-sixths the average length of stay of the MS-LTC-

DRG (Sec. 412.529 and Sec. 412.503). The average adjusted charge

reflects the average intensity of the health care services delivered by

a particular LTCH and the average cost level of that LTCH. The

resulting ratio is multiplied by that LTCH's case-mix index to

determine the standardized charge for the case.

Multiplying by the LTCH's case-mix index accounts for the fact that

the same relative charges are given greater weight at a LTCH with

higher average costs than they would at a LTCH with low average costs,

which is needed to adjust each LTCH's relative charge value to reflect

its case-mix relative to the average case-mix for all LTCHs. Because we

standardize charges in this manner, we count charges for a Medicare

patient at a LTCH with high average charges as less resource intensive

than they would be at a LTCH with low average charges. For example, a

$10,000 charge for a case at a LTCH with an average adjusted charge of

$17,500 reflects a higher level of relative resource use than a $10,000

charge for a case at a LTCH with the same case-mix, but an average

adjusted

[[Page 24213]]

charge of $35,000. We believe that the adjusted charge of an individual

case more accurately reflects actual resource use for an individual

LTCH because the variation in charges due to systematic differences in

the markup of charges among LTCHs is taken into account.

d. Treatment of Severity Levels in Developing the Proposed MS-LTC-DRG

Relative Weights

For purposes of determining the proposed MS-LTC-DRG relative

weights, as we discussed in the FY 2009 IPPS final rule (73 FR 48532

through 48533), there are three different categories of DRGs based on

volume of cases within specific MS-LTC-DRGs. MS-LTC-DRGs with at least

25 cases are each assigned a unique proposed relative weight; low-

volume proposed MS-LTC-DRGs (that is, proposed MS-LTC-DRGs that contain

between 1 and 24 cases based on a given year's claims data) are grouped

into quintiles (as described below) and assigned the proposed relative

weight of the quintile. No-volume proposed MS-LTC-DRGs (that is, no

cases in the given year's claims data were assigned to those proposed

MS-LTC-DRGs) are crosswalked to other proposed MS-LTC-DRGs based on the

clinical similarities and assigned the relative weight of the

crosswalked MS-LTC-DRG (as described in greater detail below). (We

provide in-depth discussions of our policy regarding weight-setting for

low-volume MS-LTC-DRGs in section VIII.B.3.e. of the preamble of this

proposed rule and for no-volume MS-LTC-DRGs, under Step 5 in section

VIII.B.3.f. of the preamble of this proposed rule.)

As noted above, in response to the need to account for severity and

pay appropriately for cases, we developed a severity-adjusted patient

classification system that we adopted for both the IPPS and the LTCH

PPS in FY 2008. As described in greater detail above, the MS-LTC-DRG

system can accommodate three severity levels: ``With MCC'' (most

severe); ``with CC,'' and ``without CC/MCC'' (the least severe), with

each level assigned an individual MS-LTC-DRG number. In cases with two

subdivisions, the levels are either ``with CC/MCC'' and ``without CC/

MCC'' or ``with MCC'' and ``without MCC.'' For example, under the MS-

LTC-DRG system, multiple sclerosis and cerebellar ataxia with MCC is

MS-LTC-DRG 58; multiple sclerosis and cerebellar ataxia with CC is MS-

LTC-DRG 59; and multiple sclerosis and cerebellar ataxia without CC/MCC

is MS-LTC-DRG 60. For purposes of discussion in this section, the term

``base DRG'' is used to refer to the DRG category that encompasses all

levels of severity for that DRG. For example, when referring to the

entire DRG category for multiple sclerosis and cerebellar ataxia, which

includes the above three severity levels, we would use the term ``base

DRG.''

As also noted above, while the LTCH PPS and the IPPS use the same

patient classification system, the methodology that is used to set the

DRG relative weights for use in each payment system differs because the

overall volume of cases in the LTCH PPS is much less than in the IPPS.

As a general rule, consistent with the methodology established when we

adopted the MS-LTC-DRGs in the FY 2008 IPPS final rule with comment

period (72 FR 47278 through 47281), we are proposing to determine the

proposed RY 2010 relative weights for the proposed MS-LTC-DRGs using

the following steps: (1) If a proposed MS-LTC-DRG has at least 25

cases, it is assigned its own proposed relative weight; (2) if a

proposed MS-LTC-DRG has between 1 and 24 cases, it is assigned to a

quintile for which we compute a proposed relative weight for all of the

proposed MS-LTC-DRGs assigned to that quintile; and (3) if a proposed

MS-LTC-DRG has no cases, it is crosswalked to another proposed MS-LTC-

DRG based upon clinical similarities to assign an appropriate proposed

relative weight (as described below in detail in Step 5 of section

VIII.B.3.f. of this preamble). Furthermore, in determining the proposed

RY 2010 MS-LTC-DRG relative weights, when necessary, we are proposing

to make adjustments to account for nonmonotonicity, as explained in

greater detail below in Step 6 of section VIII.B.3.f. of this preamble.

Our methodology for determining relative weights for the MS-LTC-

DRGs included an adjustment for nonmonotonicity because, theoretically,

cases under the MS-LTC-DRG system that are more severe require greater

expenditure of medical care resources and will result in higher average

charges. Therefore, in the three severity levels, weights should

increase with severity, from lowest to highest. If the weights do not

increase (that is, if based on the proposed relative weight methodology

outlined above, the proposed MS-LTC-DRG with MCC would have a lower

relative weight than one with CC, or the proposed MS-LTC-DRG without

CC/MCC would have a higher relative weight than either of the others),

there is a problem with monotonicity. Since the start of the LTCH PPS

for FY 2003 (67 FR 55990), when determining the LTC-DRG relative

weights, we have made adjustments in order to maintain monotonicity by

grouping both sets of cases together and establishing a new relative

weight for both LTC-DRGs. We continue to believe that utilizing

nonmonotonic relative weights to adjust Medicare payments would result

in inappropriate payments because, in a nonmonotonic system, cases that

are more severe and require greater expenditure of medical care

resources would be paid based on a lower relative weight than cases

that are less severe and require lower resource use. The proposed

methodology for making adjustments because of nonmonotonicity in

determining the proposed RY 2010 MS-LTC-DRG relative weights is

discussed in greater detail below in section VIII.B.3.f. (Step 6) of

the preamble of this proposed rule.

e. Low-Volume MS-LTC-DRGs

In order to account for proposed MS-LTC-DRGs with low volume (that

is, with fewer than 25 LTCH cases), consistent with the methodology we

established when we implemented the LTCH PPS (67 FR 55984 through

55995) and the methodology that we established when we implemented the

MS-LTC-DRGs in the FY 2008 IPPS final rule with comment period (72 FR

47283 through 47288), for purposes of determining the MS-LTC-DRG

relative weights, we group those ``low-volume MS-LTC-DRGs'' (that is,

MS-LTC-DRGs that contained between 1 and 24 cases annually) into one of

five categories (quintiles) based on average charges. In determining

the proposed RY 2010 MS-LTC-DRG relative weights in this proposed rule,

consistent with the methodology described above and the methodology we

used to establish the FY 2009 MS-LTC-DRG relative weights in the FY

2009 IPPS final rule (73 FR 48533 through 48540), we are proposing to

continue to employ this quintile methodology for low-volume proposed

MS-LTC-DRGs. In addition, in cases where the initial assignment of a

low-volume proposed MS-LTC-DRG to quintiles results in nonmonotonicity

within a base-DRG, in order to ensure appropriate Medicare payments,

consistent with our historical methodology, we are proposing to make

adjustments to the treatment of low-volume proposed MS-LTC-DRGs to

preserve monotonicity, as discussed in detail below in section

VIII.B.3.f. (Step 6) in this preamble.

In this proposed rule, using LTCH cases from the December 2008

update of the FY 2008 MedPAR file, we identified 282 MS-LTC-DRGs that

contained between 1 and 24 cases. This list of proposed MS-LTC-DRGs was

then

[[Page 24214]]

divided into one of the 5 low-volume quintiles, each containing a

minimum of 56 proposed MS-LTC-DRGs (282/5 = 56 with 2 proposed MS-LTC-

DRGs as the remainder). We are proposing to assign a low-volume

proposed MS-LTC-DRG to a specific low-volume quintile by sorting the

low-volume proposed MS-LTC-DRGs in ascending order by average charge in

accordance with our established methodology. Furthermore, because the

number of proposed MS-LTC-DRGs with less than 25 cases is not evenly

divisible by 5, the average charge of the low-volume quintile was used

to determine which of the low-volume quintiles contain the 2 additional

low-volume proposed MS-LTC-DRGs. Specifically, after sorting the 282

low-volume proposed MS-LTC-DRGs by ascending order by average charge,

we are proposing to assign the first fifth (1st through 56th) of low-

volume proposed MS-LTC-DRGs (with the lowest average charge) into

Quintile 1. The proposed MS-LTC-DRGs with the highest average charge

cases would be assigned into Quintile 5. Because the average charge of

the 57th low-volume proposed MS-LTC-DRG in the sorted list is closer to

the average charge of the 56th low-volume proposed MS-LTC-DRG (assigned

to Quintile 1) than to the average charge of the 58th low-volume

proposed MS-LTC-DRG (assigned to Quintile 2), we are proposing to place

it into Quintile 1 (such that Quintile 1 would contain 57 low-volume

proposed MS-LTC-DRGs before any adjustments for nonmonotonicity, as

discussed below). This process was repeated through the remaining low-

volume proposed MS-LTC-DRGs so that 2 of the 5 low-volume quintiles

contain 57 MS-LTC-DRGs (Quintiles 1 and 2) and 3 of the 5 low-volume

quintiles contain 56 MS-LTC-DRGs (Quintiles 3, 4, and 5).

Accordingly, in order to determine the proposed RY 2010 relative

weights for the proposed MS-LTC-DRGs with low volume, we are proposing

to use the five low-volume quintiles described above. The composition

of each of the five low-volume quintiles shown in the chart below was

used in determining the proposed RY 2010 MS-LTC-DRG relative weights

(as shown in Table 11 of the Addendum to this proposed rule). We

determined a proposed relative weight and (geometric) average length of

stay for each of the 5 low-volume quintiles using the methodology that

we applied to the proposed MS-LTC-DRGs (25 or more cases), as described

in section VIII.B.3.f. of the preamble of this proposed rule. We are

proposing to assign the same proposed relative weight and average

length of stay to each of the low-volume proposed MS-LTC-DRGs that make

up an individual low-volume quintile. We note that, as this system is

dynamic, it is possible that the number and specific type of MS-LTC-

DRGs with a low volume of LTCH cases will vary in the future. We use

the best available claims data in the MedPAR file to identify low-

volume MS-LTC-DRGs and to calculate the proposed relative weights based

on our methodology.

Proposed Composition of Low-Volume Quintiles for RY 2010

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MS-LTC-DRG (Version 27.0) MS-LTC-DRG Description (Version 27.0)

------------------------------------------------------------------------

Proposed Quintile 1

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026.......................... Craniotomy & endovascular intracranial

procedures w CC.

053.......................... Spinal disorders & injuries w/o CC/MCC.

060.......................... Multiple sclerosis & cerebellar ataxia w/

o CC/MCC.

066.......................... Intracranial hemorrhage or cerebral

infarction w/o CC/MCC.

068.......................... Nonspecific cva & precerebral occlusion w/

o infarct w/o MCC.

069.......................... Transient ischemia.

072.......................... Nonspecific cerebrovascular disorders w/o

CC/MCC.

078.......................... Hypertensive encephalopathy w CC.

081.......................... Nontraumatic stupor & coma w/o MCC.

089.......................... Concussion w CC.

090.......................... Concussion w/o CC/MCC.

093.......................... Other disorders of nervous system w/o CC/

MCC.

103.......................... Headaches w/o MCC.

115.......................... Extraocular procedures except orbit.

139.......................... Salivary gland procedures.

149.......................... Dysequilibrium.

184.......................... Major chest trauma w CC.

198.......................... Interstitial lung disease w/o CC/MCC.

201.......................... Pneumothorax w/o CC/MCC.

203.......................... Bronchitis & asthma w/o CC/MCC.

284.......................... Circulatory disorders w AMI, expired w

CC\*.

310.......................... Cardiac arrhythmia & conduction disorders

w/o CC/MCC.

313.......................... Chest pain.

350.......................... Inguinal & femoral hernia procedures w

MCC.

358.......................... Other digestive system O.R. procedures w/

o CC/MCC.

370.......................... Major esophageal disorders w/o CC/MCC.

376.......................... Digestive malignancy w/o CC/MCC.

387.......................... Inflammatory bowel disease w/o CC/MCC.

437.......................... Malignancy of hepatobiliary system or

pancreas w/o CC/MCC.

440.......................... Disorders of pancreas except malignancy w/

o CC/MCC.

443.......................... Disorders of liver except malig, cirr,

alc hepa w/o CC/MCC.

446.......................... Disorders of the biliary tract w/o CC/

MCC.

534.......................... Fractures of femur w/o MCC.

536.......................... Fractures of hip & pelvis w/o MCC.

544.......................... Pathological fractures & musculoskelet &

conn tiss malig w/o CC/MCC.

547.......................... Connective tissue disorders w/o CC/MCC.

556.......................... Signs & symptoms of musculoskeletal

system & conn tissue w/o MCC.

578.......................... Skin graft &/or debrid exc for skin ulcer

or cellulitis w/o CC/MCC.

601.......................... Non-malignant breast disorders w/o CC/

MCC.

[[Page 24215]]

667.......................... Prostatectomy w/o CC/MCC.

694.......................... Urinary stones w/ot esw lithotripsy w/o

MCC.

696.......................... Kidney & urinary tract signs & symptoms w/

o MCC.

725.......................... Benign prostatic hypertrophy w MCC.

726.......................... Benign prostatic hypertrophy w/o MCC.

730.......................... Other male reproductive system diagnoses

w/o CC/MCC.

746.......................... Vagina, cervix & vulva procedures w CC/

MCC\*.

803.......................... Other O.R. proc of the blood & blood

forming organs w CC.

826.......................... Myeloprolif disord or poorly diff neopl w

maj O.R. proc w MCC\*.

869.......................... Other infectious & parasitic diseases

diagnoses w/o CC/MCC.

880.......................... Acute adjustment reaction & psychosocial

dysfunction.

881.......................... Depressive neuroses.

883.......................... Disorders of personality & impulse

control.

895.......................... Alcohol/drug abuse or dependence w

rehabilitation therapy.

897.......................... Alcohol/drug abuse or dependence w/o

rehabilitation therapy w/o MCC.

918.......................... Poisoning & toxic effects of drugs w/o

MCC.

964.......................... Other multiple significant trauma w CC.

965.......................... Other multiple significant trauma w/o CC/

MCC.

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Proposed Quintile 2

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032.......................... Ventricular shunt procedures w CC.

033.......................... Ventricular shunt procedures w/o CC/MCC.

042.......................... Periph & cranial nerve & other nerv syst

proc w/o CC/MCC.

067.......................... Nonspecific cva & precerebral occlusion w/

o infarct w MCC.

080.......................... Nontraumatic stupor & coma w MCC.

083.......................... Traumatic stupor & coma, coma >1 hr w

CC\*.

087.......................... Traumatic stupor & coma, coma <1 hr w/o

CC/MCC\*\*\*.

088.......................... Concussion w MCC.

096.......................... Bacterial & tuberculous infections of

nervous system w/o CC/MCC.

102.......................... Headaches w MCC.

125.......................... Other disorders of the eye w/o MCC.

156.......................... Nasal trauma & deformity w/o CC/MCC\*\*\*.

159.......................... Dental & Oral Diseases w/o CC/MCC.

183.......................... Major chest trauma w MCC.

257.......................... Upper limb & toe amputation for circ

system disorders w/o CC/MCC.

259.......................... Cardiac pacemaker device replacement w/o

MCC.

284.......................... Circulatory disorders w AMI, expired w

CC\*\*.

285.......................... Circulatory disorders w AMI, expired w/o

CC/MCC.

294.......................... Deep vein thrombophlebitis w CC/MCC.

311.......................... Angina pectoris.

379.......................... G.I. hemorrhage w/o CC/MCC.

384.......................... Uncomplicated peptic ulcer w/o MCC.

386.......................... Inflammatory bowel disease w CC.

390.......................... G.I. obstruction w/o CC/MCC.

418.......................... Laparoscopic cholecystectomy w/o c.d.e. w

CC.

433.......................... Cirrhosis & alcoholic hepatitis w CC.

436.......................... Malignancy of hepatobiliary system or

pancreas w CC.

479.......................... Biopsies of musculoskeletal system &

connective tissue w/o CC/MCC.

497.......................... Local excision & removal int fix devices

exc hip & femur w/o CC/MCC.

535.......................... Fractures of hip & pelvis w MCC.

553.......................... Bone diseases & arthropathies w MCC.

562.......................... Fx, sprn, strn & disl except femur, hip,

pelvis & thigh w MCC\*\*\*.

598.......................... Malignant breast disorders w CC.

600.......................... Non-malignant breast disorders w CC/MCC.

644.......................... Endocrine disorders w CC.

645.......................... Endocrine disorders w/o CC/MCC.

663.......................... Minor bladder procedures w CC.

675.......................... Other kidney & urinary tract procedures w/

o CC/MCC.

685.......................... Admit for renal dialysis.

697.......................... Urethral stricture.

700.......................... Other kidney & urinary tract diagnoses w/

o CC/MCC.

722.......................... Malignancy, male reproductive system w

MCC.

723.......................... Malignancy, male reproductive system w

CC.

746.......................... Vagina, cervix & vulva procedures w CC/

MCC\*\*.

747.......................... Vagina, cervix & vulva procedures w/o CC/

MCC.

755.......................... Malignancy, female reproductive system w

CC.

759.......................... Infections, female reproductive system w/

o CC/MCC.

802.......................... Other O.R. proc of the blood & blood

forming organs w MCC.

808.......................... Major hematol/immun diag exc sickle cell

crisis & coagul w MCC\*\*\*.

815.......................... Reticuloendothelial & immunity disorders

w CC.

816.......................... Reticuloendothelial & immunity disorders

w/o CC/MCC.

[[Page 24216]]

837.......................... Chemo w acute leukemia as sdx or w high

dose chemo agent w MCC.

842.......................... Lymphoma & non-acute leukemia w/o CC/MCC.

864.......................... Fever of unknown origin.

882.......................... Neuroses except depressive.

894.......................... Alcohol/drug abuse or dependence, left

ama.

922.......................... Other injury, poisoning & toxic effect

diag w MCC\*.

976.......................... HIV w major related condition w/o CC/MCC.

986.......................... Prostatic O.R. procedure unrelated to

principal diagnosis w/o CC/MCC.

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Proposed Quintile 3

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023.......................... Craniotomy w major device implant or

acute complex CNS PDX w MCC.

029.......................... Spinal procedures w CC.

030.......................... Spinal procedures w/o CC/MCC.

058.......................... Multiple sclerosis & cerebellar ataxia w

MCC.

075.......................... Viral meningitis w CC/MCC.

083.......................... Traumatic stupor & coma, coma >1 hr w

CC\*\*.

084.......................... Traumatic stupor & coma, coma >1 hr w/o

CC/MCC\*\*.

099.......................... Non-bacterial infect of nervous sys exc

viral meningitis w/o CC/MCC.

121.......................... Acute major eye infections w CC/MCC.

124.......................... Other disorders of the eye w MCC.

158.......................... Dental & Oral Diseases w CC.

182.......................... Respiratory neoplasms w/o CC/MCC\*\*\*.

188.......................... Pleural effusion w/o CC/MCC\*\*\*.

241.......................... Amputation for circ sys disorders exc

upper limb & toe w/o CC/MCC.

290.......................... Acute & subacute endocarditis w/o CC/MCC.

327.......................... Stomach, esophageal & duodenal proc w CC.

331.......................... Major small & large bowel procedures w/o

CC/MCC.

348.......................... Anal & stomal procedures w CC.

381.......................... Complicated peptic ulcer w CC.

382.......................... Complicated peptic ulcer w/o CC/MCC.

383.......................... Uncomplicated peptic ulcer w MCC.

424.......................... Other hepatobiliary or pancreas O.R.

procedures w CC.

472.......................... Cervical spinal fusion w CC.

476.......................... Amputation for musculoskeletal sys & conn

tissue dis w/o CC/MCC.

487.......................... Knee procedures w pdx of infection w/o CC/

MCC.

493.......................... Lower extrem & humer proc except hip,

foot, femur w CC.

499.......................... Local excision & removal int fix devices

of hip & femur w/o CC/MCC.

511.......................... Shoulder, elbow or forearm proc, exc

major joint proc w CC.

517.......................... Other musculoskelet sys & conn tiss O.R.

proc w/o CC/MCC.

555.......................... Signs & symptoms of musculoskeletal

system & conn tissue w MCC.

563.......................... Fx, sprn, strn & disl except femur, hip,

pelvis & thigh w/o MCC\*\*\*.

581.......................... Other skin, subcut tiss & breast proc w/o

CC/MCC.

582.......................... Mastectomy for malignancy w CC/MCC.

597.......................... Malignant breast disorders w MCC.

620.......................... O.R. procedures for obesity w CC.

643.......................... Endocrine disorders w MCC.

656.......................... Kidney & ureter procedures for neoplasm w

MCC.

660.......................... Kidney & ureter procedures for non-

neoplasm w CC.

666.......................... Prostatectomy w CC.

668.......................... Transurethral procedures w MCC.

669.......................... Transurethral procedures w CC.

687.......................... Kidney & urinary tract neoplasms w CC.

693.......................... Urinary stones w/o esw lithotripsy w MCC.

695.......................... Kidney & urinary tract signs & symptoms w

MCC.

749.......................... Other female reproductive system O.R.

procedures w CC/MCC.

760.......................... Menstrual & other female reproductive

system disorders w CC/MCC.

781.......................... Other antepartum diagnoses w medical

complications.

809.......................... Major hematol/immun diag exc sickle cell

crisis & coagul w CC\*\*\*.

821.......................... Lymphoma & leukemia w major O.R.

procedure w CC.

835.......................... Acute leukemia w/o major O.R. procedure w

CC.

843.......................... Other myeloprolif dis or poorly diff

neopl diag w MCC.

844.......................... Other myeloprolif dis or poorly diff

neopl diag w CC\*\*.

858.......................... Postoperative or post-traumatic

infections w O.R. proc w/o CC/MCC.

866.......................... Viral illness w/o MCC.

896.......................... Alcohol/drug abuse or dependence w/o

rehabilitation therapy w MCC.

903.......................... Wound debridements for injuries w/o CC/

MCC.

905.......................... Skin grafts for injuries w/o CC/MCC.

906.......................... Hand procedures for injuries.

941.......................... O.R. proc w diagnoses of other contact w

health services w/o CC/MCC.

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[[Page 24217]]

Proposed Quintile 4

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028.......................... Spinal procedures w MCC.

077.......................... Hypertensive encephalopathy w MCC.

082.......................... Traumatic stupor & coma, coma >1 hr w

MCC.

084.......................... Traumatic stupor & coma, coma >1 hr w/o

CC/MCC\*.

131.......................... Cranial/facial procedures w CC/MCC.

133.......................... Other ear, nose, mouth & throat O.R.

procedures w CC/MCC.

157.......................... Dental & Oral Diseases w MCC.

237.......................... Major cardiovascular procedures w MCC.

243.......................... Permanent cardiac pacemaker implant w CC.

244.......................... Permanent cardiac pacemaker implant w/o

CC/MCC.

254.......................... Other vascular procedures w/o CC/MCC\*\*\*.

286.......................... Circulatory disorders except AMI, w card

cath w MCC.

287.......................... Circulatory disorders except AMI, w card

cath w/o MCC.

304.......................... Hypertension w MCC.

338.......................... Appendectomy w complicated principal diag

w MCC.

344.......................... Minor small & large bowel procedures w

MCC.

347.......................... Anal & stomal procedures w MCC.

353.......................... Hernia procedures except inguinal &

femoral w MCC.

354.......................... Hernia procedures except inguinal &

femoral w CC.

369.......................... Major esophageal disorders w CC\*\*\*.

380.......................... Complicated peptic ulcer w MCC.

423.......................... Other hepatobiliary or pancreas O.R.

procedures w MCC.

466.......................... Revision of hip or knee replacement w

MCC\*\*.

469.......................... Major joint replacement or reattachment

of lower extremity w MCC\*\*.

471.......................... Cervical spinal fusion w MCC.

480.......................... Hip & femur procedures except major joint

w MCC\*\*.

488.......................... Knee procedures w/o pdx of infection w CC/

MCC.

490.......................... Back & neck procedures except spinal

fusion w CC/MCC or disc devices.

502.......................... Soft tissue procedures w/o CC/MCC\*\*\*.

503.......................... Foot procedures w MCC.

505.......................... Foot procedures w/o CC/MCC\*\*\*.

510.......................... Shoulder, elbow or forearm proc, exc

major joint proc w MCC.

513.......................... Hand or wrist proc, except major thumb or

joint proc w CC/MCC.

514.......................... Hand or wrist proc, except major thumb or

joint proc w/o CC/MCC.

516.......................... Other musculoskelet sys & conn tiss O.R.

proc w CC.

537.......................... Sprains, strains, & dislocations of hip,

pelvis & thigh w CC/MCC.

577.......................... Skin graft &/or debrid exc for skin ulcer

or cellulitis w CC.

584.......................... Breast biopsy, local excision & other

breast procedures w CC/MCC.

624.......................... Skin grafts & wound debrid for endoc,

nutrit & metab dis w/o CC/MCC\*\*\*.

671.......................... Urethral procedures w CC/MCC.

691.......................... Urinary stones w esw lithotripsy w CC/

MCC.

711.......................... Testes procedures w CC/MCC.

800.......................... Splenectomy w CC.

814.......................... Reticuloendothelial & immunity disorders

w MCC.

826.......................... Myeloprolif disord or poorly diff neopl w

maj O.R. proc w MCC\*\*.

827.......................... Myeloprolif disord or poorly diff neopl w

maj O.R. proc w CC\*\*.

829.......................... Myeloprolif disord or poorly diff neopl w

other O.R. proc w CC/MCC.

834.......................... Acute leukemia w/o major O.R. procedure w

MCC.

844.......................... Other myeloprolif dis or poorly diff

neopl diag w CC\*\*\*.

855.......................... Infectious & parasitic diseases w O.R.

procedure w/o CC/MCC.

909.......................... Other O.R. procedures for injuries w/o CC/

MCC.

917.......................... Poisoning & toxic effects of drugs w MCC.

922.......................... Other injury, poisoning & toxic effect

diag w MCC\*\*.

923.......................... Other injury, poisoning & toxic effect

diag w/o MCC\*\*.

927.......................... Extensive burns or full thickness burns w

MV 96+ hrs w skin graft.

928.......................... Full thickness burn w skin graft or inhal

inj w CC/MCC.

933.......................... Extensive burns or full thickness burns w

MV 96+ hrs w/o skin graft.

958.......................... Other O.R. procedures for multiple

significant trauma w CC.

963.......................... Other multiple significant trauma w MCC.

983.......................... Extensive O.R. procedure unrelated to

principal diagnosis w/o CC/MCC.

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Proposed Quintile 5

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011.......................... Tracheostomy for face, mouth & neck

diagnoses w MCC.

025.......................... Craniotomy & endovascular intracranial

procedures w MCC.

031.......................... Ventricular shunt procedures w MCC.

037.......................... Extracranial procedures w MCC.

038.......................... Extracranial procedures w CC.

135.......................... Sinus & mastoid procedures w CC/MCC.

148.......................... Ear, nose, mouth & throat malignancy w/o

CC/MCC\*\*\*.

[[Page 24218]]

164.......................... Major chest procedures w CC.

168.......................... Other resp system O.R. procedures w/o CC/

MCC.

222.......................... Cardiac defib implant w cardiac cath w

AMI/HF/shock w MCC.

226.......................... Cardiac defibrillator implant w/o cardiac

cath w MCC.

227.......................... Cardiac defibrillator implant w/o cardiac

cath w/o MCC.

242.......................... Permanent cardiac pacemaker implant w

MCC.

245.......................... AICD generator procedures.

250.......................... Perc cardiovasc proc w/o coronary artery

stent or AMI w MCC.

260.......................... Cardiac pacemaker revision except device

replacement w MCC.

330.......................... Major small & large bowel procedures w

CC.

335.......................... Peritoneal adhesiolysis w MCC.

336.......................... Peritoneal adhesiolysis w CC.

405.......................... Pancreas, liver & shunt procedures w MCC.

406.......................... Pancreas, liver & shunt procedures w CC.

414.......................... Cholecystectomy except by laparoscope w/o

c.d.e. w MCC.

417.......................... Laparoscopic cholecystectomy w/o c.d.e. w

MCC.

420.......................... Hepatobiliary diagnostic procedures w

MCC.

453.......................... Combined anterior/posterior spinal fusion

w MCC.

454.......................... Combined anterior/posterior spinal fusion

w CC.

456.......................... Spinal fusion exc cerv w spinal curv,

malig or 9+ fusions w MCC.

457.......................... Spinal fusion exc cerv w spinal curv,

malig or 9+ fusions w CC.

459.......................... Spinal fusion except cervical w MCC.

466.......................... Revision of hip or knee replacement w

MCC\*\*.

467.......................... Revision of hip or knee replacement w CC.

469.......................... Major joint replacement or reattachment

of lower extremity w MCC\*\*.

470.......................... Major joint replacement or reattachment

of lower extremity w/o MCC.

480.......................... Hip & femur procedures except major joint

w MCC\*\*.

481.......................... Hip & femur procedures except major joint

w CC.

485.......................... Knee procedures w pdx of infection w MCC.

486.......................... Knee procedures w pdx of infection w CC.

492.......................... Lower extrem & humer proc except hip,

foot, femur w MCC.

498.......................... Local excision & removal int fix devices

of hip & femur w CC/MCC.

507.......................... Major shoulder or elbow joint procedures

w CC/MCC.

619.......................... O.R. procedures for obesity w MCC.

642.......................... Inborn errors of metabolism.

659.......................... Kidney & ureter procedures for non-

neoplasm w MCC.

662.......................... Minor bladder procedures w MCC.

709.......................... Penis procedures w CC/MCC.

717.......................... Other male reproductive system O.R. proc

exc malignancy w CC/MCC.

776.......................... Postpartum & post abortion diagnoses w/o

O.R. procedure.

823.......................... Lymphoma & non-acute leukemia w other

O.R. proc w MCC.

824.......................... Lymphoma & non-acute leukemia w other

O.R. proc w CC.

827.......................... Myeloprolif disord or poorly diff neopl w

maj O.R. proc w CC\*.

848.......................... Chemotherapy w/o acute leukemia as

secondary diagnosis w/o CC/MCC\*\*\*.

876.......................... O.R. procedure w principal diagnoses of

mental illness.

923.......................... Other injury, poisoning & toxic effect

diag w/o MCC\*.

957.......................... Other O.R. procedures for multiple

significant trauma w MCC.

969.......................... HIV w extensive O.R. procedure w MCC.

970.......................... HIV w extensive O.R. procedure w/o MCC.

984.......................... Prostatic O.R. procedure unrelated to

principal diagnosis w MCC.

985.......................... Prostatic O.R. procedure unrelated to

principal diagnosis w CC.

989.......................... Non-extensive O.R. proc unrelated to

principal diagnosis w/o CC/MCC\*\*\*.

------------------------------------------------------------------------

\* One of the original 282 low-volume proposed MS-LTC-DRGs initially

assigned to this low-volume quintile; removed from this low-volume

quintile in addressing nonmonotonicity (refer to step 6 in section

VIII.B.3.f.of the preamble of this proposed rule).

\*\* One of the original 282 low-volume proposed MS-LTC-DRGs initially

assigned to a different low-volume quintile but moved to this low-

volume quintile in addressing nonmonotonicity (refer to step 6 in

section VIII.B.3.f. of the preamble of this proposed rule).

\*\*\* One of the original 282 low-volume proposed MS-LTC-DRGs initially

assigned to this low-volume quintile but moved to a different low-

volume quintile in addressing nonmonotonicity (refer to step 6 in

section VIII.B.3.f. of the preamble of this proposed rule).

We note that we will continue to monitor the volume (that is, the

number of LTCH cases) in the low-volume quintiles to ensure that our

quintile assignments used in determining the proposed MS-LTC-DRG

relative weights result in appropriate payment for such cases and do

not result in an unintended financial incentive for LTCHs to

inappropriately admit these types of cases.

f. Steps for Determining the Proposed RY 2010 MS-LTC-DRG Relative

Weights

In general, we are proposing to determine the RY 2010 MS-LTC-DRG

relative weights based on the methodology established in the August 30,

2002 LTCH PPS final rule (67 FR 55989 through 55995) and consistent

with the methodology we used to determine the FY 2009 MS-LTC-DRG

relative weights in the FY 2009 IPPS final rule (73 FR 48540 through

48551). (We note that, for FY 2009, we made a modification to our

methodology for determining relative weights for MS-LTC-DRGs with no

LTCH cases (73 FR

[[Page 24219]]

48542 through 48543), which is reflected in the proposed methodology

for determining the proposed RY 2010 MS-LTC-DRG relative weights

presented below.)

In summary, for RY 2010, we are proposing to group LTCH cases to

the appropriate proposed MS-LTC-DRG, while taking into account the low-

volume proposed MS-LTC-DRGs (as described above), in order to determine

the proposed RY 2010 MS-LTC-DRG relative weights. After grouping the

cases to the appropriate MS-LTC-DRG (or low-volume quintile), we

calculate the proposed relative weights for RY 2010 by first removing

statistical outliers and cases with a length of stay of 7 days or less

(as discussed in greater detail below). Next, we adjust the number of

cases in each proposed MS-LTC-DRG (or low-volume quintile) for the

effect of SSO cases (as also discussed in greater detail below). The

SSO adjusted discharges and corresponding charges are then used to

calculate ``relative adjusted weights'' for each proposed MS-LTC-DRG

(or low-volume quintile) using the HSRV method (described above).

Below we discuss in detail the steps for calculating the proposed

RY 2010 MS-LTC-DRG relative weights. We note that, as we stated above

in section VIII.B.3.b. of the preamble of this proposed rule, we have

excluded the data of all-inclusive rate LTCHs and LTCHs that are paid

in accordance with demonstration projects that had claims in the FY

2008 MedPAR file.

Step 1--Remove statistical outliers.

The first step in the calculation of the proposed RY 2010 MS-LTC-

DRG relative weights is to remove statistical outlier cases. Consistent

with our historical relative weight methodology, we are proposing to

continue to define statistical outliers as cases that are outside of

3.0 standard deviations from the mean of the log distribution of both

charges per case and the charges per day for each MS-LTC-DRG. These

statistical outliers are removed prior to calculating the proposed

relative weights because we believe that they may represent aberrations

in the data that distort the measure of average resource use. Including

those LTCH cases in the calculation of the proposed relative weights

could result in an inaccurate proposed relative weight that does not

truly reflect relative resource use among the MS-LTC-DRGs.

Step 2--Remove cases with a length of stay of 7 days or less.

The MS-LTC-DRG relative weights reflect the average of resources

used on representative cases of a specific type. Generally, cases with

a length of stay of 7 days or less do not belong in a LTCH because

these stays do not fully receive or benefit from treatment that is

typical in a LTCH stay, and full resources are often not used in the

earlier stages of admission to a LTCH. If we were to include stays of 7

days or less in the computation of the proposed RY 2010 MS-LTC-DRG

relative weights, the value of many proposed relative weights would

decrease and, therefore, payments would decrease to a level that may no

longer be appropriate. We do not believe that it would be appropriate

to compromise the integrity of the payment determination for those LTCH

cases that actually benefit from and receive a full course of treatment

at a LTCH by including data from these very short-stays. Therefore,

consistent with our historical relative weight methodology, in

determining the proposed RY 2010 MS-LTC-DRG relative weights, we are

proposing to remove LTCH cases with a length of stay of 7 days or less.

Step 3--Adjust charges for the effects of SSOs.

After removing cases with a length of stay of 7 days or less, we

are left with cases that have a length of stay of greater than or equal

to 8 days. As the next step in the calculation of the proposed RY 2010

MS-LTC-DRG relative weights, consistent with our historical relative

weight methodology, we are proposing to adjust each LTCH's charges per

discharge for those remaining cases for the effects of SSOs (as defined

in Sec. 412.529(a) in conjunction with Sec. 412.503).

We make this adjustment by counting an SSO case as a fraction of a

discharge based on the ratio of the length of stay of the case to the

average length of stay for the MS-LTC-DRG for non-SSO cases. This has

the effect of proportionately reducing the impact of the lower charges

for the SSO cases in calculating the average charge for the MS-LTC-DRG.

This process produces the same result as if the actual charges per

discharge of an SSO case were adjusted to what they would have been had

the patient's length of stay been equal to the average length of stay

of the MS-LTC-DRG.

Counting SSO cases as full discharges with no adjustment in

determining the proposed RY 2010 MS-LTC-DRG relative weights would

lower the proposed RY 2010 MS-LTC-DRG relative weight for affected MS-

LTC-DRGs because the relatively lower charges of the SSO cases would

bring down the average charge for all cases within an MS-LTC-DRG. This

would result in an ``underpayment'' for non-SSO cases and an

``overpayment'' for SSO cases. Therefore, we are proposing to adjust

for SSO cases under Sec. 412.529 in this manner because it results in

more appropriate payments for all LTCH cases.

Step 4--Calculate the proposed RY 2010 MS-LTC-DRG relative weights

on an iterative basis.

Consistent with our historical relative weight methodology, we are

proposing to calculate the proposed RY 2010 MS-LTC-DRG relative weights

using the HSRV methodology, which is an iterative process. First, for

each LTCH case, we calculate a hospital-specific relative charge value

by dividing the SSO adjusted charge per discharge (see Step 3) of the

LTCH case (after removing the statistical outliers (see Step 1)) and

LTCH cases with a length of stay of 7 days or less (see Step 2) by the

average charge per discharge for the LTCH in which the case occurred.

The resulting ratio is then multiplied by the LTCH's case-mix index to

produce an adjusted hospital-specific relative charge value for the

case. An initial case-mix index value of 1.0 is used for each LTCH.

For each proposed MS-LTC-DRG, the proposed RY 2010 relative weight

was calculated by dividing the average of the adjusted hospital-

specific relative charge values (from above) for the proposed MS-LTC-

DRG by the overall average hospital-specific relative charge value

across all cases for all LTCHs. Using these recalculated proposed MS-

LTC-DRG relative weights, each LTCH's average relative weight for all

of its cases (that is, its case-mix) is calculated by dividing the sum

of all the LTCH's proposed MS-LTC-DRG relative weights by its total

number of cases. The LTCHs' hospital-specific relative charge values

above is multiplied by these hospital-specific case-mix indexes. These

hospital-specific case-mix adjusted relative charge values are then

used to calculate a new set of proposed MS-LTC-DRG relative weights

across all LTCHs. This iterative process is continued until there is

convergence between the weights produced at adjacent steps, for

example, when the maximum difference is less than 0.0001.

Step 5--Determine a proposed RY 2010 relative weight for MS-LTC-

DRGs with no LTCH cases.

As we stated above, we are proposing to determine the proposed RY

2010 relative weight for each proposed MS-LTC-DRG using total Medicare

allowable charges reported in the best available LTCH claims data (that

is, the December 2008 update of the FY 2008 MedPAR file for this

proposed rule). Of the proposed RY 2010 MS-LTC-DRGs, we identified a

number of proposed MS-LTC-DRGs for which there were no

[[Page 24220]]

LTCH cases in the database. That is, based on data from the FY 2008

MedPAR file used for this proposed rule, no patients who would have

been classified to those proposed MS-LTC-DRGs were treated in LTCHs

during FY 2008 and, therefore, no charge data were available for these

proposed MS-LTC-DRGs. Thus, in the process of determining the proposed

MS-LTC-DRG relative weights, we were unable to calculate proposed

relative weights for the proposed MS-LTC-DRGs with no LTCH cases using

the methodology described in Steps 1 through 4 above. However, because

patients with a number of the diagnoses under these proposed MS-LTC-

DRGs may be treated at LTCHs, consistent with our historical

methodology, we are proposing to assign a proposed relative weight to

each of the no-volume proposed MS-LTC-DRGs based on clinical similarity

and relative costliness (with the exception of ``transplant'' proposed

MS-LTC-DRGs and ``error'' proposed MS-LTC-DRGs, as discussed below). In

general, we determine proposed RY 2010 relative weights for the

proposed MS-LTC-DRGs with no LTCH cases in the FY 2008 MedPAR file used

in this proposed rule (that is, ``no-volume'' proposed MS-LTC-DRGs) by

crosswalking each no-volume proposed MS-LTC-DRG to another proposed MS-

LTC-DRG with a calculated proposed relative weight (determined in

accordance with the methodology described above). Then, the ``no-

volume'' MS-LTC-DRG is assigned the same proposed relative weight of

the MS-LTC-DRG to which it was crosswalked (as described in greater

detail below).

Specifically, in this proposed rule, as stated above, we are

proposing to determine the proposed relative weight for each proposed

MS-LTC-DRG using total Medicare allowable charges reported in the

December 2008 update of the FY 2008 MedPAR file. Of the 746 proposed

MS-LTC-DRGs for RY 2010, we identified 216 proposed MS-LTC-DRGs for

which there were no LTCH cases in the database (including the 8

``transplant'' proposed MS-LTC-DRGs and 2 ``error'' proposed MS-LTC-

DRGs). As stated above, we are proposing to assign proposed relative

weights for each of the 216 no-volume proposed MS-LTC-DRGs (with the

exception of the 8 ``transplant'' proposed MS-LTC-DRGs and the 2

``error'' proposed MS-LTC-DRGs, which are discussed below) based on

clinical similarity and relative costliness to one of the remaining 530

(746-216=530) proposed MS-LTC-DRGs for which we were able to determine

proposed relative weights based on FY 2008 LTCH claims data using the

steps described above. (For the remainder of this discussion, we refer

to one of the 530 proposed MS-LTC-DRGs for which we were able to

determine a proposed relative weight as the ``crosswalked'' proposed

MS-LTC-DRG.) Then, we are proposing to assign the no-volume proposed

MS-LTC-DRG the proposed relative weight of the crosswalked proposed MS-

LTC-DRG. (As explained below in Step 6, when necessary, we made

adjustments to account for nonmonotonicity.)

In this proposed rule, we are proposing to use the following

methodology for determining the proposed RY 2010 relative weights for

the no-volume proposed MS-LTC-DRGs: We crosswalk the no-volume proposed

MS-LTC-DRG to an proposed MS-LTC-DRG for which there are LTCH cases in

the FY 2008 MedPAR file and to which it is similar clinically in

intensity of use of resources and relative costliness as determined by

criteria such as care provided during the period of time surrounding

surgery, surgical approach (if applicable), length of time of surgical

procedure, postoperative care, and length of stay. As we explained in

the FY 2009 IPPS final rule (73 FR 48543), we evaluate the relative

costliness in determining the applicable proposed MS-LTC-DRG to which a

no-volume proposed MS-LTC-DRG was crosswalked in order to assign an

appropriate proposed relative weight for the no-volume proposed MS-LTC-

DRGs in RY 2010. In general, most of the no-volume proposed MS-LTC-DRGs

historically have not had any cases in the LTCH claims data. Therefore,

we typically are unable to evaluate relative costliness based on prior

years' LTCH claims data. In evaluating the relative costliness for most

of the no-volume proposed MS-LTC-DRGs, a group of CMS medical officers

who have extensive knowledge and familiarity with both the IPPS and

LTCH DRG-based payment systems used their DRG experience to evaluate

the relative costliness of the no-volume proposed MS-LTC-DRGs.

Specifically, the relative costliness of each of the no-volume proposed

MS-LTC-DRGs for RY 2010 was assessed by taking into consideration

factors such as relative resource use, clinical cohesiveness, and the

comparableness of services provided based on the collective IPPS and

LTCH PPS experience of those medical officers. We also note, as

discussed above, the no-volume proposed MS-LTC-DRG crosswalks are based

on both clinical similarity and relative costliness, including such

factors as care provided during the period of time surrounding surgery,

surgical approach (if applicable), length of time of surgical

procedure, postoperative care, and length of stay. We believe in the

rare event that there would be a few LTCH cases grouped to one of the

no-volume proposed MS-LTC-DRGs in RY 2010, the proposed relative

weights assigned based on the crosswalked proposed MS-LTC-DRGs would

result in an appropriate LTCH PPS payment because the proposed

crosswalks, which are based on similar clinical similarity and relative

costliness, generally require equivalent relative resource use. We then

assign the proposed relative weight of the crosswalked proposed MS-LTC-

DRG as the proposed relative weight for the no-volume proposed MS-LTC-

DRG such that both of these proposed MS-LTC-DRGs (that is, the no-

volume proposed MS-LTC-DRG and the crosswalked proposed MS-LTC-DRG)

would have the same proposed relative weight for RY 2010. We note that

if the crosswalked proposed MS-LTC-DRG has 25 cases or more, its

proposed relative weight, which is calculated using the methodology

described in steps 1 through 4 above, is assigned to the no-volume

proposed MS-LTC-DRG as well. Similarly, if the MS-LTC-DRG to which the

no-volume proposed MS-LTC-DRG is crosswalked has 24 or less cases and,

therefore, is designated to one of the low-volume quintiles for

purposes of determining the proposed relative weights, we assign the

proposed relative weight of the applicable low-volume quintile to the

no-volume proposed MS-LTC-DRG such that both of these proposed MS-LTC-

DRGs (that is, the no-volume proposed MS-LTC-DRG and the crosswalked

proposed MS-LTC-DRG) have the same proposed relative weight for RY

2010. (As we noted above, in the infrequent case where nonmonotonicity

involving a no-volume proposed MS-LTC-DRG results, additional measures

as described in Step 6 are required in order to maintain monotonically

increasing proposed relative weights.)

For this proposed rule, a list of the no-volume MS-LTC-DRGs and the

proposed MS-LTC-DRG to which it is crosswalked (that is, the

crosswalked MS-LTC-DRG) for RY 2010 is shown in the chart below.

[[Page 24221]]

Proposed No-Volume MS-LTC-DRG Crosswalk for RY 2010

------------------------------------------------------------------------

Proposed

MS-LTC-DRG (V27.0) MS-LTC-DRG description crosswalked MS-

(version 27) LTC-DRG

------------------------------------------------------------------------

9.............................. Bone marrow transplant. 823

12............................. Tracheostomy for face, 146

mouth & neck diagnoses

w CC.

13............................. Tracheostomy for face, 146

mouth & neck diagnoses

w/o CC/MCC.

20............................. Intracranial vascular 31

procedures w PDX

hemorrhage w MCC.

21............................. Intracranial vascular 32

procedures w PDX

hemorrhage w CC.

22............................. Intracranial vascular 32

procedures w PDX

hemorrhage w/o CC/MCC.

24............................. Craniotomy w major 23

device implant or

acute complex CNS PDX

w/o MCC.

27............................. Craniotomy & 26

endovascular

intracranial

procedures w/o CC/MCC.

34............................. Carotid artery stent 37

procedure w MCC.

35............................. Carotid artery stent 38

procedure w CC.

36............................. Carotid artery stent 38

procedure w/o CC/MCC.

39............................. Extracranial procedures 38

w/o CC/MCC.

61............................. Acute ischemic stroke w 70

use of thrombolytic

agent w MCC.

62............................. Acute ischemic stroke w 71

use of thrombolytic

agent w CC.

63............................. Acute ischemic stroke w 72

use of thrombolytic

agent w/o CC/MCC.

76............................. Viral meningitis w/o CC/ 75

MCC.

79............................. Hypertensive 305

encephalopathy w/o CC/

MCC.

113............................ Orbital procedures w CC/ 146

MCC.

114............................ Orbital procedures w/o 147

CC/MCC.

116............................ Intraocular procedures 125

w CC/MCC.

117............................ Intraocular procedures 125

w/o CC/MCC.

122............................ Acute major eye 125

infections w/o CC/MCC.

123............................ Neurological eye 125

disorders.

129............................ Major head & neck 146

procedures w CC/MCC or

major device.

130............................ Major head & neck 148

procedures w/o CC/MCC.

132............................ Cranial/facial 133

procedures w/o CC/MCC.

134............................ Other ear, nose, mouth 133

& throat O.R.

procedures w/o CC/MCC.

136............................ Sinus & mastoid 133

procedures w/o CC/MCC.

137............................ Mouth procedures w CC/ 133

MCC.

138............................ Mouth procedures w/o CC/ 133

MCC.

150............................ Epistaxis w MCC........ 152

151............................ Epistaxis w/o MCC...... 153

165............................ Major chest procedures 254

w/o CC/MCC.

185............................ Major chest trauma w/o 184

CC/MCC.

215............................ Other heart assist 254

system implant.

216............................ Cardiac valve & oth maj 237

cardiothoracic proc w

card cath w MCC.

217............................ Cardiac valve & oth maj 253

cardiothoracic proc w

card cath w CC.

218............................ Cardiac valve & oth maj 254

cardiothoracic proc w

card cath w/o CC/MCC.

219............................ Cardiac valve & oth maj 237

cardiothoracic proc w/

o card cath w MCC.

220............................ Cardiac valve & oth maj 254

cardiothoracic proc w/

o card cath w CC.

221............................ Cardiac valve & oth maj 254

cardiothoracic proc w/

o card cath w/o CC/MCC.

223............................ Cardiac defib implant w 243

cardiac cath w AMI/HF/

shock w/o MCC.

224............................ Cardiac defib implant w 242

cardiac cath w/o AMI/

HF/shock w MCC.

225............................ Cardiac defib implant w 243

cardiac cath w/o AMI/

HF/shock w/o MCC.

228............................ Other cardiothoracic 252

procedures w MCC.

229............................ Other cardiothoracic 253

procedures w CC.

230............................ Other cardiothoracic 254

procedures w/o CC/MCC.

231............................ Coronary bypass w PTCA 237

w MCC.

232............................ Coronary bypass w PTCA 254

w/o MCC.

233............................ Coronary bypass w 237

cardiac cath w MCC.

234............................ Coronary bypass w 254

cardiac cath w/o MCC.

235............................ Coronary bypass w/o 237

cardiac cath w MCC.

236............................ Coronary bypass w/o 254

cardiac cath w/o MCC.

238............................ Major cardiovascular 254

procedures w/o MCC.

246............................ Percutaneous 252

cardiovascular proc w

drug-eluting stent w

MCC.

247............................ Percutaneous 253

cardiovascular proc w

drug-eluting stent w/o

MCC.

248............................ Percutaneous cardiovasc 252

proc w non-drug-

eluting stent w MCC.

249............................ Percutaneous cardiovasc 253

proc w non-drug-

eluting stent w/o MCC.

251............................ Perc cardiovasc proc w/ 250

o coronary artery

stent or AMI w/o MCC.

258............................ Cardiac pacemaker 259

device replacement w

MCC.

261............................ Cardiac pacemaker 259

revision except device

replacement w CC.

262............................ Cardiac pacemaker 259

revision except device

replacement w/o CC/MCC.

263............................ Vein ligation & 301

stripping.

265............................ AICD lead procedures... 259

295............................ Deep vein 294

thrombophlebitis w/o

CC/MCC.

296............................ Cardiac arrest, 283

unexplained w MCC.

297............................ Cardiac arrest, 284

unexplained w CC.

298............................ Cardiac arrest, 284

unexplained w/o CC/MCC.

328............................ Stomach, esophageal & 358

duodenal proc w/o CC/

MCC.

332............................ Rectal resection w MCC. 356

[[Page 24222]]

333............................ Rectal resection w CC.. 357

334............................ Rectal resection w/o CC/ 358

MCC.

337............................ Peritoneal adhesiolysis 335

w/o CC/MCC.

339............................ Appendectomy w 372

complicated principal

diag w CC.

340............................ Appendectomy w 373

complicated principal

diag w/o CC/MCC.

341............................ Appendectomy w/o 371

complicated principal

diag w MCC.

342............................ Appendectomy w/o 372

complicated principal

diag w CC.

343............................ Appendectomy w/o 373

complicated principal

diag w/o CC/MCC.

345............................ Minor small & large 344

bowel procedures w CC.

346............................ Minor small & large 344

bowel procedures w/o

CC/MCC.

349............................ Anal & stomal 348

procedures w/o CC/MCC.

351............................ Inguinal & femoral 350

hernia procedures w CC.

352............................ Inguinal & femoral 350

hernia procedures w/o

CC/MCC.

355............................ Hernia procedures 354

except inguinal &

femoral w/o CC/MCC.

407............................ Pancreas, liver & shunt 406

procedures w/o CC/MCC.

408............................ Biliary tract proc 424

except only cholecyst

w or w/o c.d.e. w MCC.

409............................ Biliary tract proc 424

except only cholecyst

w or w/o c.d.e. w CC.

410............................ Biliary tract proc 424

except only cholecyst

w or w/o c.d.e. w/o CC/

MCC.

411............................ Cholecystectomy w 418

c.d.e. w MCC.

412............................ Cholecystectomy w 418

c.d.e. w CC.

413............................ Cholecystectomy w 418

c.d.e. w/o CC/MCC.

415............................ Cholecystectomy except 418

by laparoscope w/o

c.d.e. w CC.

416............................ Cholecystectomy except 418

by laparoscope w/o

c.d.e. w/o CC/MCC.

419............................ Laparoscopic 418

cholecystectomy w/o

c.d.e. w/o CC/MCC.

421............................ Hepatobiliary 424

diagnostic procedures

w CC.

422............................ Hepatobiliary 424

diagnostic procedures

w/o CC/MCC.

425............................ Other hepatobiliary or 424

pancreas O.R.

procedures w/o CC/MCC.

434............................ Cirrhosis & alcoholic 433

hepatitis w/o CC/MCC.

455............................ Combined anterior/ 457

posterior spinal

fusion w/o CC/MCC.

458............................ Spinal fusion exc cerv 457

w spinal curv, malig

or 9+ fusions w/o CC/

MCC.

460............................ Spinal fusion except 459

cervical w/o MCC.

461............................ Bilateral or multiple 480

major joint procs of

lower extremity w MCC.

462............................ Bilateral or multiple 480

major joint procs of

lower extremity w/o

MCC.

468............................ Revision of hip or knee 480

replacement w/o CC/MCC.

473............................ Cervical spinal fusion 472

w/o CC/MCC.

482............................ Hip & femur procedures 480

except major joint w/o

CC/MCC.

483............................ Major joint & limb 480

reattachment proc of

upper extremity w CC/

MCC.

484............................ Major joint & limb 480

reattachment proc of

upper extremity w/o CC/

MCC.

489............................ Knee procedures w/o pdx 488

of infection w/o CC/

MCC.

491............................ Back & neck procedures 490

except spinal fusion w/

o CC/MCC.

494............................ Lower extrem & humer 493

proc except hip, foot,

femur w/o CC/MCC.

506............................ Major thumb or joint 514

procedures.

508............................ Major shoulder or elbow 507

joint procedures w/o

CC/MCC.

509............................ Arthroscopy............ 505

512............................ Shoulder, elbow or 511

forearm proc, exc

major joint proc w/o

CC/MCC.

533............................ Fractures of femur w 480

MCC.

538............................ Sprains, strains, & 537

dislocations of hip,

pelvis & thigh w/o CC/

MCC.

583............................ Mastectomy for 582

malignancy w/o CC/MCC.

585............................ Breast biopsy, local 584

excision & other

breast procedures w/o

CC/MCC.

599............................ Malignant breast 598

disorders w/o CC/MCC.

614............................ Adrenal & pituitary 629

procedures w CC/MCC.

615............................ Adrenal & pituitary 629

procedures w/o CC/MCC.

618............................ Amputat of lower limb 617

for endocrine, nutrit,

& metabol dis w/o CC/

MCC.

621............................ O.R. procedures for 620

obesity w/o CC/MCC.

625............................ Thyroid, parathyroid & 628

thyroglossal

procedures w MCC.

626............................ Thyroid, parathyroid & 629

thyroglossal

procedures w CC.

627............................ Thyroid, parathyroid & 629

thyroglossal

procedures w/o CC/MCC.

630............................ Other endocrine, nutrit 629

& metab O.R. proc w/o

CC/MCC.

653............................ Major bladder 660

procedures w MCC.

654............................ Major bladder 660

procedures w CC.

655............................ Major bladder 660

procedures w/o CC/MCC.

657............................ Kidney & ureter 656

procedures for

neoplasm w CC.

658............................ Kidney & ureter 656

procedures for

neoplasm w/o CC/MCC.

661............................ Kidney & ureter 660

procedures for non-

neoplasm w/o CC/MCC.

664............................ Minor bladder 663

procedures w/o CC/MCC.

665............................ Prostatectomy w MCC.... 669

670............................ Transurethral 669

procedures w/o CC/MCC.

672............................ Urethral procedures w/o 671

CC/MCC.

688............................ Kidney & urinary tract 687

neoplasms w/o CC/MCC.

692............................ Urinary stones w esw 694

lithotripsy w/o CC/MCC.

[[Page 24223]]

707............................ Major male pelvic 660

procedures w CC/MCC.

708............................ Major male pelvic 660

procedures w/o CC/MCC.

710............................ Penis procedures w/o CC/ 709

MCC.

712............................ Testes procedures w/o 711

CC/MCC.

713............................ Transurethral 669

prostatectomy w CC/MCC.

714............................ Transurethral 669

prostatectomy w/o CC/

MCC.

715............................ Other male reproductive 717

system O.R. proc for

malignancy w CC/MCC.

716............................ Other male reproductive 717

system O.R. proc for

malignancy w/o CC/MCC.

718............................ Other male reproductive 717

system O.R. proc exc

malignancy w/o CC/MCC.

724............................ Malignancy, male 722

reproductive system w/

o CC/MCC.

734............................ Pelvic evisceration, 717

rad hysterectomy & rad

vulvectomy w CC/MCC.

735............................ Pelvic evisceration, 717

rad hysterectomy & rad

vulvectomy w/o CC/MCC.

736............................ Uterine & adnexa proc 754

for ovarian or adnexal

malignancy w MCC.

737............................ Uterine & adnexa proc 755

for ovarian or adnexal

malignancy w CC.

738............................ Uterine & adnexa proc 755

for ovarian or adnexal

malignancy w/o CC/MCC.

739............................ Uterine & adnexa proc 628

for non-ovarian/

adnexal malig w MCC.

740............................ Uterine & adnexa proc 755

for non-ovarian/

adnexal malig w CC.

741............................ Uterine & adnexa proc 755

for non-ovarian/

adnexal malig w/o CC/

MCC.

742............................ Uterine & adnexa proc 755

for non-malignancy w

CC/MCC.

743............................ Uterine & adnexa proc 755

for non-malignancy w/o

CC/MCC.

744............................ D&C, conization, 749

laparascopy & tubal

interruption w CC/MCC.

745............................ D&C, conization, 749

laparascopy & tubal

interruption w/o CC/

MCC.

748............................ Female reproductive 749

system reconstructive

procedures.

750............................ Other female 749

reproductive system

O.R. procedures w/o CC/

MCC.

756............................ Malignancy, female 755

reproductive system w/

o CC/MCC.

761............................ Menstrual & other 760

female reproductive

system disorders w/o

CC/MCC.

765............................ Cesarean section w CC/ 629

MCC.

766............................ Cesarean section w/o CC/ 629

MCC.

767............................ Vaginal delivery w 629

sterilization &/or D&C.

768............................ Vaginal delivery w O.R. 629

proc except steril &/

or D&C.

769............................ Postpartum & post 629

abortion diagnoses w

O.R. procedure.

770............................ Abortion w D&C, 629

aspiration curettage

or hysterotomy.

774............................ Vaginal delivery w 629

complicating diagnoses.

775............................ Vaginal delivery w/o 629

complicating diagnoses.

777............................ Ectopic pregnancy...... 629

778............................ Threatened abortion.... 759

779............................ Abortion w/o D&C....... 759

780............................ False labor............ 759

782............................ Other antepartum 781

diagnoses w/o medical

complications.

789............................ Neonates, died or 781

transferred to another

acute care facility.

790............................ Extreme immaturity or 781

respiratory distress

syndrome, neonate.

791............................ Prematurity w major 781

problems.

792............................ Prematurity w/o major 781

problems.

793............................ Full term neonate w 781

major problems.

794............................ Neonate w other 781

significant problems.

795............................ Normal newborn......... 781

799............................ Splenectomy w MCC...... 800

801............................ Splenectomy w/o CC/MCC. 800

804............................ Other O.R. proc of the 803

blood & blood forming

organs w/o CC/MCC.

810............................ Major hematol/immun 812

diag exc sickle cell

crisis & coagul w/o CC/

MCC.

820............................ Lymphoma & leukemia w 823

major O.R. procedure w

MCC.

822............................ Lymphoma & leukemia w 821

major O.R. procedure w/

o CC/MCC.

825............................ Lymphoma & non-acute 824

leukemia w other O.R.

proc w/o CC/MCC.

828............................ Myeloprolif disord or 827

poorly diff neopl w

maj O.R. proc w/o CC/

MCC.

830............................ Myeloprolif disord or 829

poorly diff neopl w

other O.R. proc w/o CC/

MCC.

836............................ Acute leukemia w/o 835

major O.R. procedure w/

o CC/MCC.

838............................ Chemo w acute leukemia 837

as sdx or w high dose

chemo agent w CC.

839............................ Chemo w acute leukemia 837

as sdx or w high dose

chemo agent w/o CC/MCC.

845............................ Other myeloprolif dis 844

or poorly diff neopl

diag w/o CC/MCC.

887............................ Other mental disorder 881

diagnoses.

915............................ Allergic reactions w 918

MCC.

916............................ Allergic reactions w/o 918

MCC.

929............................ Full thickness burn w 934

skin graft or inhal

inj w/o CC/MCC.

955............................ Craniotomy for multiple 26

significant trauma.

956............................ Limb reattachment, hip 480

& femur proc for

multiple significant

trauma.

959............................ Other O.R. procedures 958

for multiple

significant trauma w/o

CC/MCC.

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[[Page 24224]]

To illustrate this methodology for determining the proposed

relative weights for the proposed RY 2010 MS-LTC-DRGs with no LTCH

cases, we are providing the following example, which refers to the no-

volume proposed MS-LTC-DRGs crosswalk information for RY 2010 provided

in the chart above.

Example: There were no cases in the FY 2008 MedPAR file used for

this proposed rule for proposed MS-LTC-DRG 61 (Acute Ischemic Stroke

with Use of Thrombolytic Agent with MCC). We determined that

proposed MS-LTC-DRG 70 (Nonspecific Cebrovascular Disorders with

MCC) was similar clinically and based on resource use to MS-LTC-DRG

61. Therefore, we assigned the same proposed relative weight of

proposed MS-LTC-DRG 70 of 0.8612 for RY 2010 to proposed MS-LTC-DRG

61 (we refer readers to Table 11 of the Addendum to this proposed

rule).

Furthermore, for RY 2010, consistent with our historical relative

weight methodology, we are proposing to establish proposed MS-LTC-DRG

relative weights of 0.0000 for the following transplant proposed MS-

LTC-DRGs: Heart Transplant or Implant of Heart Assist System with MCC

(proposed MS-LTC-DRG 1); Heart Transplant or Implant of Heart Assist

System without MCC (proposed MS-LTC-DRG 2); Liver Transplant with MCC

or Intestinal Transplant (proposed MS-LTC-DRG 5); Liver Transplant

without MCC (proposed MS-LTC-DRG 6); Lung Transplant (proposed MS-LTC-

DRG 7); Simultaneous Pancreas/Kidney Transplant (proposed MS-LTC-DRG

8); Pancreas Transplant (proposed MS-LTC-DRG 10); and Kidney Transplant

(proposed MS-LTC-DRG 652). This is because Medicare will only cover

these procedures if they are performed at a hospital that has been

certified for the specific procedures by Medicare and presently no LTCH

has been so certified. Based on our research, we found that most LTCHs

only perform minor surgeries, such as minor small and large bowel

procedures, to the extent any surgeries are performed at all. Given the

extensive criteria that must be met to become certified as a transplant

center for Medicare, we believe it is unlikely that any LTCHs will

become certified as a transplant center. In fact, in the more than 20

years since the implementation of the IPPS, there has never been a LTCH

that even expressed an interest in becoming a transplant center.

If, in the future, a LTCH applies for certification as a Medicare-

approved transplant center, we believe that the application and

approval procedure would allow sufficient time for us to determine

appropriate weights for the MS-LTC-DRGs affected. At the present time,

we only include these eight transplant MS-LTC-DRGs in the GROUPER

program for administrative purposes only. Because we use the same

GROUPER program for LTCHs as is used under the IPPS, removing these MS-

LTC-DRGs would be administratively burdensome. Again, we note that, as

this system is dynamic, it is entirely possible that the number of MS-

LTC-DRGs with no volume of LTCH cases based on the system will vary in

the future. We used the most recent available claims data in the MedPAR

file to identify no-volume MS-LTC-DRGs and to determine the proposed

relative weights in this proposed rule.

Step 6--Adjust the proposed RY 2010 MS-LTC-DRG relative weights to

account for nonmonotonically increasing relative weights.

As discussed above in this section, the MS-DRGs (used under the

IPPS) and the MS-LTC-DRGs (used under the LTCH PPS) provide a

significant improvement in the DRG system's recognition of severity of

illness and resource usage. The MS-DRGs contain base DRGs that have

been subdivided into one, two, or three severity levels. Where there

are three severity levels, the most severe level has at least one code

that is referred to as an MCC (that is, major complication or

comorbidity). The next lower severity level contains cases with at

least one code that is a CC (that is, complication or comorbidity).

Those cases without an MCC or a CC are referred to as ``without CC/

MCC.'' When data do not support the creation of three severity levels,

the base DRG is subdivided into either two levels or the base DRG is

not subdivided. The two-level subdivisions could consist of the with

CC/MCC and the without CC/MCC. Alternatively, the other type of two-

level subdivision may consist of the MCC and without MCC.

In those base MS-LTC-DRGs that are split into either two or three

severity levels, cases classified into the ``without CC/MCC'' MS-LTC-

DRG are expected to have a lower resource use (and lower costs) than

the ``with CC/MCC'' MS-LTC-DRG (in the case of a two-level split) or

both the ``with CC'' and the ``with MCC'' MS-LTC-DRGs (in the case of a

three-level split). That is, theoretically, cases that are more severe

typically require greater expenditure of medical care resources and

will result in higher average charges. Therefore, in the three severity

levels, relative weights should increase by severity, from lowest to

highest. If the relative weights decrease as severity decreased (that

is, if within a base MS-LTC-DRG, an MS-LTC-DRG with CC has a higher

relative weight than one with MCC, or the MS-LTC-DRG without CC/MCC has

a higher relative weight than either of the others), they are

nonmonotonic. We continue to believe that utilizing nonmonotonic

relative weights to adjust Medicare payments would result in

inappropriate payments because the payment for the cases in the higher

severity level in a base MS-LTC-DRG (which are generally expected to

have higher resource use and costs) would be lower than the payment for

cases in a lower severity level within the same base MS-LTC-DRG (which

are generally expected to have lower resource use and costs).

Consequently, in general, consistent with our historical methodology,

we are proposing to combine proposed MS-LTC-DRG severity levels within

a base MS-LTC-DRG for the purpose of computing a relative weight when

necessary to ensure that monotonicity is maintained. Specifically, in

determining the proposed RY 2010 MS-LTC-DRG relative weights in this

proposed rule, we are proposing to use the same methodology to adjust

for nonmonotonicity that we used to determine the RY 2009 MS-LTC-DRG

relative weights in the FY 2009 IPPS final rule (73 FR 48549 through

48550). In determining the proposed RY 2010 MS-LTC-DRG relative weights

in this proposed rule, under each of the example scenarios provided

below, we combine severity levels within a proposed base MS-LTC-DRG as

follows:

The first example of nonmonotonically increasing relative weights

for a proposed MS-LTC-DRG pertains to a proposed base MS-LTC-DRG with a

three-level split and each of the three levels has 25 or more LTCH

cases and, therefore, none of those proposed MS-LTC-DRGs is assigned to

one of the five low-volume quintiles. In this proposed rule, if

nonmonotonicity is detected in the proposed relative weights of the

proposed MS-LTC-DRGs in adjacent severity levels (for example, the

proposed relative weight of the ``with MCC'' (the highest severity

level) is less than the ``with CC'' (the middle level), or the proposed

relative weight ``with CC'' is less than the ``without CC/MCC'' (lowest

severity level)), we combine the nonmonotonic adjacent proposed MS-LTC-

DRGs and redetermine a proposed relative weight based on the case-

weighted average of the combined LTCH cases of the nonmonotonic

proposed MS-LTC-DRGs. The case-weighted average charge is calculated by

dividing the total charges for all LTCH cases in both

[[Page 24225]]

severity levels by the total number of LTCH cases for both proposed MS-

LTC-DRGs. The same proposed relative weight is assigned to both

affected levels of the proposed base MS-LTC-DRG. If nonmonotonicity

remains an issue because the above process results in a proposed

relative weight that is still nonmonotonic to the proposed relative

weight of the remaining proposed MS-LTC-DRG within the proposed base

MS-LTC-DRG, we combine all three of the severity levels to redetermine

the proposed relative weights based on the case-weighted average charge

of the combined severity levels. This same proposed relative weight is

then assigned to each of the proposed MS-LTC-DRGs in that proposed base

MS-LTC-DRG.

A second example of nonmonotonically increasing relative weights

for a proposed base MS-LTC-DRG pertains to the situation where there

are three severity levels and one or more of the severity levels within

a proposed base MS-LTC-DRG has less than 25 LTCH cases (that is, low

volume). If nonmonotonicity occurs in the case where either the highest

or lowest severity level (``with MCC'' or ``without CC/MCC'') has 25

LTCH cases or more and the other two severity levels are low volume

(and, therefore, the other two severity levels are otherwise assigned

the proposed relative weight of the applicable low-volume quintile(s)),

we combine the data for the cases in the two adjacent low-volume

proposed MS-LTC-DRGs for the purpose of determining a proposed relative

weight. If the combination results in at least 25 cases, we redetermine

one proposed relative weight based on the case-weighted average charge

of the combined severity levels and assign this same proposed relative

weight to each of the severity levels. If the combination results in

less than 25 cases, based on the case-weighted average charge of the

combined low-volume proposed MS-LTC-DRGs, both proposed MS-LTC-DRGs are

assigned to the appropriate low-volume quintile (discussed above in

section VIII.B.3.e. of this preamble) based on the case-weighted

average charge of the combined low-volume proposed MS-LTC-DRGs. Then

the proposed relative weight of the affected low-volume quintile is

redetermined and that proposed relative weight is assigned to each of

the affected severity levels (and all of the proposed MS-LTC-DRGs in

the affected low-volume quintile). If nonmonotonicity persists, we

combine all three severity levels and redetermine one proposed relative

weight based on the case-weighted average charge of the combined

severity levels and this same proposed relative weight is assigned to

each of the three levels within that proposed base MS-LTC-DRG.

Similarly, in nonmonotonic cases where the middle level has 25

cases or more but either or both of the lowest or highest severity

level has less than 25 cases (that is, low volume), we combine the

nonmonotonic low-volume proposed MS-LTC-DRG with the middle severity-

level proposed MS-LTC-DRG (the ``with CC'') of the proposed base MS-

LTC-DRG. We redetermine one proposed relative weight based on the case-

weighted average charge of the combined severity levels, and assign

this same proposed relative weight to each of the affected proposed MS-

LTC-DRGs. If nonmonotonicity persists, we combine all three levels for

the purpose of redetermining a proposed relative weight based on the

case-weighted average charge of the combined severity levels, and

assign that proposed relative weight to each of the three severity

levels within the proposed base MS-LTC-DRG.

In the case where all three severity levels in the proposed base-

MS-LTC-DRGs are low-volume proposed MS-LTC-DRGs and two of the severity

levels are nonmonotonic in relation to each other, we combine the two

adjacent nonmonotonic severity levels. If that combination resulted in

less than 25 cases, both low-volume proposed MS-LTC-DRGs are assigned

to the appropriate low-volume quintile (discussed above in section

VIII.B.3.e. of this preamble) based on the case-weighted average charge

of the combined low-volume proposed MS-LTC-DRGs. Then the proposed

relative weight of the affected low-volume quintile is redetermined,

and that proposed relative weight is assigned to each of the affected

severity levels (and all of the proposed MS-LTC-DRGs in the affected

low-volume quintile). If the nonmonotonicity persists, we combine all

three levels of that proposed base MS-LTC-DRG for the purpose of

redetermining a proposed relative weight based on the case-weighted

average charge of the combined severity levels, and assign that

proposed relative weight to each of the three severity levels. If that

combination of all three severity levels results in less than 25 cases,

we assign that ``combined'' base MS-LTC-DRG to the appropriate low-

volume quintile based on the case-weighted average charge of the

combined low-volume proposed MS-LTC-DRGs. Then the proposed relative

weight of the affected low-volume quintile is redetermined, and that

proposed relative weight is assigned to each of the affected severity

levels (and all of the MS-LTC-DRGs in the affected low-volume

quintile). If the combination of all three severity levels resulted in

25 or more cases, we redetermine one proposed relative weight based on

the case-weighted average charge of the combined severity levels, and

assign this same proposed relative weight to all three of the severity

levels within the proposed base MS-LTC-DRG.

Similarly, in the case where all three severity levels in the

proposed base MS-LTC-DRGs are low-volume proposed MS-LTC-DRGs and two

of the severity levels were nonmonotonic in relation to each other, we

combine the two adjacent nonmonotonic severity levels. If the

combination resulted in at least 25 cases, we then redetermine one

proposed relative weight based on the case-weighted average charge of

the combined severity levels, and assign this same proposed relative

weight to both of the affected adjacent severity levels within the

proposed base MS-LTC-DRG. If the nonmonotonicity persists, we combine

all three levels of that proposed base MS-LTC-DRG for the purpose of

redetermining a proposed relative weight based on the case-weighted

average charge of the combined severity levels, and assign that

proposed relative weight to each of the three severity levels within

the proposed base MS-LTC-DRG.

Another example of nonmonotonicity involves a proposed base MS-LTC-

DRG with three severity levels where at least one of the severity

levels has no LTCH cases. As discussed above in Step 5, we are

proposing to crosswalk a proposed no-volume MS-LTC-DRG to a proposed

MS-LTC-DRG that has at least one case based on resource use intensity

and clinical similarity. The no-volume proposed MS-LTC-DRG is assigned

the same proposed relative weight as the proposed MS-LTC-DRG to which

it is crosswalked. For many no-volume proposed MS-LTC-DRGs, as shown in

the chart above in Step 5, the application of our methodology results

in a crosswalked proposed MS-LTC-DRG that is the adjacent severity

level in the same proposed base MS-LTC-DRG. Consequently, in most

instances, the no-volume proposed MS-LTC-DRG and the adjacent proposed

MS-LTC-DRG to which it is crosswalked do not result in nonmonotonicity

because both of these severity levels would have the same proposed

relative weight. (In this proposed rule, under our methodology for the

treatment of no-volume proposed

[[Page 24226]]

MS-LTC-DRGs, in the case where the no-volume proposed MS-LTC-DRG was

either the highest or lowest severity level, the crosswalked proposed

MS-LTC-DRG is typically the middle level (``with CC'') within the same

proposed base MS-LTC-DRG, and, therefore, the no-volume proposed MS-

LTC-DRG (either the ``with MCC'' or the ``without CC/MCC'') and the

crosswalked proposed MS-LTC-DRG (the ``with CC'') have the same

proposed relative weight. Consequently, no adjustment for monotonicity

is necessary.) However, if our methodology for determining proposed

relative weights for no-volume proposed MS-LTC-DRGs results in

nonmonotonicity with the third severity level in the base MS-LTC-DRG,

all three severity levels are combined in order to redetermine one

proposed relative weight based on the case-weighted average charge of

the combined severity levels. This same proposed relative weight is

assigned to each of the three severity levels in the base MS-LTC-DRG.

Thus far in the discussion, we have presented examples of

nonmonotonicity in a proposed base MS-LTC-DRG that has three severity

levels. Under our methodology for the treatment of nonmonotonicity, we

are proposing to apply the same process where the proposed base MS-LTC-

DRG contains only two severity levels. For example, if nonmonotonicity

occurs in a proposed base MS-LTC-DRG with two severity levels (that is,

the relative weight of the higher severity level is less than the lower

severity level), where both of the MS-LTC-DRGs have at least 25 cases

or where one or both of the MS-LTC-DRGs are low volume (that is, less

than 25 cases), we combine the two proposed MS-LTC-DRGs of that

proposed base MS-LTC-DRG for the purpose of redetermining a proposed

relative weight based on the combined case-weighted average charge for

both severity levels. This same proposed relative weight is assigned to

each of the two severity levels in the proposed base MS-LTC-DRG.

Specifically, if the combination of the two severity levels results in

at least 25 cases, we redetermine one proposed relative weight based on

the case-weighted average charge, and assign that proposed relative

weight to each of the two proposed MS-LTC-DRGs. If the combination

results in less than 25 cases, we assign both proposed MS-LTC-DRGs to

the appropriate low-volume quintile (discussed above in section

VIII.B.3.e. of this preamble) based on their combined case-weighted

average charge. Then the proposed relative weight of the affected low-

volume quintile is redetermined, and that proposed relative weight is

assigned to each of the two severity levels within the proposed base

MS-LTC-DRG (and all of the proposed MS-LTC-DRGs in the affected low-

volume quintile).

Step 7--Calculate the RY 2010 budget neutrality factor.

As we established in the RY 2008 LTCH PPS final rule (72 FR 26882),

under the broad authority conferred upon the Secretary under section

123 of Public Law 106-113, as amended by section 307(b) of Public Law

106-554, to develop the LTCH PPS, beginning with the MS-LTC-DRG update

for FY 2008, the annual update to the MS-LTC-DRG classifications and

relative weights is done in a budget neutral manner such that estimated

aggregate LTCH PPS payments would be unaffected, that is, would be

neither greater than nor less than the estimated aggregate LTCH PPS

payments that would have been made without the MS-LTC-DRG

classification and relative weight changes. Specifically, in that same

final rule, we established a requirement under Sec. 412.517(b) that

the annual update to the MS-LTC-DRG classifications and relative

weights be done in a budget neutral manner. (For a detailed discussion

on the establishment of the budget neutrality requirement to update the

MS-LTC-DRG classifications and relative weights, we refer readers to

the RY 2008 LTCH PPS final rule (72 FR 26880 through 26884).) The MS-

LTC-DRG classifications and relative weights are updated annually based

on the most recent available LTCH claims data to reflect changes in

relative LTCH resource use. Under the budget neutrality requirement,

for each annual update, the MS-LTC-DRG relative weights are uniformly

adjusted to ensure that estimated aggregate payments under the LTCH PPS

would not be affected (that is, decreased or increased). Consistent

with that provision, we are proposing to update the proposed MS-LTC-DRG

classifications and relative weights for RY 2010 based on the most

recent available LTCH data, and to include a budget neutrality

adjustment that is applied in determining the proposed RY 2010 MS-LTC-

DRG relative weights.

To ensure budget neutrality in the proposed update to the MS-LTC-

DRG classifications and relative weights under Sec. 412.517(b),

consistent with the budget neutrality methodology we established in the

FY 2008 IPPS final rule with comment period (72 FR 47295 through

47296), in determining the budget neutrality adjustment for RY 2010 in

this proposed rule, we are proposing to use a method that is similar to

the methodology used under the IPPS. Specifically, for RY 2010, after

recalibrating the proposed MS-LTC-DRG proposed relative weights as we

do under the methodology as described in detail in Steps 1 through 6

above, we are proposing to calculate and apply a normalization factor

to those proposed relative weights to ensure that estimated payments

are not influenced by changes in the composition of case types or the

changes to the classification system. That is, the normalization

adjustment is intended to ensure that the recalibration of the proposed

MS-LTC-DRG relative weights (that is, the process itself) neither

increases nor decreases total estimated payments.

To calculate the normalization factor for RY 2010, we are proposing

to use the following steps: (1) We use the most recent available LTCH

claims data (FY 2008) and group them using the proposed RY 2010 GROUPER

(Version 27.0) and the proposed RY 2010 MS-LTC-DRG relative weights

(determined above in Steps 1 through 6 above) to calculate the average

case-mix index (CMI); (2) we group the same LTCH claims data (FY 2008)

using the FY 2009 GROUPER (Version 26.0) and FY 2009 relative weights

(established in the FY 2009 IPPS final rule (73 FR 48528 through

48551)) and calculate the average CMI; and (3) we compute the ratio of

these average CMIs by dividing the average CMI for FY 2009 (determined

in Step 2) by the average CMI for RY 2010 (determined in Step 1). In

determining the proposed MS-LTC-DRG relative weights for RY 2010, based

on the latest available LTCH claims data, the normalization factor is

estimated as 1.1147455, which is applied in determining each proposed

RY 2010 MS-LTC-DRG relative weight. That is, each proposed MS-LTC-DRG

relative weight is multiplied by 1.1147455 in the first step of the

budget neutrality process. Accordingly, the proposed RY 2010 MS-LTC-DRG

relative weights in Table 11 in the Addendum of this proposed rule

reflect this normalization factor. We also ensure that estimated

aggregate LTCH PPS payments (based on the most recent available LTCH

claims data) after reclassification and recalibration (the proposed RY

2010 MS-LTC-DRG classifications and relative weights) are equal to

estimated aggregate LTCH PPS payments (for the same most recent

available LTCH claims data) before reclassification and recalibration

(the existing RY 2009 MS-LTC-DRG classifications and relative weights).

[[Page 24227]]

Therefore, similar to the methodology used to determine the proposed

IPPS DRG reclassification and recalibration budget neutrality factor

discussed in section II.A.4.a. of the Addendum to this proposed rule,

we used FY 2008 discharge data to simulate payments and compare

estimated aggregate LTCH PPS payments using the FY 2009 MS-LTC-DRGs and

relative weights to estimate aggregate LTCH PPS payments using the

proposed RY 2010 MS-LTC-DRGs and relative weights. As noted above, the

most recent available LTCH claims data for this proposed rule are from

the December 2008 update of the FY 2008 MedPAR file. Consistent with

our historical policy of using the best available data, we are

proposing to use the most recently available claims data for

determining the budget neutrality adjustment factor in the final rule.

Specifically, we determined the proposed RY 2010 budget neutrality

adjustment factor in this proposed rule using the following steps: (1)

We simulate estimated total LTCH PPS payments using the normalized

proposed relative weights for RY 2010 and proposed GROUPER Version 27.0

(as described above in this section); (2) we simulate estimated total

LTCH PPS payments using the FY 2009 GROUPER (Version 26.0) and FY 2009

MS-LTC-DRG relative weights (as established in the FY 2009 IPPS final

rule (73 FR 48528 through 48551)); and (3) we calculate the ratio of

these estimated total LTCH PPS payments by dividing the estimated total

LTCH PPS payments using the FY 2009 GROUPER (Version 26.0) and the FY

2009 MS-LTC-DRG relative weights (determined in Step 2) by the

estimated total LTCH PPS payments using the proposed RY 2010 GROUPER

(Version 27.0) and the normalized proposed MS-LTC-DRG relative weights

for RY 2010 (determined in Step 1). Then, each of the normalized

proposed relative weights is multiplied by the budget neutrality

adjustment factor to determine the proposed budget neutral RY 2010

relative weight for each proposed MS-LTC-DRG.

Accordingly, in determining the proposed RY 2010 MS-LTC-DRG

relative weights in this proposed rule, based on the most recent

available LTCH claims data, we are proposing to establish a budget

neutrality adjustment factor of 0.993192, which is applied to the

normalized proposed relative weights (described above). The proposed RY

2010 MS-LTC-DRG relative weights in Table 11 in the Addendum to this

proposed rule reflect this proposed budget neutrality factor.

Table 11 in the Addendum to this proposed rule lists the proposed

MS-LTC-DRGs and their respective proposed relative weights, geometric

mean length of stay, and five-sixths of the geometric mean length of

stay (used in determining SSO payments under Sec. 412.529) for RY

2010.

C. Proposed Changes to the LTCH Payment Rates and Other Changes to the

RY 2010 LTCH PPS

1. Overview of Development of the LTCH Payment Rates

The LTCH PPS was effective beginning with a LTCH's first cost

reporting period beginning on or after October 1, 2002. Effective with

that cost reporting period, LTCHs are paid, during a 5-year transition

period, a total LTCH prospective payment that is comprised of an

increasing proportion of the LTCH PPS Federal rate and a decreasing

proportion based on reasonable cost-based principles, unless the

hospital makes a one-time election to receive payment based on 100

percent of the Federal rate, as specified in Sec. 412.533. New LTCHs

(as defined at Sec. 412.23(e)(4)) are paid based on 100 percent of the

Federal rate, with no phase-in transition payments.

The basic methodology for determining LTCH PPS Federal prospective

payment rates is set forth at Sec. 412.515 through Sec. 412.536. In

this section, we discuss the factors that would be used to update the

LTCH PPS standard Federal rate for the 2010 LTCH PPS rate year that

would be effective for LTCH discharges occurring on or after October 1,

2009 through September 30, 2010. When we implemented the LTCH PPS in

the August 30, 2002 LTCH PPS final rule (67 FR 56029 through 56031), we

computed the LTCH PPS standard Federal payment rate for FY 2003 by

updating the latest available (FY 1998 or FY 1999) Medicare inpatient

operating and capital cost data, using the excluded hospital market

basket.

Section 123(a)(1) of the BBRA requires that the PPS developed for

LTCHs be budget neutral for the initial year of implementation.

Therefore, in calculating the standard Federal rate under Sec.

412.523(d)(2), we set total estimated LTCH PPS payments equal to

estimated payments that would have been made under the reasonable cost-

based payment methodology had the LTCH PPS not been implemented.

Section 307(a)(2) of the BIPA specified that the increases to the

target amounts and the cap on the target amounts for LTCHs for FY 2002

provided for by section 307(a)(1) of the BIPA shall not be considered

in the development and implementation of the LTCH PPS. Section

307(a)(2) of the BIPA also specified that enhanced bonus payments for

LTCHs provided for by section 122 of BBRA were not to be taken into

account in the development and implementation of the LTCH PPS.

Furthermore, as specified at Sec. 412.523(d)(1), the initial

standard Federal rate was reduced by an adjustment factor to account

for the estimated proportion of outlier payments under the LTCH PPS to

total estimated LTCH PPS payments (8 percent). For further details on

the development of the FY 2003 standard Federal rate, we refer readers

to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037),

and for subsequent updates to the LTCH PPS Federal rate we refer

readers to the following final rules: RY 2004 LTCH PPS final rule (68

FR 34134 through 34140), RY 2005 LTCH PPS final rule (69 FR 25682

through 25684), RY 2006 LTCH PPS final rule (70 FR 24179 through

24180), RY 2007 LTCH PPS final rule (71 FR 27819 through 27827), RY

2008 LTCH PPS final rule (72 FR 26870 through 27029), and RY 2009 LTCH

PPS final rule (73 FR 26800 through 26804). The proposed update to the

LTCH PPS standard Federal rate for RY 2010 is presented in section V.A.

of the Addendum to this proposed rule. Two of the components of the

proposed update to the LTCH PPS standard Federal rate for RY 2010 are

discussed below.

2. Market Basket for LTCHs Reimbursed Under the LTCH PPS

a. Overview

Historically, the Medicare program has used a market basket to

account for price increases in the services furnished by providers. The

market basket used for the LTCH PPS includes both operating and

capital-related costs of LTCHs because the LTCH PPS uses a single

payment rate for both operating and capital-related costs. The

development of the initial LTCH PPS standard Federal rate for FY 2003,

using the excluded hospital with capital market basket, is discussed in

further detail in the August 30, 2002 LTCH PPS final rule (67 FR 56027

through 56033).

In that final rule (67 FR 56016 through 56017 and 56030), which

implemented the LTCH PPS, we established the use of the excluded

hospital with capital market basket as the LTCH PPS market basket. The

excluded hospital with capital market basket was also used to update

the limits on LTCHs' operating costs for inflation under the TEFRA

reasonable

[[Page 24228]]

cost-based payment system. We explained that we believe the use of the

excluded hospital with capital market basket to update LTCHs' payments

for inflation was appropriate because the excluded hospital market

basket (with a capital component) measures price increases of the

services furnished by excluded hospitals, including LTCHs. For further

details on the development of the excluded hospital with capital market

basket, we refer readers to the RY 2004 LTCH PPS final rule (68 FR

34134 through 34137).

As discussed in the RY 2007 LTCH PPS final rule (71 FR 27810),

based on our research, we did not develop a market basket specific to

LTCH services. We were unable to create a separate market basket

specifically for LTCHs at that time due to the small number of

facilities and the limited amount of data that was reported (for

instance, only approximately 15 percent of LTCHs reported contract

labor cost data for 2002). In that same final rule, under the broad

authority conferred upon the Secretary by section 123 of the BBRA as

amended by section 307(b) of the BIPA, we adopted the rehabilitation,

psychiatric, long-term care (RPL) market basket as the appropriate

market basket of goods and services under the LTCH PPS for discharges

occurring on or after July 1, 2006. Specifically, beginning with the

2007 LTCH PPS rate year, for the LTCH PPS, we adopted the use of the

RPL market basket which is based on FY 2002 cost report data. We chose

to use the FY 2002 Medicare cost report data because those data were

the most recent, relatively complete cost data for IRFs, IPFs, and

LTCHs available at the time of rebasing.

The RPL market basket was determined based on the operating and

capital costs of freestanding IRFs, freestanding IPFs, and LTCHs. As we

explained in the RY 2007 LTCH PPS final rule, we believed a market

basket based on the data of IRFs, IPFs, and LTCHs was appropriate to

use under the LTCH PPS because those data were the best available data

that reflect the cost structures of LTCHs. For further details on the

development of the RPL market basket, including the methodology for

determining the operating and capital portions of the RPL market

basket, we refer readers to the RY 2007 LTCH PPS final rule (71 FR

27810 through 27817).

b. Proposed Market Basket Under the LTCH PPS for RY 2010

When we initially created the FY 2002-based RPL market basket, we

were unable to create a separate market basket specifically for LTCHs

due, in part, to the small number of facilities and the limited data

that were provided in the Medicare cost reports. Over the last several

years, however, the number of LTCH facilities submitting valid Medicare

cost report data has increased. Based on this development, as well as

our desire to move from one RPL market basket to three stand-alone and

provider-specific market baskets (for IRFs, IPFs, and LTCHs,

respectively), we plan to begin exploring the viability of creating

these market baskets for future use. However, as we discussed in the FY

2010 IRF PPS proposed rule, we are conducting further research to

assist us in understanding the reasons for the variations in costs and

cost structure between freestanding IRFs and hospital-based IRFs. We

also are researching the reasons for similar variations in costs and

cost structure between freestanding IPFs and hospital-based IPFs.

Therefore, as we continue to explore the development of stand-alone

market baskets for LTCHs, IRFs and IPFs, respectively, we believe that

it is appropriate to continue to use the FY 2002-based RPL market

basket for LTCHs, IRFs and IPFs under their respective PPSs.

Accordingly, in this proposed rule, we are proposing to continue to use

the FY 2002-based RPL market basket under the LTCH PPS for RY 2010, as

we continue to believe it is the best available data that reflect the

cost structure of LTCHs. We are hopeful that progress can be made in

the near future with respect to creating stand-alone market baskets for

LTCHs, IRFs, and IPFs and, as a result, may propose to rebase the

appropriate market basket(s) for subsequent updates in the future.

c. Proposed Market Basket Update for LTCHs for RY 2010

Consistent with our historical practice, we estimate the RPL market

basket update based on IHS Global Insight, Inc.'s forecast using the

most recent available data. IHS Global Insight, Inc. is a nationally

recognized economic and financial forecasting firm that contracts with

CMS to forecast the components of the hospital market baskets. Based on

IHS Global Insight Inc.'s first quarter 2009 forecast, the proposed RY

2010 market basket estimate for the LTCH PPS using the FY 2002-based

RPL market basket is 2.4 percent. This includes increases in both the

operating section and the capital section of the FY 2002-based RPL

market basket. In addition, consistent with our historical practice of

using market basket estimates based on the most recent available data,

we are proposing that if more recent data are available when we develop

the final rule, we would use such data, if appropriate. (As discussed

in greater detail in section V. of the Addendum to this proposed rule,

for RY 2010, we are proposing to update the LTCH PPS standard Federal

rate by -0.2 percent. The proposed update reflects an adjustment based

on the most recent market basket estimate (currently 2.4 percent as

discussed above) and adjustments to account for the increase in case-

mix in the prior periods (FYs 2007 through 2009) that resulted from

changes in documentation and coding practices rather than increases in

patients' severity of illness.)

d. Proposed Labor-Related Share Under the LTCH PPS for RY 2010

As discussed in section V.B. of the Addendum to this proposed rule,

under the authority of section 123 of the BBRA as amended by section

307(b) of the BIPA, we established an adjustment to the LTCH PPS

Federal rate to account for differences in LTCH area wage levels at

Sec. 412.525(c). The labor-related portion of the LTCH PPS Federal

rate, hereafter referred to as the labor-related share, is adjusted to

account for geographic differences in area wage levels by applying the

applicable LTCH PPS wage index.

The labor-related share is determined by identifying the national

average proportion of operating and capital costs that are related to,

influenced by, or vary with the local labor market. We continue to

classify a cost category as labor-related if the costs are labor-

intensive and vary with the local labor market. In addition, as

discussed above, we are proposing to continue to use the FY 2002-based

RPL market basket under the LTCH PPS for RY 2010. Given this, we are

proposing to continue to define the labor-related share as the national

average proportion of operating costs that are attributable to wages

and salaries, employee benefits, contract labor, professional fees,

labor-intensive services, and a labor-related portion of capital based

on the FY 2002-based RPL market basket. (Additional information on the

development of the FY 2002-based RPL market basket used under the LTCH

PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27809

through 27818).)

The proposed labor-related share for RY 2010 would be the sum of

the proposed RY 2010 relative importance of each labor-related cost

category, and would reflect the different rates of price change for

these cost categories between the base year (FY 2002) and RY 2010. The

sum of the proposed relative importance for RY 2010 for operating costs

(wages and salaries, employee

[[Continued on page 24229]]

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[[pp. 24229-24278]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24228]]

[[Page 24229]]

benefits, professional fees, and all-other labor-intensive services)

would be 71.961 as shown in the chart below. The portion of capital

that is influenced by the local labor market is estimated to be 46

percent. Because the relative importance for capital in RY 2010 would

be 8.572 percent of the FY 2002-based RPL market basket, we are

proposing to take 46 percent of 8.572 percent to determine the proposed

labor-related share of capital for RY 2010. The result would be 3.943

percent, which we are proposing to add to 71.961 percent for the

operating cost amount to determine the total proposed labor-related

share for RY 2010. Thus, the labor-related share that we are proposing

to use for LTCH PPS in RY 2010 would be 75.904 percent.

The chart below shows the proposed RY 2010 relative importance

labor-related share using the FY 2002-based RPL market basket.

Proposed RY 2010 Labor-Related Share Based on the FY 2002-Based RPL

Market Basket

------------------------------------------------------------------------

FY 2002-based RPL

market basket

labor-related

Cost category share relative

importance

(percent) RY 2010

------------------------------------------------------------------------

Wages and Salaries................................... 53.064

Employee Benefits.................................... 13.880

Professional Fees.................................... 2.894

All Other Labor-Intensive Services................... 2.123

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Subtotal......................................... 71.961

Labor-Related Share of Capital Costs (46 percent).... 3.943

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Total Labor-Related Share........................ 75.904

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3. Proposed Adjustment for Changes in LTCHs' Case-Mix Due to Changes in

Documentation and Coding Practices That Occurred in a Prior Period

a. Background

Beginning in RY 2007, in updating the standard Federal rate for the

LTCH PPS, we have accounted for increases in payments from a past

period due to changes in documentation and coding practices.

Specifically, in the RY 2007 LTCH PPS final rule (71 FR 27820), we

explained that rather than solely using the most recent estimate of the

LTCH PPS market basket increase as the basis of the update factor for

the standard Federal rate for RY 2007, we believed that based on our

ongoing monitoring of LTCHs' case mix, it was appropriate to also

adjust the standard Federal rate to account for the changes in

documentation and coding practices (rather than patients' severity of

illness) in addition to the estimated increase in the LTCH PPS market

basket. Accordingly, we established at Sec. 412.523(c)(3)(iii) of the

regulations that the update to the standard Federal rate for the 2007

LTCH PPS rate year was zero percent, based on the most recent estimate

of the LTCH PPS market basket increase of 3.4 percent and an equivalent

negative adjustment to account for changes in case-mix due to changes

in documentation and coding practices in a prior period (FY 2004).

In the RY 2008 LTCH PPS final rule (72 FR 26880 through 26890), we

continued to monitor and analyze LTCHs' case-mix and applied an update

to the standard Federal rate of 0.71 percent, based on the most recent

estimate of the market basket increase (3.2 percent) and an adjustment

to account for changes in documentation and coding practices (-2.49

percent) in the prior period, FY 2005. Similarly, for RY 2009, as

discussed in the RY 2009 final rule (73 FR 26805 through 26812), the

standard Federal rate was updated using an update factor of 2.7

percent, based on the most recent estimate of the market basket

increase (3.6 percent) and an adjustment to account for changes in

case-mix due to documentation and coding practices (-0.9 percent) in

the prior period, FY 2006.

b. Evaluation of FY 2007 Claims Data

For RY 2010, we continue to believe that changes in the LTCH PPS

payment rates should accurately reflect changes in LTCHs' true cost of

treating patients, and should not be influenced by changes in

documentation and coding that do not reflect increases in patients'

severity of illness. Accordingly, consistent with previous years, we

are proposing to analyze LTCHs' case-mix index (CMI) changes in the

prior period, FY 2007, and if applicable, determine an appropriate

adjustment to account for changes in documentation and coding

practices. As we explained in the RY 2007 final rule (71 FR 27819

through 27823), a LTCH's CMI is defined as its case-weighted average

LTC-DRG relative weight for all its discharges in a given period.

Changes in CMI consist of two components: ``real'' CMI changes and

``apparent'' CMI changes. Real CMI increase is defined as the increase

in the average LTC-DRG relative weights resulting from the hospital's

treatment of more resource intensive patients. Apparent CMI increase is

defined as the increase in CMI due to changes in documentation and

coding practices (including better documentation of the medical record

by physicians and more complete coding of the medical record by

coders). In previous years, analysis of the most recent available LTCH

CMI data focused on quantifying the portion of CMI change in a prior

period that is attributable to apparent CMI change. However, beginning

in RY 2010, we are proposing to revise our methodology to determine the

proposed documentation and coding adjustment, consistent with the IPPS

proposed methodology for case-mix analysis under the IPPS, which is

discussed in detail in section II.D.4 of the preamble of this proposed

rule. We note that section II.D.4 of the preamble of this proposed rule

discusses the proposed analysis in the context of the MS-DRG

documentation and coding adjustments for FY 2008 and FY 2009 authorized

by Public Law 110-90 for the IPPS, and we note that the requirements of

Public Law 110-90 do not apply to the LTCH PPS. However, section

123(a)(1) of Public Law 106-113 (BBRA), as amended by section 307(b) of

Public Law 106-554 (BIPA), provides broad authority to the Secretary in

developing the LTCH PPS, including the authority for establishing

appropriate adjustments. The stated purpose of the proposed CMI

analysis for the IPPS is to measure and corroborate the extent of the

overall national average changes in case-mix since the adoption of the

MS-DRGs, which we believe is also relevant in determining appropriate

adjustments to account for changes in documentation and coding under

the LTCH PPS because, as stated above, the same DRG-based patient

classification system is used under both the LTCH PPS and the IPPS

(referred to as the MS-LTC-DRGs and MS-DRGs, respectively).

Accordingly, under the broad authority afforded by the statute to make

appropriate adjustments for the LTCH PPS, we believe it is appropriate

to propose to use the same methodology that we are proposing to use

under the IPPS as described in section II.D.4. of the preamble of this

proposed rule and which is discussed in further detail below in this

section.

Accordingly, consistent with the proposed IPPS CMI analysis

methodology, we conducted a thorough evaluation of LTCH claims data in

order to assess the case-mix changes that do not reflect real changes

in patients' severity of illness. The results of this evaluation were

used by our actuaries to determine if any payment adjustments are

necessary to ensure appropriate payments under the LTCH PPS.

Specifically, to evaluate the FY 2007 LTCH claims data, we performed

the proposed analysis plan in the following

[[Page 24230]]

manner. We first divided the CMI obtained by grouping the FY 2007 LTCH

claims data from the December 2007 update of the MedPAR files through

the FY 2007 GROUPER (Version 24.0) by the CMI obtained by grouping

these same FY 2007 LTCH claims through the FY 2006 GROUPER (Version

23.0). This results in a value of 0.974. Because these are the same FY

2007 LTCH cases grouped using the two GROUPERs, we attribute this

change primarily to two factors: (1) The effect of changes in

documentation and coding; and (2) the measurement effect from the

calibration of the GROUPER. We estimated the measurement effect from

the calibration of the GROUPER by dividing the CMI obtained by grouping

the FY 2006 LTCH claims through the FY 2007 GROUPER by the CMI obtained

by grouping these same LTCH claims through the FY 2006 GROUPER. This

results in a value of 0.969. In order to isolate the documentation and

coding effect, we then divided the combined effect of the changes in

documentation and coding and measurement (0.974) by the measurement

effect (0.969) to yield 1.005. Therefore, our estimate of the

documentation and coding increase that occurred in FY 2007 is 0.5

percent.

As in prior years, the FY 2006 and FY 2007 MedPAR files are

available to the public to allow independent analysis of the

documentation and coding effect in FY 2007. We are seeking public

comment on our proposed methodology and analysis.

c. Evaluation of FY 2008 Claims Data

In prior years, we based documentation and coding adjustments on an

analysis of the most recent available LTCH data and have established

the adjustments in a timely manner, as the data became available, to

account for each prior period where LTCHs were paid based on case-mix

changes that do not reflect increased patients' severity of illness.

Due to the change in the LTCH update cycle in RY 2010, we now have data

available to analyze case-mix changes for FY 2008 as well as FY 2007.

Accordingly, we believe it is also appropriate at this time to evaluate

documentation and coding changes in FY 2008 based on the most recent

available LTCH claims data. Accordingly, analogous to our evaluation of

the FY 2007 LTCH claims data as discussed above, we analyzed the FY

2008 LTCH claims data from the December 2008 update of the MedPAR files

as well. That is, we first divided the CMI obtained by grouping the FY

2008 LTCH claims through the FY 2008 GROUPER (Version 25.0) by the CMI

obtained by grouping these same FY 2008 LTCH claims through the FY 2007

GROUPER (Version 24.0). This results in a value of 1.011. We estimated

the measurement effect from the calibration of the GROUPER by dividing

the CMI obtained by grouping the FY 2007 LTCH claims through the FY

2008 GROUPER by the CMI obtained by grouping these same LTCH claims

through the FY 2007 GROUPER. This results in a value of 0.999. We then

divided the combined effect of the changes in documentation and coding

measurement (1.011) by the measurement effect (0.999) to yield 1.013.

Therefore, based on the results of the analysis, the documentation and

coding increase that occurred in FY 2008 is 1.3 percent.

As noted above, the FY 2007 and FY 2008 MedPAR files are available

to the public to allow independent analysis of the documentation and

coding effect in FY 2008. We are seeking public comment on our proposed

methodology and analysis.

d. Proposed RY 2010 Documentation and Coding Adjustment

Based on analysis of the most recent available LTCH claims data as

described above, we are proposing to apply a cumulative adjustment for

changes in documentation and coding that do not reflect an increase in

patients' severity of illness of -1.8 percent (that is, -0.5 percent

for FY 2007 plus -1.3 percent for FY 2008 equals -1.8 percent).

Accordingly, as discussed in section V.A.2. of the Addendum to this

proposed rule, we are proposing to update the proposed RY 2010 LTCH PPS

standard Federal rate by 0.6 percent, which is based on the most recent

estimate of the market basket increase (2.4 percent) and a proposed

adjustment to account for changes in documentation and coding practices

(-1.8 percent). We also are proposing that if more recent data are

available for the final rule, we would use those data to establish a

final update to the RY 2010 LTCH PPS standard Federal rate, if

applicable.

D. Monitoring

In the August 30, 2002 final rule (67 FR 56014), we described an

ongoing monitoring component to the new LTCH PPS. Specifically, we

discussed analysis of the various policies that we believe would

provide equitable payment for stays that reflect less than the full

course of treatment and reduce the incentives for inappropriate

admissions, transfers, or premature discharges of patients that are

present in a discharge-based PPS. As a result of our ongoing data

analysis, we revisited a number of our original policies and since the

FY 2003 implementation of the LTCH PPS, we have identified behaviors by

certain LTCHs that lead to inappropriate Medicare payments and have

formulated policies that we believe have resulted in fair and

reasonable payments for treatments delivered to Medicare beneficiaries

by LTCHs.

In the RY 2009 LTCH PPS proposed rule, we summarized policy

initiatives that we have issued as a result of our ongoing monitoring

program (73 FR 5373 through 5374). While we are not proposing to make

any new payment adjustments for RY 2010 as a result of our monitoring

activity, we note that we will continue to pursue our ongoing

monitoring program that involves the CMS Office of Research and

Development (ORDI), existing QIO monitoring, medical review activities

conducted by Medicare contractors (that is, fiscal intermediaries or

MACs), and studies described in the RY 2006 LTCH PPS final rule (70 FR

24211).

E. Research Conducted by the Research Triangle Institute, International

(RTI)

At this time, we are not proposing any additional specific changes

to payment policies under the LTCH PPS based on the findings made thus

far under our ongoing research contract with the Research Triangle

Institute, International (RTI). However, we believe that, in light of

continuing concerns regarding RTI's evaluation of the feasibility of

establishing patient-level and facility-level criteria for LTCHs, it is

appropriate to provide an update on RTI's most recent analyses and

findings.

At the beginning of FY 2005, CMS contracted with RTI for a

comprehensive evaluation of the feasibility of developing patient-level

and facility-level characteristics for LTCHs that could distinguish

LTCH patients from those patients treated in other hospitals. In prior

Federal Register notices, we have summarized the results of the ongoing

work and posted the reports on both Phase I and Phase II of RTI's

research on the CMS Web site at http://www.cms.hhs.gov/

LongTermCareHospitalPPS/02a\_RTIReports.asp#TopOfPage.

In the RY 2009 LTCH PPS proposed rule, in addition to a description

of RTI's research, we described the results of two technical expert

panels held during 2007 (73 FR 5374 through 5376). In these analyses,

RTI used CY 2004 Medicare claims data to examine the range of patient

types admitted to LTCHs, their characteristics to determine if they

were all medically complex, as suggested by many, and their outcomes to

examine whether the higher cost LTCH service was

[[Page 24231]]

distinguishable from outcomes for similar patients treated in areas

without LTCHs. These analyses controlled for case-mix severity and

examined the differences between beneficiaries discharged from acute

care hospitals to LTCHs compared to those who did not use LTCHs. The

results suggested LTCH cases were not uniquely distinguishable from

those in other acute care settings, in terms of their severity of

illness and reasons for admission. RTI's findings, which were

consistent with the findings of MedPAC that were included in the

MedPAC's June 2004 Report to the Congress (p. 127), indicated that, for

a small subset of patients (those that had been in the IPPS for

ventilator weaning), LTCHs achieved better outcomes at lower Medicare

program costs. RTI's findings also agreed with MedPAC's findings that

it found no differences in the other populations and that the severity

of cases admitted to LTCHs varied.

In the earlier reports, RTI also examined whether the average

Medicare payment per episode (across the IPPS, LTCH, and any other

associated services used during the episode of care) differed when

LTCHs were used. The issue under examination was whether the payments

per episode were similar and whether the outcomes were similar. To

examine this, RTI examined the top 50 types of cases likely to be

admitted to an LTCH and broke down the costs across an episode of care.

Those patients discharged to the LTCH had average payments per episode

that were $20,000 higher and no shorter episodes of care or IPPS

lengths of stay. Hospital readmission rates were also higher among the

LTCH users. However, it is unclear whether this reflects a more

complicated case that was not identified as such--being discharged to

the LTCH--or whether higher readmission was needed because the patient

was transferred from the IPPS inappropriately and needed more general

acute care rather than specialized LTCH services. LTCHs restrict their

admissions to patients who are hemodynamically stable, unlike IPPS

hospitals which provide intensive care, step-down care, and general

medical care. However, the analysis also showed variation in the types

of cases admitted to LTCHs. Additional analysis of the differences in

post-intensive care IPPS use for these two types of cases is also being

completed.

In the third phase of this study, RTI presented these findings to a

technical expert panel comprised of physicians treating complex cases

in LTCHs, IPPS hospitals, IRFs, and SNFs. The technical expert panel

members were asked to focus on the more complex cases and consider

whether LTCHs treat a unique population or use a unique set of

treatment practices. The panel discussed the distinguishing

characteristics of their respective populations and found great

overlap. The panel, including the LTCH physicians, reached a general

consensus that LTCHs do not treat a unique population. The types of

cases treated in LTCHs may also be treated in IPPS hospitals or IRFs,

depending on the primary condition. The panel noted that these complex

cases needed specialized treatments, including higher level nursing and

physician oversight, interdisciplinary teams to monitor infections and

other complications, as well as adequate numbers of cases to ensure

appropriate experience for treating these cases. Many LTCHs have these

facility-level characteristics although they were not mandated. Acute

care hospitals that treat these types of cases frequently have these

characteristics as well. All of the panel members agreed that

interdisciplinary teams and higher nurse staffing levels were necessary

to meet the needs of these patients. A recommendation was made that

Medicare should establish Centers of Excellence for treating the

medically complex or critically ill populations. These centers may be

LTCHs or other hospitals with the staffing and resources to treat these

cases, a critical volume of admissions to ensure experience with these

complex cases, and a consistent payment approach for these cases across

hospitals. (RTI's Phase III Report is posted on the CMS Web site at:

http://www.cms.hhs.gov.)

RTI also examined the adequacy of the payment rates for LTCHs.

Medicare cost reports were used to analyze trends in overall

profitability and Medicare profitability for some of the more common

conditions in LTCHs. Service-specific CCRs were computed to estimate

costs for individual MedPAR claims in CY 2006. Half of these claims

were paid under the rules applicable to LTCH PPS RY 2007. Data on costs

and payments of claims were then used to reassess patterns in

profitability by LTC-DRG. RTI found that aggregate LTCH facility PPS

margins declined from 11.7 percent in FY 2004 to 7.1 percent in FY

2006. For the subset of RY 2007 claims, the aggregate margin was 5.4

percent. The median PPS margin in FY 2006 was 8.7 percent among for-

profit LTCHs, 7.2 percent for private nonprofits, and -5.4 percent in

publicly-owned LTCHs. However, RTI found that these differences in

facility margins by type of ownership were explained by differences in

case-mix. Systematic variation in profitability by type of DRG was even

stronger in the FY 2006 data than in the FY 2004 data and publicly

owned LTCHs continued to admit a larger proportion of patients with

lower weighted (and, therefore, lower paid) DRGs.

RTI found that excess LTCH profitability relative to other PPS

settings in aggregate appears to have been reduced. However, margins

varied substantially for different types of cases. The ratio of PPS

payments to PPS costs were more than 30 percent higher than an industry

baseline, while cases for aftercare and rehabilitation had payment

ratios that were more than 10 percent below the baseline.

Persistent concerns regarding appropriate Medicare payments for

patients who are treated in LTCHs as well as in other provider settings

resulted in the enactment of a statutory provision under section 114(b)

of the MMSEA directing the Secretary to conduct a study for purposes of

determining medical necessity, appropriateness of admission, and

continued stay at, and discharge from, LTCHs and to submit a report to

the Congress within 18 months after the date of enactment of the MMSEA

(December 29, 2007) on the study, along with recommendations for

legislation and administrative actions for implementing national LTCH

facility and patient criteria, as the Secretary determines appropriate.

The statute further states that ``[I]n conducting the study and

preparing the report under this subsection, the Secretary shall

consider--(A) recommendations contained in a report to Congress by the

Medicare Payment Advisory Commission in June 2004 for long-term care

hospital-specific facility and patient criteria to ensure that patients

admitted to long-term care hospitals are medically complex and

appropriate to receive long-term care hospital services; and (B)

ongoing work by the Secretary to evaluate and determine the feasibility

of such recommendations.''

In fulfillment of this statutory mandate, CMS' Office of Research,

Development, and Information awarded a contract to Kennell and

Associates and RTI for additional analysis of data on Medicare payments

and facility costs for the treatment of similar patients in LTCHs and

alternative providers as well as patient outcomes and the range of

hospital-level care delivered in each setting. We intend to post this

report on the CMS Web site once it has been submitted to Congress.

[[Page 24232]]

F. Proposed Technical Corrections of LTCH PPS Regulations

While we are not proposing any new payment policy changes at this

time, we are taking this opportunity to propose two technical

corrections to regulation text that we believe will clarify our

existing policy at Sec. 412.525 relating to adjustments to the Federal

prospective payment to LTCHs.

First, at Sec. 412.525(a)(2), the regulations currently state that

``The fixed-loss amount is determined for the long-term care hospital

rate year using the LTC-DRG relative weights that are in effect on July

1 of the rate year.'' As stated earlier, in the RY 2009 LTCH PPS final

rule, we revised the LTCH PPS payment rate update cycle in order to

consolidate the timing of the annual update of the payment rates with

the update of the MS-LTC-DRG classifications to October 1, beginning

October 1, 2009 (73 FR 26792 through 26798). At that time, at Sec.

412.503, we specified a new definition for ``long-term care hospital

prospective payment system rate year.'' Under Sec. 412.503, the term

``long-term care hospital prospective payment system rate year'' means:

(1) From July 1, 2003, and ending on or before June 30, 2008, the 12-

month period of July 1 through June 30; (2) from July 1, 2008, and

ending on September 30, 2009, the 15-month period of July 1, 2008,

through September 30, 2009; and (3) beginning on or after October 1,

2009, the 12-month period of October 1 through September 30. At

Sec. Sec. 412.535(b) and (c), we described the resulting new

publication schedule of Federal prospective payment rates. However, we

neglected to make a conforming change to the regulations at Sec.

412.525(a)(2) to reflect this new schedule. Currently, the language of

Sec. 412.525(a)(2) still links the determination of the fixed-loss

amount to a July 1 effective date. The annual calculation of the fixed-

loss amount, which is the amount used to limit the loss that a hospital

will incur under the outlier policy for a case with unusually high

costs, is directly linked to the calculation of the annual update of

the Federal prospective payment rate (73 FR 26821). When we changed the

annual update of the LTCH PPS rate year to coincide with the update in

the MS-LTC-DRG relative weights to October 1, we should have changed

the language at Sec. 412.525(a)(2) regarding the calculation of the

fixed-loss amount to conform with this new schedule. Therefore, in this

proposed rule, we are proposing to revise Sec. 412.525(a)(2) to

accurately reflect the basis (effective LTC-DRG relative weights) for

calculating the annual fixed-loss amount for high-cost outlier

payments, in order to cover the various update cycles that have been in

effect under the LTCH PPS. Specifically, we are proposing to revise

Sec. 412.525(a)(2) to specify that the fixed-loss amount is determined

for the LTCH rate year using the MS-LTC-DRG relative weights that are

in effect at the start of the applicable LTCH PPS rate year, as defined

in Sec. 412.503. (We note that the regulation text at Sec.

412.525(a)(2) uses the term ``LTC-DRG'' rather than ``MS-LTC-DRG''

because the term ``LTC-DRG'' includes ``MS-LTC-DRG'' generally

applicable to any year. Specifically, in our regulations at Sec.

412.503, we state that ``[a]ny reference to the term `LTC-DRG' shall be

considered a reference to the term `MS-LTC-DRG' when applying the

provisions of this subpart for policy descriptions and payment

calculations for discharges from a long-term care hospital occurring on

or after October 1, 2007.'')

We also are proposing to clarify our existing policy at Sec.

412.525(d) so that it more accurately reflects existing policy

regarding payment adjustments under the LTCH PPS. In paragraph (d) of

Sec. 412.525, we provide that CMS adjusts the Federal prospective

payment to account for--(1) short-stay outliers at Sec. 412.529; (2) a

3-day or less interruption of stay and a greater than 3-day

interruption of stay, as provided for in Sec. 412.531; (3) patients

who are transferred to onsite providers and readmitted to a LTCH as

provided for in Sec. 412.532; and (4) long-term care HwHs and

satellite facilities of LTCHs as provided in Sec. 412.534.

We finalized the policy at Sec. 412.525(d)(4), which refers to the

percentage threshold payment adjustment for co-located long-term care

HwHs and satellite facilities in the FY 2005 IPPS final rule (69 FR

49191 through 49214), and it was codified in the FY 2007 IPPS final

rule (71 FR 48122). We adopted a similar policy in the RY 2008 LTC PPS

final rule (72 FR 26910 through 26944) that provides for an adjustment

to the LTCH PPS payment for LTCHs and satellite facilities of LTCHs

that discharge Medicare patients admitted from hospitals not located in

the same building or on the same campus as the LTCH or the satellite

facility of the LTCH, as specified at Sec. 412.536. We inadvertently

omitted the inclusion of this policy in the regulation text at Sec.

412.525(d). Therefore, in order to ensure that the applicable

regulatory text reflects existing policy, we are proposing to add a

paragraph (d)(5) to Sec. 412.525 that specifically provides that CMS

adjusts the Federal LTCH PPS payment amount for LTCHs and satellite

facilities of LTCHs that discharged Medicare patients admitted from a

hospital not located in the same building or on the same campus as the

LTCH or the satellite facility of the LTCH, as provided in Sec.

412.536.

IX. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider

MedPAC's recommendations regarding hospital inpatient payments. Under

section 1886(e)(5) of the Act, the Secretary must publish in the annual

proposed and final IPPS rules the Secretary's recommendations regarding

MedPAC's recommendations. We have reviewed MedPAC's March 2009 ``Report

to the Congress: Medicare Payment Policy'' and have given the

recommendations in the report careful consideration in conjunction with

the proposed policies set forth in this proposed rule.

MedPAC's Recommendation 2A-1 states that ``[t]he Congress should

increase payment rates for the acute inpatient and outpatient

prospective payment systems in 2010 by the projected rate of increase

in the hospital market basket index, concurrent with implementation of

a quality incentive payment program.'' This recommendation is discussed

in Appendix B to this proposed rule.

MedPAC's Recommendation 2A-2 states that ``[t]he Congress should

reduce the indirect medical education adjustment in 2010 by 1

percentage point to 4.5 percent per 10 percent increment in the

resident-to-bed ratio. The funds obtained by reducing the indirect

medical education adjustment should be used to fund a quality incentive

payment program.''

Response to Recommendation 2A-2: Redirecting funds obtained by

reducing the IME adjustment to fund a quality incentive payment program

is consistent with the value-based purchasing initiatives to improve

the quality of care. However, section 502(a) of Public Law 108-173

modified the formula multiplier (c) to be used in the calculation of

the IME adjustment beginning midway through FY 2004 and provided for a

new schedule of formula multipliers for FYs 2005 and thereafter.

Consequently, given the existing statutory requirement regarding the

IME formula multiplier, CMS does not have the authority to implement

MedPAC's recommendation to reduce the IME adjustment in FY 2010.

For further information relating specifically to the MedPAC reports

or to obtain a copy of the reports, contact

[[Page 24233]]

MedPAC at (202) 653-7226, or visit MedPAC's Web site at: http://

www.medpac.gov.

XI. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to

the prospective payment system, we have established a process under

which commenters can gain access to raw data on an expedited basis.

Generally, the data are now available on compact disc (CD) format.

However, many of the files are available on the Internet at: http://

www.cms.hhs.gov/AcuteInpatientPPS. Data files and the cost for each

file, if applicable, are listed below. Anyone wishing to purchase CDs

should submit a written request along with a company check or money

order (payable to CMS-PUF) to cover the cost to the following address:

Centers for Medicare & Medicaid Services, Public Use Files, Accounting

Division, P.O. Box 7520, Baltimore, MD 21207-0520, (410) 786-3691.

Files on the Internet may be downloaded without charge.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet

S-3, Parts II and III from FY 2006 Medicare cost reports used to create

the proposed FY 2010 prospective payment system wage index. Multiple

versions of this file are created each year. For a complete schedule on

the release of different versions of this file, we refer readers to the

wage index schedule in section III.K. of the preamble of this proposed

rule.

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Wage data PPS fiscal

Processing year year year

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2009.......................................... 2006 2010

2008.......................................... 2005 2009

2007.......................................... 2004 2008

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Media: Internet at: http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/

list.asp#TopOfPage.

Periods Available: FY 2007 through FY 2010 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the 2007-2008 occupational mix survey data to be

used to compute the occupational mix adjustment wage indexes. Multiple

versions of this file are created each year. For a complete schedule on

the release of different versions of this file, we refer readers to the

wage index schedule in section III.K. of the preamble of this proposed

rule.

Media: Internet at: http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/

list.asp#TopOfPage.

Period Available: FY 2010 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational

Category Public Use File

This file contains each hospital's occupational mix adjustment

factors by occupational category. Two versions of these files are

created each year. They support the following:

Notice of proposed rulemaking published in the Federal

Register.

Final rule published in the Federal Register.

Media: Internet at: http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/

list.asp#TopOfPage.

Period Available: FY 2010 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed

and final rule.

Media: Internet at: http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN/

list.asp#TopOfPage.

Periods Available: FY 2007 through FY 2010 IPPS Update.

5. FY 2010 IPPS SSA/FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by

the Social Security Administration (SSA) and the Federal Information

Processing Standards (FIPS), county name, and a historical list of

Metropolitan Statistical Areas (MSAs).

Media: Internet at: http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/

list.asp#TopOfPage.

Period Available: FY 2010 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal

years ending on or after September 30, 1996. These data files contain

the highest level of cost report status.

Media: Internet at: http://www.cms.hhs.gov/CostReports/02\_

HospitalCostReport.asp and Compact Disc (CD).

File Cost: $100.00 per year.

7. Provider-Specific File

This file is a component of the PRICER program used in the fiscal

intermediary's or the MAC's system to compute DRG/MS-DRG payments for

individual bills. The file contains records for all prospective payment

system eligible hospitals, including hospitals in waiver States, and

data elements used in the prospective payment system recalibration

processes and related activities. Beginning with December 1988, the

individual records were enlarged to include pass-through per diems and

other elements.

Media: Internet at: http://www.cms.hhs.gov/

ProspMedicareFeeSvcPmtGen/03\_psf\_text.asp.

Period Available: FY 2010 IPPS Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number

as published in each year's update of the Medicare hospital inpatient

prospective payment system. The case-mix index is a measure of the

costliness of cases treated by a hospital relative to the cost of the

national average of all Medicare hospital cases, using DRG/MS-DRG

weights as a measure of relative costliness of cases. Two versions of

this file are created each year. They support the following:

Notice of proposed rulemaking published in the Federal

Register.

Final rule published in the Federal Register.

Media: Internet at: http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/

list.asp#TopOfPage.

Periods Available: FY 1985 through FY 2010.

9. MS-DRG Relative Weights (Also Table 5--MS-DRGs)

This file contains a listing of MS-DRGs, MS-DRG narrative

descriptions, relative weights, and geometric and arithmetic mean

lengths of stay as published in the Federal Register. There are two

versions of this file as published in the Federal Register.

Notice of proposed rulemaking.

Final rule.

Media: Internet at: http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/

list.asp#TopOfPage.

Periods Available: FY 2006 through FY 2010 IPPS Update

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's

hospital impatient prospective payment systems for operating and

capital-related costs. The data are taken from various sources,

including the Provider-Specific File, Minimum Data Sets, and prior

impact files. The data set is abstracted from an internal file used for

the impact analysis of the changes to the prospective payment systems

published in the Federal Register.

Media: Internet at: http://www.cms.hhs.gov/AcuteInpatientPPS/

[[Page 24234]]

FFD/list.aspTopOfPage and http://www.cms.hhs.gov/

AcuteInpatientPPS/HIF/list.asp#TopOfPage.

Periods Available: FY 1994 through FY 2010 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS-DRG relative

weights. It contains mean, maximum, minimum, standard deviation, and

coefficient of variation statistics by MS-DRG for length of stay and

standardized charges. The BOR tables are ``Before Outliers Removed''

and the AOR is ``After Outliers Removed.'' (Outliers refer to

statistical outliers, not payment outliers.)

Two versions of this file are created each year. They support the

following:

Notice of proposed rulemaking published in the Federal

Register.

Final rule published in the Federal Register.

Media: Internet at: http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/

list.asp#TopOfPage.

Periods Available: FY 2006 through FY 2010 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used

to calculate relative weights to determine payments under the hospital

inpatient operating and capital prospective payment systems. Variables

include wage index, cost-of-living adjustment (COLA), case-mix index,

indirect medical education (IME) adjustment, disproportionate share,

and the Core-Based Statistical Area (CBSA). The file supports the

following:

Notice of proposed rulemaking published in the Federal

Register.

Final rule published in the Federal Register.

Media: Internet at: http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/

list.asp#TopOfPage.

Periods Available: FY 2010 IPPS Update.

For further information concerning these data files, contact the

CMS Public Use Files Hotline at (410) 786-3691.

Commenters interested in discussing any data used in constructing

this proposed rule should contact Nisha Bhat at (410) 786-5320.

B. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to

provide 60-day notice in the Federal Register and solicit public

comment before a collection of information requirement is submitted to

the Office of Management and Budget (OMB) for review and approval. In

order to fairly evaluate whether an information collection should be

approved by OMB, section 3506(c)(2)(A) of the PRA requires that we

solicit comment on the following issues:

The need for the information collection and its usefulness

in carrying out the proper functions of our agency.

The accuracy of our estimate of the information collection

burden.

The quality, utility, and clarity of the information to be

collected.

Recommendations to minimize the information collection

burden on the affected public, including automated collection

techniques.

We are soliciting public comment on each of these issues for the

following sections of this document that contain information collection

requirements (ICRs):

A. ICRs Regarding Payment Adjustment for Medicare DSHs (Sec. 412.106)

Proposed Sec. 412.106(b)(4)(iv) would permit hospitals to count

Medicaid-eligible inpatient days in the numerator of the Medicaid

fraction of the DPP in the DSH payment adjustment calculation by one of

the following methodologies, as long as no such days are counted more

than once for any hospital in a cost reporting period: date of

discharge; date of admission; or dates of service. To avoid ``double

counting,'' a hospital would be required to report to CMS any changes

to the methodology it uses to count days in the numerator of the

Medicaid fraction of the DPP. The burden associated with this proposed

requirement would be the time and effort necessary for a hospital to

report to CMS changes to the methodology it uses to count days in the

numerator of its Medicaid fraction of the DPP.

This requirement is subject to the PRA. While we believe the burden

is minimal, we are unable to accurately quantify the burden because we

cannot estimate the number of expected submissions from hospitals

reporting changes to their respective methodology for counting days in

the numerator of the Medicaid fraction of the DPP for the Medicare DSH

payment adjustment calculation. We are soliciting public comments on

the possible annual number of submissions pertaining to changes to the

methodologies used to count days in the numerator of a hospital's

Medicaid fraction of the DPP, and will reevaluate this issue in the

final rule stage of rulemaking.

B. ICRs Regarding Payments for GME (Sec. 413.75)

Existing regulations at Sec. 413.75(b) permit hospitals that share

residents to elect to form a Medicare GME affiliated group if they are

in the same or contiguous urban or rural areas, if they are under

common ownership, or if they are jointly listed as program sponsors or

major participating institutions in the same program. The purpose of a

Medicare GME affiliated group is to provide flexibility to hospitals in

structuring rotations under an aggregate FTE resident cap when they

share residents. The existing regulations at Sec. 413.79(f)(1) specify

that each hospital in a Medicare GME affiliated group must submit a

Medicare GME affiliation agreement (as defined under Sec. 413.75(b))

to the Medicare fiscal intermediary or MAC servicing the hospital and

send a copy to CMS' Central Office no later than July 1 of the

residency program year during which the Medicare GME affiliation

agreement will be in effect.

In section V.G. of the preamble of this proposed rule, we discuss

our proposed change to specify in regulations that a hospital that is

new after July 1 and that begins training residents for the first time

after the July 1 start date of that academic year would be permitted to

submit a Medicare GME affiliation agreement prior to the end of its

cost reporting period in order to participate in an existing Medicare

GME affiliated group for the remainder of the academic year. The burden

associated with this proposed requirement would be the time and effort

it would take for the new hospital to develop and submit the Medicare

GME affiliation agreement. It is difficult for us to estimate the

annual burden associated with this proposal because we cannot estimate

the additional number of hospitals that would be permitted to submit

Medicare GME affiliation agreements in any given year as a result of

the proposed change. However, we believe the number of affected

hospitals would be very small because, under the proposed change, a

hospital would not only have to start training residents after July 1,

but would also need to be a new hospital after July 1. We note that

this proposal would merely apply established procedures to provide

increased flexibility to a new hospital to join an existing GME

affiliated group such that, in its first year, it may train and receive

IME and direct GME payments relating to FTE for residents that could

otherwise be counted for purposes of IME and direct GME at another

hospital. We believe the proposed expansion of the existing policy

regarding the submission of

[[Page 24235]]

Medicare GME affiliation agreements for hospitals that are new after

July 1 and that begin to train residents after July 1 would amount to a

minimal paperwork burden. Nevertheless, we are soliciting public

comments on the possible number of annual submissions of Medicare GME

affiliation agreements under this proposed change.

C. Additional Information Collection Requirements

This proposed rule imposes collection of information requirements

as outlined in the regulation text and specified above. However, this

proposed rule also makes reference to several associated information

collections that are not discussed in the regulation text contained in

this document. The following is a discussion of these information

collections, some of which have already received OMB approval.

1. Present on Admission (POA) Indicator Reporting

Section II.F.6. of the preamble discusses the POA indicator

reporting program. As stated earlier, collection of POA indicator data

is necessary to identify which conditions were acquired during

hospitalization for the HAC payment provision and for broader public

health uses of Medicare data. Through Change Request 5499 dated May 11,

2007, CMS issued instructions that require IPPS hospitals to submit POA

indicator data for all diagnosis codes on Medicare claims. The burden

associated with this requirement is the time and effort necessary to

place the appropriate POA indicator codes on Medicare claims. This

requirement is subject to the PRA; however, the associated burden is

currently approved under OMB control number 0938-0997 with an

expiration date of August 31, 2009.

2. Proposed Add-On Payments for New Services and Technologies

Section II.I.1. of the preamble of this proposed rule discusses

add-on payments for new services and technologies. Specifically, this

section states that applicants for add-on payments for new medical

services or technologies for FY 2011 must submit a formal request. A

formal request includes a full description of the clinical applications

of the medical service or technology and the results of any clinical

evaluations demonstrating that the new medical service or technology

represents a substantial clinical improvement. In addition, the request

must contain a significant sample of the data to demonstrate that the

medical service or technology meets the high-cost threshold. We

detailed the burden associated with this requirement in the September

7, 2001 IPPS final rule (66 FR 46902). As stated in that final rule,

collection of the information for this requirement is conducted on an

individual case-by-case basis. We believe the associated burden is

thereby exempt from the PRA as stipulated under 5 CFR 1320.3(h)(6).

Similarly, we also believe the burden associated with this requirement

is exempt from the PRA under 5 CFR 1320.3(c), which defines the agency

collection of information subject to the requirements of the PRA as

information collection imposed on 10 or more persons within any 12-

month period. This information collection does not impact 10 or more

entities in a 12-month period. In FYs 2008, 2009, and 2010, we received

1, 4, and 5 applications, respectively.

3. Reporting of Hospital Quality Data for Annual Hospital Payment

Update

As discussed in section V.A. of the preamble of this proposed rule,

the RHQDAPU program was originally established to implement section

501(b) of Public Law 108-173, thereby expanding our voluntary Hospital

Quality Initiative (HQI). The RHQDAPU program originally consisted of a

``starter set'' of 10 quality measures. OMB approved the collection of

data associated with the original starter set of quality measures under

OMB control number 0938-0918, with a current expiration date of January

31, 2010.

As part of our implementation of section 5001(a) of the DRA, we

expanded the number of quality measures reported in the RHQDAPU

program. Specifically, section 1886(b)(3)(B)(viii)(III) of the Act,

added by section 5001(a) of the DRA, requires that the Secretary expand

the ``starter set'' of 10 quality measures that were established by the

Secretary as of November 1, 2003, to include measures ``that the

Secretary determines to be appropriate for the measurement of the

quality of care furnished by hospitals in inpatient settings.'' Under

this provision, we established additional program measures to bring the

total number of measures to 30. The burden associated with these

reporting requirements is currently approved under OMB control number

0938-1022, with a current expiration date of June 30, 2011.

In the FY 2009 IPPS proposed rule (73 FR 23527), we solicited

public comments on several considerations for expanding and updating

quality measures. We responded to the public comments received in the

FY 2009 IPPS final rule (73 FR 48433). We also expanded and finalized

the RHQDAPU program measure set for FY 2010. As part of the expansion

effort, two measures were finalized in the CY 2009 OPPS/ASC final rule

with comment period (73 FR 68781).

In this FY 2010 IPPS proposed rule, we are proposing to add a total

of four new measures, to harmonize two existing measures, and to retire

one measure, which would increase the total number of measures in the

RHQDAPU program from 42 in FY 2010 to 46 in FY 2011. Specifically, we

are proposing to add four new measures, two new chart-abstracted

measures, and two new structural measures. The new chart-abstracted

measures include the addition of SCIP-Infection-9: Postoperative

Urinary Catheter Removal on Postoperative Day 1 or 2, and SCIP-

Infection-10: Perioperative Temperature Management to the existing SCIP

measure set. As stated in V.A.3. of the preamble of this proposed rule,

the new structural measures include (1) Participation in a Systematic

Clinical Database Registry for Stroke Care; and (2) Participation in a

Systematic Clinical Database Registry for Nursing Sensitive Care. We

are submitting a revised version of the information collection request

approved under OMB control number 0938-1022, to obtain approval for the

new measures.

Section V.A.9. of the preamble of this proposed rule addresses the

reconsideration and appeal procedures for a hospital that we believe

did not meet the RHQDAPU program requirements. If a hospital disagrees

with our determination, it may submit a written request to CMS to

reconsider our decision. The hospital's letter must explain the reasons

why it believes it did meet the RHQDAPU program requirements. While

this is a reporting requirement, the burden associated with it is not

subject to the PRA under 5 CFR 1320.4(a)(2). The burden associated with

information collection requirements imposed subsequent to an

administrative action is not subject to the PRA.

4. Occupational Mix Adjustment to the FY 2010 Index (Hospital Wage

Index Occupational Mix Survey)

Section II.D. of the preamble of this proposed rule discusses the

proposed occupational mix adjustment to the FY 2010 wage index. While

the preamble does not contain any new ICRs, it is important to note

that there is an OMB-approved information collection request associated

with the hospital wage index. Section 304(c) of Public Law 106-554

amended section 1886(d)(3)(E) of the Act to require CMS to collect data

at

[[Page 24236]]

least once every 3 years on the occupational mix of employees for each

short-term, acute care hospital participating in the Medicare program

in order to construct an occupational mix adjustment to the wage index.

We collect the data via the occupational mix survey.

The burden associated with this information collection requirement

is the time and effort required to collect and submit the data in the

Hospital Wage Index Occupational Mix Survey to CMS. The aforementioned

burden is subject to the PRA; however, it is currently approved under

OMB control number 0938-0907, with an expiration date of February 28,

2011.

5. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.I.3. of the preamble of this proposed rule discusses

revisions to the wage index based on hospital redesignations. As stated

in that section, under section 1886(d)(10) of the Act, the MGCRB has

the authority to accept short-term IPPS hospital applications

requesting geographic reclassification for wage index or standardized

payment amounts and to issue decisions on these requests by hospitals

for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and

effort necessary for an IPPS hospital to complete and submit an

application for reclassification to the MGCRB. While this requirement

is subject to the PRA, it is currently approved under OMB control

number 0938-0573, with an expiration date of December 31, 2011.

If you comment on these information collection and recordkeeping

requirements, please do either of the following:

1. Submit your comments electronically as specified in the

ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory

Affairs, Office of Management and Budget, Attention: CMS Desk Officer,

[CMS-1406-P], Fax: (202) 395-6974; or E-mail: OIRA\_

submission@omb.eop.gov.

C. Response to Comments

Because of the large number of public comments we normally receive

on Federal Register documents, we are not able to acknowledge or

respond to them individually. We will consider all comments we receive

by the date and time specified in the DATES section of this preamble,

and, when we proceed with a subsequent document, we will respond to the

comments in the preamble to that document.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare,

Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico,

Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and

recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping

requirements.

For the reasons stated in the preamble of this proposed rule, the

Centers for Medicare & Medicaid Services is proposing to amend 42 CFR

Chapter IV as follows:

PART 412--PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL

SERVICES

1. The authority citation for Part 412 continues to read as

follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42

U.S.C. 1302 and 1395hh), and sec. 124 of Public Law 106-113 (113

Stat. 1501A-332).

2. Section 412.22 is amended by revising paragraph (h)(2)(iii)(A)

to read as follows:

Sec. 412.22 Excluded hospitals and hospital units: General rules.

\* \* \* \* \*

(h) \* \* \*

(2) \* \* \*

(iii) \* \* \*

(A) Effective for cost reporting periods beginning on or after

October 1, 2002, it is not under the control of the governing body or

chief executive officer of the hospital in which it is located, and it

furnishes inpatient care through the use of medical personnel who are

not under the control of the medical staff or chief medical officer of

the hospital in which it is located.

(1) Except as provided in paragraph (h)(2)(iii)(A)(2) of this

section, effective for cost reporting periods beginning on or after

October 1, 2009, the governing body of the hospital of which the

satellite facility is a part is not under the control of any third

entity that controls both the governing body of the hospital of which

the satellite facility is a part and the hospital with which the

satellite facility is co-located.

(2) If a hospital and its satellite facility were excluded from the

inpatient prospective payment system under the provisions of this

section for the most recent cost reporting period beginning prior to

October 1, 2009, the hospital does not have to meet the requirements of

paragraph (h)(2)(iii)(A)(1) of this section, with respect to that

satellite facility, in order to retain its IPPS-excluded status.

(3) A hospital described in paragraph (h)(2)(iii)(A)(2) of this

section that establishes an additional satellite facility in a cost

reporting period beginning on or after October 1, 2009, must meet the

criteria in this section, including the provisions of paragraph

(h)(2)(iii)(A)(1) of this section with respect to the additional

satellite facility, in order to be excluded from the inpatient

prospective payment system.

\* \* \* \* \*

3. Section 412.64 is amended by revising paragraph (c) to read as

follows:

Sec. 412.64 Federal rates for inpatient operating costs for Federal

fiscal year 2005 and subsequent fiscal years.

\* \* \* \* \*

(c) Computing the standardized amount. CMS computes an average

standardized amount that is applicable to all hospitals located in all

areas, updated by the applicable percentage increase specified in

paragraph (d) of this section. CMS standardizes the average

standardized amount by excluding an estimate of indirect medical

education payments.

\* \* \* \* \*

Sec. 412.87 [Amended]

4. In Sec. 412.87, paragraph (b)(1), remove the word ``relating''

and insert in its place the word ``relative''.

5. Section 412.105 is amended by revising paragraph (b)(4) to read

as follows:

Sec. 412.105 Special treatment: Hospitals that incur indirect costs

for graduate medical education programs.

\* \* \* \* \*

(b) \* \* \*

(4) Beds otherwise countable under this section used for outpatient

observation services or skilled nursing swing-bed services;

\* \* \* \* \*

6. Section 412.106 is amended by--

a. Revising paragraph (a)(1)(ii)(B).

b. Adding a new paragraph (b)(4)(iv).

The revision and addition read as follows:

Sec. 412.106 Special treatment: Hospitals that service a

disproportionate share of low-income patients.

(a) \* \* \*

(1) \* \* \*

[[Page 24237]]

(ii) \* \* \*

(B) Beds otherwise countable under this section used for outpatient

observation services or skilled nursing swing-bed services;

\* \* \* \* \*

(b) \* \* \*

(4) \* \* \*

(iv) For cost reporting periods beginning on or after October 1,

2009, the hospital must report the days in the numerator of the

fraction in the second computation in a cost reporting period based on

the date of discharge, the date of admission, or the dates of service.

If a hospital seeks to change its methodology for reporting days in the

numerator of the fraction in the second computation, the hospital must

notify CMS, through its fiscal intermediary or MAC, in writing at least

30 days before the beginning of the cost reporting period in which the

change would apply. The written notification must specify the

methodology the hospital will use and the cost reporting period to

which the requested change would apply. Such a change will be effective

only on the first day of a cost reporting period. If a hospital changes

its methodology for reporting such days, CMS or the fiscal intermediary

or MAC may adjust the number of days reported for a cost reporting

period if it determines that any of those days have been counted in a

prior cost reporting period.

\* \* \* \* \*

Sec. 412.113 [Amended]

7. In paragraph (c)(2)(i)(B) of Sec. 412.113, the cross-reference

``Sec. 410.66'' is removed and the cross-reference ``Sec. 410.69'' is

added in its place.

8. Section 412.322 is amended by removing and reserving paragraph

(c) to read as follows:

Sec. 412.322 Indirect medical education adjustment factor.

\* \* \* \* \*

(c) [Reserved].

\* \* \* \* \*

9. Section 412.523 is amended by adding a new paragraph (c)(3)(vi)

to read as follows:

Sec. 412.523 Methodology for calculating the Federal prospective

payment rates.

\* \* \* \* \*

(c) \* \* \*

(3) \* \* \*

(vi) For long-term care hospital prospective payment system rate

year beginning October 1, 2009 and ending September 30, 2010. The

standard Federal rate for long-term care hospital prospective payment

system rate year beginning October 1, 2009 and ending September 30,

2010 is the standard Federal rate for the previous long-term care

hospital prospective payment system rate year updated by 0.6 percent.

The standard Federal rate is adjusted, as appropriate, as described in

paragraph (d) of this section.

\* \* \* \* \*

10. Section 412.525 is amended by--

a. Revising paragraph (a)(2).

b. Revising paragraph (d)(1).

c. Adding a new paragraph (d)(5).

The revisions and addition read as follows:

Sec. 412.525 Adjustments to the Federal prospective payment.

(a) \* \* \*

(2) The fixed-loss amount is determined for the long-term care

hospital rate year using the LTC-DRG relative weights that are in

effect on the start of the applicable long-term care hospital

prospective payment system rate year, as defined in Sec. 412.503.

\* \* \* \* \*

(d) \* \* \*

(1) Short-stay outliers, as provided for in Sec. 412.529.

\* \* \* \* \*

(5) Long-term care hospitals and satellites of long-term care

hospitals that discharged Medicare patients admitted from a hospital

not located in the same building or on the same campus as the long-term

care hospital or satellite of the long-term care hospital, as provided

in Sec. 412.536.

PART 413--PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR

END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED

PAYMENT RATES FOR SKILLED NURSING FACILITIES

11. The authority citation for Part 413 continues to read as

follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and

(n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act

(42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n),

1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of

Public Law 106-133 (113 Stat. 1501A-332).

12. Section 413.65 is amended by--

a. Revising paragraph (a)(1)(ii)(G).

b. Revising paragraph (a)(1)(ii)(H).

The revisions read as follows:

Sec. 413.65 Requirements for a determination that a facility or an

organization has provider-based status.

(a) \* \* \*

(1) \* \* \*

(ii) \* \* \*

(G) Independent diagnostic testing facilities furnishing only

services paid under a fee schedule, such as facilities that furnish

only screening mammography services (as defined in section 1861(jj) of

the Act), facilities that furnish only clinical diagnostic laboratory

tests, other than those clinical diagnostic laboratories operating as

parts of CAHs, or facilities that furnish only some combination of

these services. Clinical diagnostic laboratories operating as parts of

CAHs must meet the applicable provider-based requirements.

(H) Facilities, other than those operating as parts of CAHs,

furnishing only physical, occupational, or speech therapy to ambulatory

patients, throughout any period during which the annual financial cap

amount on payment for coverage of physical, occupational, or speech

therapy, as described in section 1833(g)(2) of the Act, is suspended by

legislation.

\* \* \* \* \*

13. Section 413.70 is amended by--

a. Revising paragraph (b)(1)(i).

b. Removing paragraph (b)(2)(iii).

c. Revising the heading of paragraph (b)(3).

d. Revising paragraph (b)(3)(ii)(A).

e. Adding a new paragraph (b)(7).

The revisions and addition read as follows:

Sec. 413.70 Payment for services of a CAH.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(i) Unless the CAH elects to be paid for services to its

outpatients under the method specified in paragraph (b)(3) of this

section, the amount of payment for outpatient services of a CAH is

determined under paragraph (b)(2) of this section.

\* \* \* \* \*

(3) Election to be paid reasonable costs for facility services plus

fee schedule for professional services. \* \* \*

(ii) \* \* \*

(A) For facility services not including any services for which

payment may be made under paragraph (b)(3)(ii)(B) of this section, the

reasonable costs of the services as determined in accordance with the

provisions of section 1861(v)(1)(A) of the Act and the applicable

principles of cost reimbursement specified in this part and in Part 415

of this subchapter, except that the lesser of costs or charges

principle and the RCE payment principle are excluded when determining

payment for CAH outpatient services; and

\* \* \* \* \*

[[Page 24238]]

(7) Payment for clinical diagnostic laboratory tests included as

outpatient CAH services.

(i) Payment for clinical diagnostic laboratory tests is not subject

to the Medicare Part B deductible and coinsurance amounts.

(ii) Subject to the provisions of paragraphs (b)(7)(iii) through

(b)(7)(vi) of this section, payment to a CAH for clinical diagnostic

laboratory tests will be made at 101 percent of reasonable costs of the

services as determined in accordance with paragraph (b)(2)(i) of this

section.

(iii) For services furnished before July 1, 2009, payment to a CAH

for clinical diagnostic laboratory tests will be made under paragraph

(b)(7)(ii) of this section only if the individual is an outpatient of

the CAH, as defined in Sec. 410.2 of this chapter, and is physically

present in the CAH at the time the specimen is collected.

(iv) Except as provided in paragraphs (b)(7)(iii) and (b)(7)(v) of

this section, payment to a CAH for clinical diagnostic laboratory tests

will be made under paragraph (b)(7)(ii) of this section only if the

individual is an outpatient of the CAH, as defined in Sec. 410.2 of

this chapter, without regard to whether the individual is physically

present in the CAH at the time the specimen is collected and at least

one of the following conditions is met:

(A) The individual is receiving outpatient services in the CAH on

the same day the specimen is collected; or

(B) The specimen is collected by an employee of the CAH.

(v) Notwithstanding paragraph (b)(7)(iv) of this section, payment

for outpatient clinical diagnostic laboratory tests will not be made

under paragraph (b)(7)(ii) of this section if the billing rules under

Sec. 411.15(p) of this chapter apply.

(vi) Payment for clinical diagnostic laboratory tests for which

payment may not be made under paragraph (b)(7)(iii) or paragraph

(b)(7)(iv) of this section will be made in accordance with the

provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Act.

\* \* \* \* \*

14. Section 413.79 is amended by--

a. Revising paragraph (f)(1).

b. Redesignating paragraph (f)(6) and paragraph (f)(7).

c. Adding a new paragraph (f)(6).

d. Moving paragraph (l) so that it appears after paragraph (k)(7)

and is the last paragraph in the section.

The revisions and addition read as follows:

Sec. 413.79 Direct GME payments: Determination of the weighted number

of FTE residents.

\* \* \* \* \*

(f) \* \* \*

(1) Except as provided in paragraph (f)(6) of this section, each

hospital in the Medicare GME affiliated group must submit the Medicare

GME affiliation agreement, as defined under Sec. 413.75(b) of this

section, to the CMS fiscal intermediary or MAC servicing the hospital

and send a copy to the CMS Central Office no later than July 1 of the

residency program year during which the Medicare GME affiliation

agreement will be in effect.

\* \* \* \* \*

(6) Effective October 1, 2009, a hospital that is new after July 1

and begins training residents for the first time after the July 1 start

date of an academic year may receive a temporary adjustment to its FTE

resident cap to reflect its participation in an existing Medicare GME

affiliated group by submitting the Medicare GME affiliation agreement,

as defined under Sec. 413.75(b), to the CMS fiscal intermediary or MAC

servicing the hospital and sending a copy to the CMS Central Office

prior to the end of the first cost reporting period during which the

hospital begins training residents. The Medicare GME affiliation

agreement must specify the effective period for the agreement, which

may begin no earlier than the date the affiliation agreement is

submitted to CMS. Each of the other hospitals participating in the

Medicare GME affiliated group must submit an amended Medicare GME

affiliation agreement that reflects the participation of the new

hospital to the CMS fiscal intermediary or MAC servicing the hospital

and send a copy to the CMS Central Office no later than June 30 of the

residency program year during which the Medicare GME affiliation

agreement will be in effect. For purposes of this paragraph, a new

hospital is one for which a new Medicare provider agreement takes

effect in accordance with Sec. 489.13 of this chapter.

\* \* \* \* \*

PART 415--SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS,

SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN

CERTAIN SETTINGS

15. The authority citation for Part 415 continues to read as

follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42

U.S.C. 1302 and 1395hh).

Sec. 415.152 [Amended]

16. In Sec. 415.152, under paragraph (1) of the definition of

``Approved graduate medical education (GME) program'', remove the

phrase ``the Committee on Hospitals of the Bureau of Professional

Education of''.

PART 489--PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

17. The authority citation for Part 489 continues to read as

follows:

Authority: Secs. 1102, 1819, 1820(e), 1861, 1864(m), 1866, 1869,

and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i-3, 1395x,

1395aa(m), 1395cc, 1395ff, and 1395hh).

18. Section 489.24 is amended by revising paragraph (a)(2) to read

as follows:

Sec. 489.24 Special responsibilities of Medicare hospitals in

emergency cases.

(a) \* \* \*

(2)(i) When a waiver has been issued in accordance with section

1135 of the Act that includes a waiver under section 1135(b)(3) of the

Act, sanctions under this section for an inappropriate transfer or for

the direction or relocation of an individual to receive medical

screening at an alternate location do not apply to a hospital with a

dedicated emergency department if the following conditions are met:

(A) If relating to an inappropriate transfer, the transfer arises

out of the circumstances of the emergency.

(B) If relating to the direction or relocation of an individual to

receive medical screening at an alternate location, the direction or

relocation is pursuant to an appropriate State emergency preparedness

plan or, in the case of a public health emergency that involves a

pandemic infectious disease, pursuant to a State pandemic preparedness

plan.

(C) The hospital does not discriminate on the basis of an

individual's source of payment or ability to pay.

(D) The hospital is located in an emergency area during an

emergency period, as those terms are defined in section 1135(g)(1) of

the Act.

(E) There has been a determination that a waiver of sanctions is

necessary.

(ii) A waiver of these sanctions is limited to a 72-hour period

beginning upon the implementation of a hospital disaster protocol,

except that, if a public health emergency involves a pandemic

infectious disease (such as pandemic influenza), the waiver will

continue in effect until the termination of the applicable declaration

of a public health emergency, as provided under section 1135(e)(1)(B)

of the Act.

\* \* \* \* \*

[[Page 24239]]

(Catalog of Federal Domestic Assistance Program No. 93.773,

Medicare--Hospital Insurance; and Program No. 93.774, Medicare--

Supplementary Medical Insurance Program)

Dated: April 17, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: May 1, 2009.

Kathleen Sebelius,

Secretary.

Editorial Note: The following Addendum and appendixes will not

appear in the Code of Federal Regulations.

Addendum--Proposed Schedule of Standardized Amounts, Update Factors,

and Rate-of-Increase Percentages Effective With Cost Reporting Periods

Beginning on or After October 1, 2009

I. Summary and Background

In this Addendum, we are setting forth a description of the methods

and data we used to determine the proposed prospective payment rates

for Medicare hospital inpatient operating costs and Medicare hospital

inpatient capital-related costs for FY 2010 for acute care hospitals.

We also are setting forth the proposed rate-of-increase percentages for

updating the target amounts for certain hospitals excluded from the

IPPS for FY 2010. We note that, because certain hospitals excluded from

the IPPS are paid on a reasonable cost basis subject to a rate-of-

increase ceiling (and not by the IPPS), these hospitals are not

affected by the proposed figures for the standardized amounts, offsets,

and budget neutrality factors. Therefore, in this proposed rule, we are

proposing the rate-of-increase percentages for updating the target

amounts for certain hospitals excluded from the IPPS that are effective

for cost reporting periods beginning on or after October 1, 2009.

In addition, we are setting forth a description of the methods and

data we used to determine the proposed standard Federal rate that would

be applicable to Medicare LTCHs for RY 2010.

In general, except for SCHs, MDHs, and hospitals located in Puerto

Rico, each hospital's payment per discharge under the IPPS is based on

100 percent of the Federal national rate, also known as the national

adjusted standardized amount. This amount reflects the national average

hospital cost per case from a base year, updated for inflation.

Currently, SCHs are paid based on whichever of the following rates

yields the greatest aggregate payment: the Federal national rate; the

updated hospital-specific rate based on FY 1982 costs per discharge;

the updated hospital-specific rate based on FY 1987 costs per

discharge; the updated hospital-specific rate based on FY 1996 costs

per discharge; or for cost reporting periods beginning on or after

January 1, 2009, the updated hospital-specific rate based on the FY

2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically have been

paid based on the Federal national rate or, if higher, the Federal

national rate plus 50 percent of the difference between the Federal

national rate and the updated hospital-specific rate based on FY 1982

or FY 1987 costs per discharge, whichever was higher. (MDHs did not

have the option to use their FY 1996 hospital-specific rate.) However,

section 5003(a)(1) of Public Law 109-171 extended and modified the MDH

special payment provision that was previously set to expire on October

1, 2006, to include discharges occurring on or after October 1, 2006,

but before October 1, 2011. Under section 5003(b) of Public Law 109-

171, if the change results in an increase to an MDH's target amount, we

must rebase an MDH's hospital-specific rates based on its FY 2002 cost

report. Section 5003(c) of Public Law 109-171 further required that

MDHs be paid based on the Federal national rate or, if higher, the

Federal national rate plus 75 percent of the difference between the

Federal national rate and the updated hospital-specific rate. Further,

based on the provisions of section 5003(d) of Public Law 109-171, MDHs

are no longer subject to the 12-percent cap on their DSH payment

adjustment factor.

For hospitals located in Puerto Rico, the payment per discharge is

based on the sum of 25 percent of an updated Puerto Rico-specific rate

based on average costs per case of Puerto Rico hospitals for the base

year and 75 percent of the Federal national rate. (We refer readers to

section II.D.3. of this Addendum for a complete description.)

As discussed below in section II. of this Addendum, we are

proposing to make changes in the determination of the prospective

payment rates for Medicare inpatient operating costs for acute care

hospitals for FY 2010. In section III. of this Addendum, we discuss our

proposed policy changes for determining the prospective payment rates

for Medicare inpatient capital-related costs for FY 2010. In section

IV. of this Addendum, we are setting forth our proposed changes for

determining the rate-of-increase limits for certain hospitals excluded

from the IPPS for FY 2010. In section V. of this Addendum, we are

proposing to make changes in the determination of the standard Federal

rate for LTCHs under the LTCH PPS for RY 2010. The tables to which we

refer in the preamble of this proposed rule are presented in section

VI. of this Addendum.

II. Proposed Changes to Prospective Payment Rates for Hospital

Inpatient Operating Costs for Acute Care Hospitals for FY 2010

The basic methodology for determining prospective payment rates for

hospital inpatient operating costs for acute care hospitals for FY 2005

and subsequent fiscal years is set forth at Sec. 412.64. The basic

methodology for determining the prospective payment rates for hospital

inpatient operating costs for hospitals located in Puerto Rico for FY

2005 and subsequent fiscal years is set forth at Sec. Sec. 412.211 and

412.212. Below we discuss the factors used for determining the proposed

prospective payment rates for FY 2010.

In summary, the proposed standardized amounts set forth in Tables

1A, 1B, and 1C of section VI. of this Addendum reflect--

Equalization of the standardized amounts for urban and

other areas at the level computed for large urban hospitals during FY

2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of

the Act, updated by the applicable percentage increase required under

sections 1886(b)(3)(B)(i)(XX) and 1886(b)(3)(B)(viii) of the Act.

The labor-related share that is applied to the

standardized amounts and Puerto Rico-specific standardized amounts to

give the hospital the highest payment, as provided for under sections

1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act.

Proposed updates of 2.1 percent for all areas (that is,

the estimated full market basket percentage increase of 2.1 percent),

as required by section 1886(b)(3)(B)(i)(XX) of the Act, as amended by

section 5001(a)(1) of Public Law 109-171, and reflecting the

requirements of section 1886(b)(3)(B)(viii) of the Act, as added by

section 5001(a)(3) of Public Law 109-171, to reduce the applicable

percentage increase by 2.0 percentage points for a hospital that fails

to submit data, in a form and manner specified by the Secretary,

relating to the quality of inpatient care furnished by the hospital.

A proposed update of 2.1 percent to the Puerto Rico-

specific standardized amount (that is, the full estimated rate-of-

increase in the hospital market basket for IPPS hospitals), as provided

for under Sec. 412.211(c), which states that we update the Puerto

Rico-specific

[[Page 24240]]

standardized amount using the percentage increase specified in Sec.

412.64(d)(1), or the percentage increase in the market basket index for

prospective payment hospitals for all areas.

An adjustment to the standardized amount to ensure budget

neutrality for DRG recalibration and reclassification, as provided for

under section 1886(d)(4)(C)(iii) of the Act.

An adjustment to ensure the wage index and labor share

update and changes are budget neutral, as provided for under section

1886(d)(3)(E)(i) of the Act. We note that section 1886(d)(3)(E)(i) of

the Act requires that we do not consider the labor-related share of 62

percent to compute wage index budget neutrality.

An adjustment to ensure the effects of geographic

reclassification are budget neutral, as provided for in section

1886(d)(8)(D) of the Act, by removing the FY 2009 budget neutrality

factor and applying a revised factor.

An adjustment to remove the FY 2009 outlier offset and

apply an offset for FY 2010, as provided for in section 1886(d)(3)(B)

of the Act.

An adjustment to ensure the effects of the rural community

hospital demonstration required under section 410A of Public Law 108-

173 are budget neutral, as required under section 410A(c)(2) of Public

Law 108-173.

As discussed below and in section II.D. of the preamble to

this proposed rule, an adjustment to eliminate the effect of

documentation and coding changes that do not reflect real changes in

case-mix provided for under section 1886(d)(3)(A)(vi) of the Act.

We note that, beginning in FY 2008, we applied the budget

neutrality adjustment for the rural floor to the hospital wage indices

rather than the standardized amount. As we did for FY 2009, for FY

2010, we are proposing to continue to apply the rural floor budget

neutrality adjustment to hospital wage indices rather than the

standardized amount. In addition, instead of applying the budget

neutrality adjustment for the imputed floor adopted under section

1886(d)(3)(E) of the Act to the standardized amount, for FY 2010, we

are proposing to continue to apply the imputed floor budget neutrality

adjustment to the wage indices. As we did for FY 2009, we also are

proposing to continue to apply the budget neutrality adjustments for

the rural floor and imputed rural floor at the State level rather than

the national level. For a complete discussion of the budget neutrality

changes concerning the rural floor and the imputed floor, including the

within-State budget neutrality adjustment, we refer readers to section

III.B.2.b. of the preamble of the FY 2009 IPPS final rule and this

proposed rule.

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per

discharge averages of adjusted hospital costs from a base period

(section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in

accordance with the provisions of section 1886(d) of the Act. For

Puerto Rico hospitals, the Puerto Rico-specific standardized amount is

based on per discharge averages of adjusted target amounts from a base

period (section 1886(d)(9)(B)(i) of the Act), updated and otherwise

adjusted in accordance with the provisions of section 1886(d)(9) of the

Act. The September 1, 1983 interim final rule (48 FR 39763) contained a

detailed explanation of how base-year cost data (from cost reporting

periods ending during FY 1981) were established for urban and rural

hospitals in the initial development of standardized amounts for the

IPPS. The September 1, 1987 final rule (52 FR 33043 and 33066) contains

a detailed explanation of how the target amounts were determined and

how they are used in computing the Puerto Rico rates.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to

update base-year per discharge costs for FY 1984 and then standardize

the cost data in order to remove the effects of certain sources of cost

variations among hospitals. These effects include case-mix, differences

in area wage levels, cost-of-living adjustments for Alaska and Hawaii,

IME costs, and costs to hospitals serving a disproportionate share of

low-income patients.

In accordance with section 1886(d)(3)(E) of the Act, the Secretary

estimates, from time to time, the proportion of hospitals' costs that

are attributable to wages and wage-related costs. In general, the

standardized amount is divided into labor-related and nonlabor-related

amounts; only the proportion considered to be the labor-related amount

is adjusted by the wage index. Section 1886(d)(3)(E) of the Act

requires that 62 percent of the standardized amount be adjusted by the

wage index, unless doing so would result in lower payments to a

hospital than would otherwise be made. (Section 1886(d)(9)(C)(iv)(II)

of the Act extends this provision to the labor-related share for

hospitals located in Puerto Rico.)

For FY 2010, we are proposing to rebase and revise the national and

Puerto Rico-specific labor-related and nonlabor-related shares from the

percentages established for FY 2009. Specifically, under section

1886(d)(3)(E) of the Act, the Secretary estimates from time to time the

proportion of payments that are labor-related: ``The Secretary shall

adjust the proportion (as estimated by the Secretary from time to time)

of hospitals' costs which are attributable to wages and wage-related

costs of the DRG prospective payment rates. \* \* \*'' We refer to the

proportion of hospitals' costs that are attributable to wages and wage-

related costs as the ``labor-related share.'' For FY 2010, as discussed

in section IV.B.4. of the preamble of this proposed rule, we are

proposing a labor-related share of 67.1 percent for the national

standardized amounts and 60.3 percent for the Puerto Rico-specific

standardized amount. Consistent with section 1886(d)(3)(E) of the Act,

we are proposing to apply the wage index to a labor-related share of 62

percent for all non-Puerto Rico hospitals whose wage indexes are less

than or equal to 1.0000. For all non-Puerto Rico hospitals whose wage

indices are greater than 1.0000, we are proposing to apply the wage

index to a labor-related share of 67.1 percent of the national

standardized amount. For hospitals located in Puerto Rico, we are

proposing to apply a labor-related share of 60.3 percent if its Puerto

Rico-specific wage index is less than or equal to 1.0000. For hospitals

located in Puerto Rico whose Puerto Rico-specific wage index values are

greater than 1.0000, we are proposing to apply a labor-related share of

62 percent.

The proposed standardized amounts for operating costs appear in

Tables 1A, 1B, and 1C of the Addendum to this proposed rule.

2. Computing the Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning

with FY 2004 and thereafter, an equal standardized amount be computed

for all hospitals at the level computed for large urban hospitals

during FY 2003, updated by the applicable percentage update. Section

1886(d)(9)(A)(ii)(II) of the Act equalizes the Puerto Rico-specific

urban and rural area rates. Accordingly, we are proposing to calculate

FY 2010 national and Puerto Rico standardized amounts irrespective of

whether a hospital is located in an urban or rural location.

3. Updating the Average Standardized Amount

In accordance with section 1886(d)(3)(A)(iv)(II) of the Act, we are

[[Page 24241]]

proposing to update the equalized standardized amount for FY 2010 by

the full estimated market basket percentage increase for hospitals in

all areas, as specified in section 1886(b)(3)(B)(i)(XX) of the Act, as

amended by section 5001(a)(1) of Public Law 109-171. The percentage

increase in the market basket reflects the average change in the price

of goods and services comprising routine, ancillary, and special care

unit hospital inpatient services. The most recent forecast of the

hospital market basket increase for FY 2010 is 2.1 percent. Thus, for

FY 2010, the proposed update to the average standardized amount is 2.1

percent for hospitals in all areas. The estimated market basket

increase of 2.1 percent is based on Global Insight, Inc.'s 2009 first

quarter forecast of the hospital market basket increase (as discussed

in Appendix B of this proposed rule).

Section 1886(b)(3)(B) of the Act specifies the mechanism to be used

to update the standardized amount for payment for inpatient hospital

operating costs. Section 1886(b)(3)(B)(viii) of the Act, as added by

section 5001(a)(3) of Public Law 109-171, provides for a reduction of

2.0 percentage points from the update percentage increase (also known

as the market basket update) for FY 2007 and each subsequent fiscal

year for any ``subsection (d) hospital'' that does not submit quality

data, as discussed in section V.A. of the preamble of this proposed

rule. The proposed standardized amounts in Tables 1A through 1C of

section VI. of this Addendum reflect these differential amounts.

Section 412.211(c) states that we update the Puerto Rico-specific

standardized amount using the percentage increase specified in Sec.

412.64(d)(1) or the percentage increase in the market basket index for

prospective payment hospitals for all areas. We are proposing to apply

the full rate-of-increase in the hospital market basket for IPPS

hospitals to the Puerto Rico-specific standardized amount. Therefore,

the proposed update to the Puerto Rico-specific standardized amount is

2.1 percent.

Although the update factors for FY 2010 are set by law, we are

required by section 1886(e)(4) of the Act to recommend, taking into

account MedPAC's recommendations, appropriate update factors for FY

2010 for both IPPS hospitals and hospitals and hospital units excluded

from the IPPS. Section 1886(e)(5)(A) of the Act requires that we

publish our proposed recommendations in the Federal Register for public

comment. Our recommendation on the update factors is set forth in

Appendix B of this proposed rule.

4. Other Adjustments to the Average Standardized Amount

As in the past, we are proposing to adjust the FY 2010 standardized

amount to remove the effects of the FY 2009 geographic

reclassifications and outlier payments before applying the FY 2010

updates. We then apply budget neutrality offsets for outliers and

geographic reclassifications to the standardized amount based on FY

2010 payment policies.

We do not remove the prior year's budget neutrality adjustments for

reclassification and recalibration of the DRG weights and for updated

wage data because, in accordance with sections 1886(d)(4)(C)(iii) and

1886(d)(3)(E) of the Act, estimated aggregate payments after updates in

the DRG relative weights and wage index should equal estimated

aggregate payments prior to the changes. If we removed the prior year's

adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS

payments before and after making changes that are required to be budget

neutral (for example, changes to DRG classifications, recalibration of

the DRG relative weights, updates to the wage index, and different

geographic reclassifications). We include outlier payments in the

simulations because they may be affected by changes in these

parameters.

We also are proposing to adjust the standardized amount this year

by an estimated amount to ensure that aggregate payments made by the

Secretary do not exceed the amount of payments that would have been

made in the absence of the rural community hospital demonstration

program, as required under section 410A of Public Law 108-173. This

demonstration is required to be budget neutral under section 410A(c)(2)

of Public Law 108-173. For FY 2010, we are not proposing to apply

budget neutrality for the imputed floor to the standardized amount, but

to apply it instead to the wage index, as discussed in section III.B.2.

of the preamble to this proposed rule. For FY 2010, we also are

proposing to apply an adjustment to eliminate the effect of

documentation and coding changes that do not reflect real changes in

case-mix using the Secretary's authority under section

1886(d)(3)(A)(vi) of the Act.

a. Proposed Recalibration of DRG Weights and Updated Wage Index--Budget

Neutrality Adjustment

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in

FY 1991, the annual DRG reclassification and recalibration of the

relative weights must be made in a manner that ensures that aggregate

payments to hospitals are not affected. As discussed in section II. of

the preamble of this proposed rule, we normalized the recalibrated DRG

weights by an adjustment factor so that the average case weight after

recalibration is equal to the average case weight prior to

recalibration. However, equating the average case weight after

recalibration to the average case weight before recalibration does not

necessarily achieve budget neutrality with respect to aggregate

payments to hospitals because payments to hospitals are affected by

factors other than average case weight. Therefore, as we have done in

past years, we are proposing to make a budget neutrality adjustment to

ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is

met.

Section 1886(d)(3)(E)(i) of the Act requires us to update the

hospital wage index on an annual basis beginning October 1, 1993. This

provision also requires us to make any updates or adjustments to the

wage index in a manner that ensures that aggregate payments to

hospitals are not affected by the change in the wage index. In

addition, under section 1886(d)(3)(E)(i) of the Act, as we established

in the FY 2006 final rule (70 FR 47395), we are implementing the

revised and rebased labor share in a budget neutral manner.

Specifically, section 1886(d)(3)(E)(i) of the Act directs us to

determine a labor-related share that reflects the ``proportion \* \* \* of

hospitals' costs which are attributable to wages and wage-related

costs.'' In addition, section 1886(d)(3)(E)(i) of the Act requires that

we implement the wage index adjustment in a budget neutral manner.

However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related

share at 62 percent for hospitals with a wage index less than or equal

to 1.0, and section 1886(d)(3)(E)(i) of the Act provides that the

Secretary shall calculate the budget neutrality adjustment for the

adjustments or updates made under that provision as if section

1886(d)(3)(E)(ii) of the Act had not been enacted. In other words,

these two sections of the statute require that we implement the

proposed revision of the labor-related share to 67.1 percent (compared

to the prior 69.7 percent) (as well as the wage index updates) in a

budget neutral manner, but that our budget neutrality

[[Page 24242]]

adjustment should not take into account the requirement that we set the

labor-related share for hospitals with indices less than or equal to

1.0 at the more advantageous level of 62 percent. Therefore, for

purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i)

of the Act prohibits us from taking into account the fact that

hospitals with a wage index less than or equal to 1.0 are paid using a

labor-related share of 62 percent. Consistent with current policy, for

FY 2010, we are proposing to adjust 100 percent of the wage index

factor for occupational mix. We describe the occupational mix

adjustment in section III.D. of the preamble to this proposed rule.

For FY 2010, to comply with the requirement that DRG

reclassification and recalibration of the relative weights be budget

neutral for the Puerto Rico standardized amount and the hospital-

specific rates, we used FY 2008 discharge data to simulate payments and

compared aggregate payments using the FY 2009 relative weights to

aggregate payments using the proposed FY 2010 relative weights. Based

on this comparison, we computed a proposed budget neutrality adjustment

factor equal to 0.997663. As discussed in section IV. of this Addendum,

we would also apply the DRG reclassification and recalibration budget

neutrality factor of 0.997663 to the hospital-specific rates that are

to be effective for cost reporting periods beginning on or after

October 1, 2009.

In order to meet the statutory requirements that we do not take

into account the labor-related share of 62 percent when computing wage

index budget neutrality and that we budget neutralize any changes in

payments as a result of the proposed FY 2010 rebased and revised labor

share, it was necessary to use a three-step process to comply with the

requirements that DRG reclassification and recalibration of the

relative weights and the updated wage index and labor-related share

have no effect on aggregate payments for IPPS hospitals. We first

determined a proposed DRG reclassification and recalibration budget

neutrality factor of 0.997663 by using the same methodology described

above to determine the proposed DRG reclassification and recalibration

budget neutrality factor for the Puerto Rico standardized amount and

hospital-specific rates. Secondly, to compute a budget neutrality

factor for wage index and labor-related share changes, we used FY 2008

discharge data to simulate payments and compared aggregate payments

using the proposed FY 2010 relative weights, FY 2009 wage indices, and

applied the FY 2009 labor share of 69.7 percent to all hospitals

(regardless of whether the hospital's wage index was above or below

1.0) to aggregate payments using the proposed FY 2010 relative weights,

proposed FY 2010 wage indices, and applied the proposed rebased and

revised labor share for FY 2010 of 67.1 percent to all hospitals

(regardless of whether the hospital's proposed wage index was above or

below 1.0). In addition, we applied the proposed DRG reclassification

and recalibration budget neutrality factor (derived in the first step)

to the rates that were used to simulate payments for this comparison of

aggregate payments from FY 2009 to FY 2010. By applying this

methodology, we determined a budget neutrality factor for the proposed

wage index and labor-related share changes of 1.000404. Finally, we

multiplied the proposed DRG reclassification and recalibration proposed

budget neutrality factor of 0.997663 (derived in the first step) by the

proposed budget neutrality factor for proposed wage index changes of

1.000404 (derived in the second step) to determine the proposed DRG

reclassification and recalibration and updated wage index and labor-

related share budget neutrality factor of 0.998066.

b. Reclassified Hospitals--Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that, effective with

discharges occurring on or after October 1, 1988, certain rural

hospitals are deemed urban. In addition, section 1886(d)(10) of the Act

provides for the reclassification of hospitals based on determinations

by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be

reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required

to adjust the standardized amount to ensure that aggregate payments

under the IPPS after implementation of the provisions of sections

1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the

aggregate prospective payments that would have been made absent these

provisions. We note that the wage index adjustments provided under

section 1886(d)(13) of the Act are not budget neutral. Section

1886(d)(13)(H) of the Act provides that any increase in a wage index

under section 1886(d)(13) shall not be taken into account ``in applying

any budget neutrality adjustment with respect to such index'' under

section 1886(d)(8)(D) of the Act. To calculate the proposed budget

neutrality factor for FY 2010, we used FY 2008 discharge data to

simulate payments, and compared total IPPS payments prior to any

reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10)

of the Act to total IPPS payments after such reclassifications. Based

on these simulations, we calculated a proposed adjustment factor of

0.991690 to ensure that the effects of these provisions are budget

neutral, consistent with the statute.

The proposed FY 2010 budget neutrality adjustment factor is applied

to the standardized amount after removing the effects of the FY 2009

budget neutrality adjustment factor. We note that the proposed FY 2010

budget neutrality adjustment reflects FY 2010 wage index

reclassifications approved by the MGCRB or the Administrator.

c. Proposed Rural Floor and Imputed Floor Budget Neutrality Adjustment

As discussed in section III.B.2.b. of the preamble of the FY 2009

IPPS final rule (73 FR 48570 through 48574), we adopted as final State-

level budget neutrality for the rural and imputed floors, effective

beginning with the FY 2009 wage index. In response to the public's

concerns and taking into account the potentially significant payment

cuts that could occur to hospitals in some States if we implemented

this change with no transition, we decided to phase in, over a 3-year

period, the transition from the national rural floor budget neutrality

adjustment on the wage index to the State-level rural floor budget

neutrality adjustment on the wage index. In FY 2009, hospitals received

a blended wage index that was comprised of 20 percent of the wage index

adjusted by applying the State-level rural and imputed floor budget

neutrality adjustment and 80 percent of the wage index adjusted by

applying the national budget neutrality adjustment. For FY 2010, the

blended wage index will be determined by adding 50 percent of the wage

index adjusted by applying the State-level rural and imputed floor

budget neutrality adjustment and 50 percent of the wage index adjusted

by applying the national budget neutrality adjustment. In FY 2011, the

adjustment will be completely transitioned to the State-level

methodology, such that the wage index will be determined by applying

100 percent of the State-level budget neutrality adjustment. As stated

earlier, we note that the rural floor budget neutrality adjustment is

applied to the wage index and not the standardized amount. However,

because these blended wage indices reflecting the 50 percent State-

level rural and imputed floor budget neutrality adjustment and

[[Page 24243]]

the 50 percent national rural and imputed floor budget neutrality

adjustment are used in calculating the FY 2010 outlier threshold (as

discussed below), we are explaining our calculation of the proposed

rural floor budget neutrality adjustments (in this section) below.

In order to compute a budget neutral wage index that is a blend of

50 percent of the wage index adjusted by the State-level rural and

imputed floor budget neutrality adjustment and 50 percent of the wage

index adjusted by the national rural and imputed floor budget

neutrality adjustment, similar to our calculation of the FY 2009 wage

index (73 FR 48570 through 48574), we used FY 2008 discharge data and

proposed FY 2010 wage indices to simulate IPPS payments. First, we

compared the national simulated payments without the rural and imputed

floors applied to national simulated payments with the rural and

imputed floors applied to determine the national rural and imputed

floor budget neutrality adjustment factor of 0.997466. This national

adjustment was then applied to the wage indices to produce a national

rural and imputed floor budget neutral wage index, which was used in

determining the proposed FY 2010 blended wage indices for the second

year of the transition (as described below). We then used the same

methodology to determine each State's rural or imputed floor budget

neutrality adjustment by comparing each State's total simulated

payments with and without the rural or imputed floor applied. These

State-level rural and imputed floor budget neutrality factors were then

applied to the wage indices to produce a State-level rural and imputed

floor budget neutral wage index, which was used in determining the

proposed FY 2010 blended wage indices for the second year of the

transition (as described below).

To determine the proposed FY 2010 wage indices for the second year

of the transition, we then blended the national and State-level wage

index values (computed above) by taking 50 percent of the national

rural and imputed floor budget neutral wage index and 50 percent of the

State-level rural and imputed floor budget neutral wage index. Because

of interactive effects between the payment factors applied under the

IPPS and/or rounding issues, the blended wage index calculated above

does not necessarily result in overall budget neutrality. That is,

aggregate IPPS payments simulated using the blended budget neutral wage

index may not be equal to aggregate IPPS payments simulated using the

wage index prior to the application of the rural and imputed floors.

Therefore, in order to ensure that national payments overall remain

budget neutral after application of the rural and imputed floors, an

additional adjustment factor of 1.00016 must be applied to the blended

wage indexes calculated as described above.

d. Proposed Case-Mix Budget Neutrality Adjustment

(1) Adjustment to the Proposed FY 2010 IPPS Standardized Amount

As stated earlier, beginning in FY 2008, we adopted the MS-DRG

patient classification system for the IPPS to better recognize

patients' severity of illness in Medicare payment rates. In the FY 2008

IPPS final rule with comment period (73 FR 47175 through 47186), we

indicated that we believe the adoption of the MS-DRGs had the potential

to lead to increases in aggregate payments without a corresponding

increase in actual patient severity of illness due to the incentives

for changes in documentation and coding. In that final rule, using the

Secretary's authority under section 1886(d)(3)(A)(vi) of the Act to

maintain budget neutrality by adjusting the national standardized

amounts to eliminate the effect of changes in documentation and coding

that do not reflect real change in case-mix, we established prospective

documentation and coding adjustments of -1.2 percent for FY 2008, -1.8

percent for FY 2009, and -1.8 percent for FY 2010 (for a total

adjustment of -4.8 percent). On September 29, 2007, Public Law 110-90

was enacted. Section 7 of Public Law 110-90 included a provision that

reduces the documentation and coding adjustment for the MS-DRG system

that we adopted in the FY 2008 IPPS final rule with comment period to -

0.6 percent for FY 2008 and -0.9 percent for FY 2009. To comply with

the provision of section 7(a) of Public Law 110-90, in a final rule

that appeared in the Federal Register on November 27, 2007 (72 FR

66886), we changed the IPPS documentation and coding adjustment for FY

2008 to -0.6 percent, and revised the FY 2008 national standardized

amounts (as well as other payment factors and thresholds) accordingly,

with these revisions being effective as of October 1, 2007. For FY

2009, section 7(a) of Public Law 110-90 required a documentation and

coding adjustment of -0.9 percent instead of the -1.8 percent

adjustment specified in the FY 2008 IPPS final rule with comment

period. As required by statute, we applied a documentation and coding

adjustment of -0.9 percent to the FY 2009 IPPS national standardized

amounts. The documentation and coding adjustments established in the FY

2008 IPPS final rule with comment period are cumulative. As a result,

the -0.9 percent documentation and coding adjustment in FY 2009 was in

addition to the -0.6 percent adjustment in FY 2008, yielding a combined

effect of -1.5 percent.

As discussed in section II.D. of the preamble to this proposed

rule, we estimated a 2.5 percent change in FY 2008 case-mix due to

changes in documentation and coding that do not reflect real changes in

case-mix for discharges occurring during FY 2008, which exceeded the -

0.6 percent prospective documentation and coding adjustment applied

under section 7(a) of Public Law 110-90 by 1.9 percentage points. Under

section 7(b)(1)(A) of Public Law 119-90, the Secretary is required to

make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the

Act to the average standardized amounts for subsequent fiscal years so

as to eliminate the full effect of the coding and classification

changes that do not reflect real changes in case-mix. In addition, we

note that the Secretary has the authority to make this prospective

adjustment in FY 2010 under section 1886(d)(3)(A)(vi) of the Act. As we

have consistently stated since the initial implementation of the MS-DRG

system, we do not believe it is appropriate for expenditures under the

IPPS to increase due to MS-DRG-related changes in documentation and

coding that do not reflect real changes in case-mix.

Therefore, we are proposing to reduce the average standardized

amounts under section 1886(d) of the Act in FY 2010 by -1.9 percent,

the difference between changes in documentation and coding that do not

reflect real changes in case-mix for discharges occurring during FY

2008 and the prospective adjustment applied under Public Law 110-90. We

are proposing to leave this adjustment in place for subsequent fiscal

years in order to ensure that changes in documentation and coding

resulting from the adoption of the MS-DRGs do not lead to an increase

in aggregate payments not reflective of an increase in real case-mix.

Thus, the proposed cumulative adjustment to the average standardized

amounts for FY 2010 is -3.4 percent (that is, the existing -1.5 percent

plus the proposed -1.9 percent). We note that because we are proposing

to apply a cumulative offset of -3.4 percent to the FY 2010

standardized amount, we are proposing to apply a factor of 0.967 (1

divided by

[[Page 24244]]

1.034) in determining the FY 2010 standardized amount. We refer readers

to section II.D. of the preamble of this proposed rule for a complete

discussion of our proposed -1.9 percent adjustment to the average

standardized amounts under section 1886(d) of the Act in FY 2010.

As also discussed in section II.D. of the preamble of this proposed

rule, we will address any differences between the increase in FY 2009

case-mix due to documentation and coding that did not reflect real

changes in case-mix for discharges occurring during FY 2009 and the -

0.9 percent prospective documentation and coding adjustment applied

under section 7(a) of Public Law 110-90 in the FY 2011 rulemaking

cycle. Furthermore, we are seeking public comment on the proposed -1.9

percent prospective adjustment to the standardized amounts under

section 1886(d) of the Act and addressing in the FY 2011 rulemaking

cycle any differences between the increase in FY 2009 case-mix due to

documentation and coding changes that did not reflect real changes in

case-mix for discharges occurring during FY 2009 and the -0.9 percent

prospective documentation and coding adjustment applied under section

7(a) of Public Law 110-90. We note that we are also seeking public

comment on our intent to address the requirements of section 7(b)(1)(B)

of Public Law 110-90 through future rulemaking.

(2) Proposed Adjustment to the FY 2010 Hospital-Specific Rates for SCHs

and MDHs

As discussed in section II.D. of the preamble to this proposed

rule, because hospitals (SCHs and MDHs) paid based in whole or in part

on the hospital-specific rate use the same MS-DRG system as other

hospitals, we believe they have the potential to realize increased

payments from documentation and coding changes that do not reflect real

increases in patients' severity of illness. Under section

1886(d)(3)(A)(vi) of the Act, Congress stipulated that hospitals paid

based on the standardized amount should not receive additional payments

based on the effect of documentation and coding changes that do not

reflect real changes in case-mix. Similarly, we believe that hospitals

paid based on the hospital-specific rate should not have the potential

to realize increased payments due to documentation and coding changes

that do not reflect real increases in patients' severity of illness.

While we continue to believe that section 1886(d)(3)(A)(vi) of the Act

does not provide explicit authority for application of the

documentation and coding adjustment to the hospital-specific rates, we

believe that we have the authority to apply the documentation and

coding adjustment to the hospital-specific rates using our special

exceptions and adjustment authority under section 1886(d)(5)(I)(i) of

the Act. The special exceptions and adjustment authority authorizes us

to provide ``for such other exceptions and adjustments to [IPPS]

payment amounts \* \* \* as the Secretary deems appropriate.'' We

indicated that, for the FY 2010 rulemaking, we planned to examine our

FY 2008 claims data for hospitals paid based on the hospital-specific

rate. We also indicated that if we found evidence of significant

increases in case-mix for patients treated in these hospitals that does

not reflect real changes in case-mix, we would consider proposing

application of the documentation and coding adjustments to the FY 2010

hospital-specific rates under our authority in section 1886(d)(5)(I)(i)

of the Act.

We performed a retrospective evaluation of the FY 2008 claims data

for SCHs and MDHs using the same methodology described in section II.D

of the preamble of this proposed rule for other IPPS hospitals. We

found that, independently for both SCHs and MDHs, the change due to

documentation and coding that did not reflect real changes in case-mix

for discharges occurring during FY 2008 slightly exceeded the 2.5

percent result discussed earlier, but did not significantly differ from

that result.

Therefore, consistent with our statements in prior IPPS rules, we

are proposing to use our authority under section 1886(d)(5)(I)(i) of

the Act to prospectively adjust the hospital-specific rates by -2.5

percent in FY 2010 for our estimated documentation and coding effect in

FY 2008 that does not reflect real changes in case-mix. We are

proposing to leave this adjustment in place for subsequent fiscal years

in order to ensure that changes in documentation and coding resulting

from the adoption of the MS-DRGs do not lead to an increase in

aggregate payments for SCHs and MDHs not reflective of an increase in

real case-mix. This proposed -2.5 percent adjustment to the hospital-

specific rates exceeds the proposed -1.9 percent adjustment to the

national standardized amount under section 7(b)(1)(A) of Public Law

110-90 because, unlike the national standardized rates, the FY 2008

hospital-specific rates were not previously reduced in order to account

for anticipated changes in documentation and coding that do not reflect

real changes in case-mix resulting from the adoption of the MS-DRGs. We

note that because we are proposing to apply a offset of -2.5 percent to

the FY 2010 hospital-specific rates, we are proposing to apply a factor

of 0.976 (1 divided by 1.025) to adjust the FY 2010 hospital-specific

rates. We refer readers to section II.D. of the preamble of this

proposed rule for a complete discussion on our proposal to

prospectively adjust the hospital-specific rates by -2.5 percent in FY

2010.

We will address in the FY 2011 rulemaking cycle any change in FY

2009 case-mix due to documentation and coding that did not reflect real

changes in case-mix for discharges occurring during FY 2009. We note

that, unlike the national standardized rates, the FY 2009 hospital-

specific rates were not previously reduced in order to account for

anticipated changes in documentation and coding that do not reflect

real changes in case-mix resulting from the adoption of the MS-DRGs.

We are seeking public comment on the proposed -2.5 percent

prospective adjustment to the hospital-specific rates of SCHs and MDHs

and addressing in the FY 2011 rulemaking cycle any changes in FY 2009

case-mix due to changes in documentation and coding that do not reflect

real changes in case-mix for discharges occurring during FY 2009. We

intend to update our analysis with FY 2008 data on claims paid through

March 2008 for the FY 2010 IPPS final rule.

(3) Proposed Adjustment to the FY 2010 Puerto Rico Standardized Amount

As stated in section II.D. of the preamble to this proposed rule,

we believe that we have the authority to apply the documentation and

coding adjustment to the Puerto Rico-specific standardized amount using

our special exceptions and adjustment authority under section

1886(d)(5)(I)(i) of the Act. Similar to SCHs and MDHs that are paid

based on the hospital-specific rate, we believe that Puerto Rico

hospitals that are paid based on the Puerto Rico-specific standardized

amount should not have the potential to realize increased payments due

to documentation and coding changes that do not reflect real increases

in patients' severity of illness. Consistent with the approach

described for SCHs and MDHs, in the FY 2009 final rule, we indicated

that we planned to examine our FY 2008 claims data for hospitals in

Puerto Rico. We indicated in the FY 2009 IPPS proposed rule (73 FR

48449) that if we found evidence of significant

[[Page 24245]]

increases in case-mix for patients treated in these hospitals, we would

consider proposing application of the documentation and coding

adjustments to the FY 2010 Puerto Rico-specific standardized amount

under our authority in section 1886(d)(5)(I)(i) of the Act.

We performed a retrospective evaluation of the FY 2008 claims data

for Puerto Rico hospitals using the same methodology described in

section II.D. of the preamble of this proposed rule for IPPS hospitals

paid under the national standardized amounts under section 1886(d) of

the Act. We found that, for Puerto Rico hospitals, the increase in

payments for discharges occurring during FY 2008 due to documentation

and coding changes that did not reflect real changes in case-mix for

discharges occurring during FY 2008 was approximately 1.1 percent.

Given these documentation and coding increases, consistent with our

statements in prior IPPS rules, we are proposing to use our authority

under section 1886(d)(5)(I)(i) of the Act to adjust the Puerto Rico-

specific standardized amount by -1.1 percent in FY 2010 to account for

the FY 2008 documentation and coding changes that are not due to

changes in real case-mix and to leave that adjustment in place for

subsequent fiscal years. As the proposed -1.1 percent adjustment will

be applied to the Puerto Rico-specific rate that accounts for 25

percent of payment to Puerto Rico hospitals and the other 75 percent is

accounted for by the similar proposed adjustment that is applied to the

national standardized amount, the overall proposed adjustment for

documentation and coding changes will be slightly less for Puerto Rico

hospitals as compared to other hospitals that are paid based on 100

percent of the national standardized amount. We note that, as with the

hospital-specific rates, the Puerto Rico-specific standardized amount

had not previously been reduced based on estimated changes in

documentation and coding associated with the adoption of the MS-DRGs.

Furthermore, we note that because we are proposing to apply a offset of

-1.1 percent to the FY 2010 Puerto Rico-specific standardized amount,

we are proposing to apply a factor of 0.989 (1 divided by 1.011) to

adjust the FY 2010 Puerto Rico-specific standardized amount. We refer

readers to section II.D. of the preamble of this proposed rule for a

complete discussion on our proposal to adjust the Puerto Rico-specific

standardized amount by -1.1 percent in FY 2010.

We will address in the FY 2011 rulemaking cycle any change in FY

2009 case-mix due to documentation and coding changes that do not

reflect real changes in case-mix for discharges occurring during FY

2009. We note that, unlike the national standardized rates, the FY 2009

Puerto Rico-specific standardized amount was not previously reduced in

order to account for anticipated changes in documentation and coding

that do not reflect real changes in case-mix resulting from the

adoption of the MS-DRGs.

We are seeking public comment on the proposed -1.1 percent

prospective adjustment to the Puerto Rico-specific standardized amount

under section 1886(d)(5)(I)(i) of the Act and addressing in the FY 2011

rulemaking cycle any changes in FY 2009 case-mix due to documentation

and coding changes that do not reflect real changes in case-mix for

discharges occurring during FY 2009. We intend to update our analysis

with FY 2008 data on claims paid through March 2008 for the FY 2010

IPPS final rule.

e. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition

to the basic prospective payments for ``outlier'' cases involving

extraordinarily high costs. To qualify for outlier payments, a case

must have costs greater than the sum of the prospective payment rate

for the DRG, any IME and DSH payments, any new technology add-on

payments, and the ``outlier threshold'' or ``fixed-loss'' amount (a

dollar amount by which the costs of a case must exceed payments in

order to qualify for an outlier payment). We refer to the sum of the

prospective payment rate for the DRG, any IME and DSH payments, any new

technology add-on payments, and the outlier threshold as the outlier

``fixed-loss cost threshold.'' To determine whether the costs of a case

exceed the fixed-loss cost threshold, a hospital's CCR is applied to

the total covered charges for the case to convert the charges to

estimated costs. Payments for eligible cases are then made based on a

marginal cost factor, which is a percentage of the estimated costs

above the fixed-loss cost threshold. The marginal cost factor for FY

2010 is 80 percent, the same marginal cost factor we have used since FY

1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier

payments for any year are projected to be not less than 5 percent nor

more than 6 percent of total operating DRG payments plus outlier

payments. Section 1886(d)(3)(B) of the Act requires the Secretary to

reduce the average standardized amount by a factor to account for the

estimated proportion of total DRG payments made to outlier cases.

Similarly, section 1886(d)(9)(B)(iv) of the Act requires the Secretary

to reduce the average standardized amount applicable to hospitals

located in Puerto Rico to account for the estimated proportion of total

DRG payments made to outlier cases. More information on outlier

payments may be found on the CMS Web site at http://www.cms.hhs.gov/

AcuteInpatientPPS/04\_outlier.asp#TopOfPage.

(1) Proposed FY 2010 Outlier Fixed-Loss Cost Threshold

For FY 2010, we are proposing to continue to use the same

methodology used for FY 2009 (73 FR 48763 through 48766) to calculate

the outlier threshold. Similar to the methodology used in the FY 2009

IPPS final rule, for FY 2010, we are proposing to apply an adjustment

factor to the CCRs to account for cost and charge inflation (as

explained below). As we have done in the past, to calculate the

proposed FY 2010 outlier threshold we simulated payments by applying

proposed FY 2010 rates and policies using cases from the FY 2008 MedPAR

files. Therefore, in order to determine the proposed FY 2010 outlier

threshold, we inflate the charges on the MedPAR claims by 2 years, from

FY 2008 to FY 2010.

We are proposing to continue to use a refined methodology that

takes into account the lower inflation in hospital charges that are

occurring as a result of the outlier final rule (68 FR 34494), which

changed our methodology for determining outlier payments by

implementing the use of more current CCRs. Our refined methodology uses

more recent data that reflect the rate-of-change in hospital charges

under the new outlier policy.

Using the most recent data available, we calculated the 1-year

average annualized rate-of-change in charges-per-case from the last

quarter of FY 2007 in combination with the first quarter of FY 2008

(July 1, 2007 through December 31, 2007) to the last quarter of FY 2008

in combination with the first quarter of FY 2009 (July 1, 2008 through

December 31, 2008). This rate of change was 7.29 percent (1.0729) or

15.11 percent (1.1511) over 2 years.

As we have done in the past, we established the proposed FY 2010

outlier threshold using hospital CCRs from the December 2008 update to

the Provider-Specific File (PSF)--the most recent available data at the

time of this proposed rule. This file includes CCRs that reflect

implementation of the

[[Page 24246]]

changes to the policy for determining the applicable CCRs that became

effective August 8, 2003 (68 FR 34494).

As discussed in the FY 2007 IPPS final rule (71 FR 48150), we

worked with the Office of Actuary to derive the methodology described

below to develop the CCR adjustment factor. For FY 2010, we are

proposing to continue to use the same methodology to calculate the CCR

adjustment by using the FY 2008 operating cost per discharge increase

in combination with the actual FY 2008 operating market basket

percentage increase determined by IHS Global Insight, Inc., as well as

the charge inflation factor described above to estimate the adjustment

to the CCRs. (We note that the FY 2008 actual (otherwise referred to as

``final'') operating market basket percentage increase reflects

historical data, whereas the published FY 2008 operating market basket

update factor was based on IHS Global Insight, Inc.'s 2007 third

quarter forecast with historical data through the first quarter of

2008.) By using the operating market basket percentage increase and the

increase in the average cost per discharge from hospital cost reports,

we are using two different measures of cost inflation. For FY 2010, we

determined the adjustment by taking the percentage increase in the

operating costs per discharge from FY 2006 to FY 2007 (1.0460) from the

cost report and dividing it by the final operating market basket

percentage increase from FY 2007 (1.0360). This operation removes the

measure of pure price increase (the market basket) from the percentage

increase in operating cost per discharge, leaving the nonprice factors

in the cost increase (for example, quantity and changes in the mix of

goods and services). We repeated this calculation for 2 prior years to

determine the 3-year average of the rate of adjusted change in costs

between the operating market basket percentage increase and the

increase in cost per case from the cost report (the FY 2004 to FY 2005

percentage increase of operating costs per discharge of 1.0584 divided

by the FY 2005 final operating market basket percentage increase of

1.0390, the FY 2005 to FY 2006 percentage increase of operating costs

per discharge of 1.0578 divided by FY 2006 final operating market

basket percentage increase of 1.0400). For FY 2010, we averaged the

differentials calculated for FY 2005, FY 2006, and FY 2007, which

resulted in a mean ratio of 1.0151. We multiplied the 3-year average of

1.0151 by the FY 2008 final operating market basket percentage increase

of 1.0400, which resulted in an operating cost inflation factor of 5.56

percent or 1.056. We then divided the operating cost inflation factor

by the 1-year average change in charges (1.072893) and applied an

adjustment factor of 0.9840 to the operating CCRs from the PSF.

As stated in the FY 2009 IPPS final rule (73 FR 48763), we continue

to believe it is appropriate to apply only a 1-year adjustment factor

to the CCRs. On average, it takes approximately 9 months for a fiscal

intermediary or MAC to tentatively settle a cost report from the fiscal

year end of a hospital's cost reporting period. The average ``age'' of

hospitals' CCRs from the time the fiscal intermediary or the MAC

inserts the CCR in the PSF until the beginning of FY 2009 is

approximately 1 year. Therefore, as stated above, we believe a 1-year

adjustment factor to the CCRs is appropriate.

We used the same methodology for the capital CCRs and determined

the adjustment by taking the percentage increase in the capital costs

per discharge from FY 2006 to FY 2007 (1.0488) from the cost report and

dividing it by the final capital market basket percentage increase from

FY 2007 (1.0130). We repeated this calculation for 2 prior years to

determine the 3-year average of the rate of adjusted change in costs

between the capital market basket percentage increase and the increase

in cost per case from the cost report (the FY 2004 to FY 2005

percentage increase of capital costs per discharge of 1.0329 divided by

the FY 2005 final capital market basket percentage increase of 1.0090,

the FY 2005 to FY 2006 percentage increase of capital costs per

discharge of 1.0467 divided by the FY 2006 final capital market basket

percentage increase of 1.0110). For FY 2010, we averaged the

differentials calculated for FY 2005, FY 2006, and FY 2007, which

resulted in a mean ratio of 1.0314. We multiplied the 3-year average of

1.0314 by the FY 2008 final capital market basket percentage increase

of 1.0140, which resulted in a capital cost inflation factor of 4.59

percent or 1.0459. We then divided the capital cost inflation factor by

the 1-year average change in charges (1.072893) and applied an

adjustment factor of 0.9748 to the capital CCRs from the PSF. We are

proposing to use the same charge inflation factor for the capital CCRs

that was used for the operating CCRs. The charge inflation factor is

based on the overall billed charges. Therefore, we believe it is

appropriate to apply the charge factor to both the operating and

capital CCRs.

As stated above, for FY 2010, we are applying the proposed FY 2010

rates and policies using cases from the FY 2008 MedPAR files in

calculating the proposed outlier threshold. Therefore, for purposes of

estimating the proposed outlier threshold for FY 2010, it is necessary

to take into account the remaining projected case-mix growth when

calculating the outlier threshold that results in outlier payments

being 5.1 percent of total payments for FY 2010. As discussed above and

in section II.D. of the preamble of this proposed rule, our actuaries

estimated that maintaining budget neutrality for changes in case-mix

due to the adoption of the MS-DRGs requires an adjustment of -4.8

percent to the national standardized amount. For FY 2008, our estimate

of the case-mix increase due to documentation and coding in FY 2008 is

2.5 percent, which is already included within the claims data (FY 2008

MedPAR files) used to calculate the proposed FY 2010 threshold. In

addition, we stated that, even with our assumption that there will be

no continued changes in documentation and coding in FY 2009, the use of

the FY 2009 relative weights will result in an additional 0.7 percent

case-mix increase due to the documentation and coding effect in FY

2009. Therefore, we project that an additional 1.6 percent case-mix

growth occurred since 2008 (4.8 percent - 2.5 percent (case-mix growth

in FY 2008) - 0.7 percent (FY 2009 relative weights effect) = 1.6

percent). As a result, we inflated the FY 2008 claims data by an

additional 1.6 percent for the additional case-mix growth projected to

have occurred since FY 2008. If we did not take into account the

remaining 1.6 percent projected case-mix growth, our estimate of total

FY 2010 payments would be too low, and as a result, our proposed

outlier threshold would be too high, such that estimated outlier

payments would be less than our projected 5.1 percent of total

payments. While we assume 1.6 percent case-mix growth for IPPS

hospitals in our outlier threshold calculations, the proposed FY 2010

national standardized amounts used to calculate the proposed outlier

threshold reflect the proposed cumulative adjustment of -3.4 percent

(as described above in this section).

Using this methodology, we are proposing an outlier fixed-loss cost

threshold for FY 2010 equal to the prospective payment rate for the

DRG, plus any IME and DSH payments, and any add-on payments for new

technology, plus $24,240.

As we did in establishing the FY 2009 outlier threshold (73 FR

57891), in our projection of FY 2010 outlier payments, we are not

proposing to make any

[[Page 24247]]

adjustments for the possibility that hospitals' CCRs and outlier

payments may be reconciled upon cost report settlement. We continue to

believe that, due to the policy implemented in the June 9, 2003 outlier

final rule (68 FR 34494), CCRs will no longer fluctuate significantly

and, therefore, few hospitals will actually have these ratios

reconciled upon cost report settlement. In addition, it is difficult to

predict the specific hospitals that will have CCRs and outlier payments

reconciled in any given year. We also noted that reconciliation occurs

because hospitals' actual CCRs for the cost reporting period are

different than the interim CCRs used to calculate outlier payments when

a bill is processed. Our simulations assume that CCRs accurately

measure hospital costs based on information available to us at the time

we set the outlier threshold. For these reasons, we are not making any

assumptions about the effects of reconciliation on the outlier

threshold calculation.

We also note that there are some factors that contributed to a

higher proposed fixed-loss outlier threshold for FY 2010 compared to FY

2009. First, as stated below in section II.A.4.e.(3) of this Addendum,

we are currently projecting 5.4 percent of total IPPS payment will be

paid as outliers in FY 2009 or 0.3 percentage points greater than the

5.1 percent originally estimated. If we do not increase the FY 2009

threshold in FY 2010, we would continue to make outlier payments in

excess of the 5.1 percent target. In addition, because overall payments

are projected to be lower in FY 2010 compared to FY 2009, even more

cases would qualify for outlier payments. In order to maintain outlier

payments at 5.1 percent, the outlier threshold must be further

increased to decrease the amount of cases that would qualify as

outliers. Together, we believe that the above factors cumulatively

contributed to a higher proposed fixed-loss outlier threshold in FY

2010 compared to FY 2009.

(2) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we

establish an outlier threshold that is applicable to both hospital

inpatient operating costs and hospital inpatient capital-related costs.

When we modeled the combined operating and capital outlier payments, we

found that using a common threshold resulted in a lower percentage of

outlier payments for capital-related costs than for operating costs. We

project that the thresholds for FY 2010 will result in outlier payments

that will equal 5.1 percent of operating DRG payments and 5.5 percent

of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are

proposing to reduce the FY 2010 standardized amount by the same

percentage to account for the projected proportion of payments paid as

outliers.

The outlier adjustment factors that would be applied to the

standardized amount for the proposed FY 2010 outlier threshold are as

follows:

------------------------------------------------------------------------

Operating

standardized Capital

amounts federal rate

------------------------------------------------------------------------

National.................................... 0.948996 0.945405

Puerto Rico................................. 0.952493 0.938327

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We are proposing to apply the outlier adjustment factors to the

proposed FY 2010 rates after removing the effects of the FY 2009

outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we

apply hospital-specific CCRs to the total covered charges for the case.

Estimated operating and capital costs for the case are calculated

separately by applying separate operating and capital CCRs. These costs

are then combined and compared with the outlier fixed-loss cost

threshold.

The June 9, 2003 outlier final rule (68 FR 34494) eliminated the

application of the statewide average CCRs for hospitals with CCRs that

fell below 3 standard deviations from the national mean CCR. However,

for those hospitals for which the fiscal intermediary or MAC computes

operating CCRs greater than 1.183 or capital CCRs greater than 0.146,

or hospitals for whom the fiscal intermediary or MAC is unable to

calculate a CCR (as described at Sec. 412.84(i)(3) of our

regulations), we still use statewide average CCRs to determine whether

a hospital qualifies for outlier payments.\11\ Table 8A in this

Addendum contains the proposed statewide average operating CCRs for

urban hospitals and for rural hospitals for which the fiscal

intermediary or MAC is unable to compute a hospital-specific CCR within

the above range. Effective for discharges occurring on or after October

1, 2009, these statewide average ratios would replace the ratios

published in the IPPS final rule for FY 2009 (73 FR 48994 through

48995). Table 8B in this Addendum contains the comparable proposed

statewide average capital CCRs. Again, the proposed CCRs in Tables 8A

and 8B would be used during FY 2010 when hospital-specific CCRs based

on the latest settled cost report are either not available or are

outside the range noted above. For an explanation of Table 8C, we refer

readers to section V. of this Addendum.

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\11\ These figures represent 3.0 standard deviations from the

mean of the log distribution of CCRs for all hospitals.

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We finally note that we published a manual update (Change Request

3966) to our outlier policy on October 12, 2005, which updated Chapter

3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual

update covered an array of topics, including CCRs, reconciliation, and

the time value of money. We encourage hospitals that are assigned the

statewide average operating and/or capital CCRs to work with their

fiscal intermediary or MAC on a possible alternative operating and/or

capital CCR as explained in Change Request 3966. Use of an alternative

CCR developed by the hospital in conjunction with the fiscal

intermediary or MAC can avoid possible overpayments or underpayments at

cost report settlement, thus ensuring better accuracy when making

outlier payments and negating the need for outlier reconciliation. We

also note that a hospital may request an alternative operating or

capital CCR ratio at any time as long as the guidelines of Change

Request 3966 are followed. To download and view the manual instructions

on outlier and CCRs, we refer readers to CMS Web site: http://

www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.

(3) FY 2008 and FY 2009 Outlier Payments

In the FY 2009 IPPS final rule (73 FR 48766), we stated that, based

on available data, we estimated that actual FY 2008 outlier payments

would be approximately 4.7 percent of actual total DRG payments. This

estimate was computed based on simulations using the FY 2007 MedPAR

file (discharge data for FY 2007 claims). That is, the estimate of

actual outlier payments did not reflect actual FY 2008 claims, but

instead reflected the application of FY 2008 rates and policies to

available FY 2007 claims.

Our current estimate, using available FY 2008 claims data, is that

actual outlier payments for FY 2008 were approximately 4.8 percent of

actual total DRG payments. Thus, the data indicate that, for FY 2008,

the percentage of actual outlier payments relative to actual total

payments is higher than we projected before FY 2008. Consistent with

the policy and statutory interpretation we have maintained since the

inception of the IPPS, we do not plan to make retroactive adjustments

to

[[Page 24248]]

outlier payments to ensure that total outlier payments for FY 2008 are

equal to 5.1 percent of total DRG payments.

We currently estimate that actual outlier payments for FY 2009 will

be approximately 5.4 percent of actual total DRG payments, 0.3

percentage points higher than the 5.1 percent we projected in setting

the outlier policies for FY 2009. This estimate is based on simulations

using the FY 2008 MedPAR file (discharge data for FY 2008 claims). We

used these data to calculate an estimate of the actual outlier

percentage for FY 2009 by applying FY 2009 rates and policies,

including an outlier threshold of $20,045 to available FY 2008 claims.

f. Proposed Rural Community Hospital Demonstration Program Adjustment

(Section 410A of Public Law 108-173)

Section 410A of Public Law 108-173 requires the Secretary to

establish a demonstration that will modify reimbursement for inpatient

services for up to 15 small rural hospitals. Section 410A(c)(2) of

Public Law 108-173 requires that ``[i]n conducting the demonstration

program under this section, the Secretary shall ensure that the

aggregate payments made by the Secretary do not exceed the amount which

the Secretary would have paid if the demonstration program under this

section was not implemented.'' As discussed in section V.I. of the

preamble to this proposed rule, we have satisfied this requirement by

proposing an adjustment to the national IPPS rates by a factor that is

sufficient to account for the added costs of this demonstration. We

estimate that the average additional annual payment that will be made

to each participating hospital under the demonstration will be

approximately $1,124,126. We based this estimate on the recent

historical experience of the difference between inpatient cost and

payment for hospitals that are participating in the demonstration

program. For 13 participating hospitals, the projected total annual

impact of the demonstration program for FY 2010 is $14,613,632. In

addition, because the cost reports of all hospitals participating in

the demonstration in its first year (that is, FY 2005) have been

finalized, we are able to determine how much the cost of the

demonstration program exceeded the amount that was offset by the budget

neutrality adjustment for FY 2005. For all 13 hospitals that

participated in the demonstration in FY 2005, the amount is $7,179,461.

Therefore, the projected total annual impact of the demonstration

program for FY 2010 is $21,793,093. The proposed budget neutrality

adjustment factor applied to the Federal rate to calculate Medicare

inpatient prospective payments as a result of the demonstration is

0.999790. This budget neutrality adjustment factor may be different in

the FY 2010 IPPS final rule to the extent that we have more recent

data.

In order to achieve budget neutrality, we are proposing to adjust

the national IPPS rates by an amount sufficient to account for the

added costs of this demonstration. In other words, we are proposing to

apply budget neutrality across the payment system as a whole rather

than merely across the participants of this demonstration, consistent

with past practice. We believe that the language of the statutory

budget neutrality requirement permits the agency to implement the

budget neutrality provision in this manner. The statutory language

requires that ``aggregate payments made by the Secretary do not exceed

the amount which the Secretary would have paid if the demonstration \* \*

\* was not implemented,'' but does not identify the range across which

aggregate payments must be held equal.

5. Proposed FY 2010 Standardized Amount

The proposed adjusted standardized amount is divided into labor-

related and nonlabor-related portions. Tables 1A and 1B of this

Addendum contain the national standardized amounts that we are

proposing to apply to all hospitals, except hospitals located in Puerto

Rico, for FY 2010. The proposed Puerto Rico-specific amounts are shown

in Table 1C of this Addendum. The proposed amounts shown in Tables 1A

and 1B differ only in that the labor-related share applied to the

standardized amounts in Table 1A is the proposed revised labor-related

share of 67.1 percent, and Table 1B is 62 percent. In accordance with

sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are

applying a labor-related share of 62 percent, unless application of

that percentage would result in lower payments to a hospital than would

otherwise be made. In effect, the statutory provision means that we

will apply a labor-related share of 62 percent for all hospitals (other

than those in Puerto Rico) whose wage indexes are less than or equal to

1.0000.

In addition, Tables 1A and 1B include proposed standardized amounts

reflecting the proposed full 2.1 percent update for FY 2010, and the

proposed standardized amounts reflecting the 2.0 percentage point

reduction to the update (a 0.1 percent update) applicable for hospitals

that fail to submit quality data consistent with section

1886(b)(3)(B)(viii) of the Act.

Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of

the Puerto Rico payment rate is based on the discharge-weighted average

of the national large urban standardized amount (this proposed amount

is set forth in Table 1A). The proposed labor-related and nonlabor-

related portions of the national average standardized amounts for

Puerto Rico hospitals for FY 2010 are set forth in Table 1C of this

Addendum. This table also includes the proposed Puerto Rico

standardized amounts. The labor-related share applied to the proposed

Puerto Rico specific standardized amount is the proposed labor-related

share of 60.3 percent, or 62 percent, depending on which provides

higher payments to the hospital. (Section 1886(d)(9)(C)(iv) of the Act,

as amended by section 403(b) of Pub. L. 108-173, provides that the

labor-related share for hospitals located in Puerto Rico be 62 percent,

unless the application of that percentage would result in lower

payments to the hospital.)

The following table illustrates the proposed changes from the FY

2009 national standardized amount. The second column shows the proposed

changes from the FY 2009 standardized amounts for hospitals that

satisfy the quality data submission requirement for receiving the full

update (2.1 percent). The third column shows the proposed changes for

hospitals receiving the reduced update (0.1 percent). The first row of

the table shows the proposed updated (through FY 2009) average

standardized amount after restoring the FY 2008 offsets for outlier

payments, demonstration budget neutrality, the geographic

reclassification budget neutrality, and the documentation and coding

adjustment for FY 2008 and FY 2009. The DRG reclassification and

recalibration and wage index budget neutrality factors are cumulative.

Therefore, the FY 2009 factor is not removed from this table. We also

have added separate rows to this table to reflect the different labor-

related shares that apply to hospitals.

[[Page 24249]]

Comparison of FY 2009 Standardized Amounts to the Proposed FY 2010 Standardized Amount With Full and Reduced Update

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Full update (2.1 percent); Full update (2.1 percent); Reduced update (0.1 percent); Reduced update (0.1

wage index is greater than wage index is less than or wage index is greater than percent); wage index is less

1.0000 equal to 1.0000 1.0000 than or equal to 1.0000

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FY 2009 Base Rate, after Labor: $3,711.57............. Labor: $3,429.47............. Labor: $3,711.57............. Labor: $3,429.47.

removing geographic Nonlabor: $1,819.83.......... Nonlabor: $2,101.93.......... Nonlabor: $1,819.83.......... Nonlabor: $2,101.93.

reclassification budget

neutrality, demonstration

budget neutrality, Actual FY

08 and FY 09 documentation

and coding adjustment, and

outlier offset (based on the

labor-related share

percentage for FY 2010).

Proposed FY 2010 Update 1.021........................ 1.021........................ 1.001........................ 1.001.

Factor.

Proposed FY 2010 DRG 0.998066..................... 0.998066..................... 0.998066..................... 0.998066.

Recalibration and Wage Index

Budget Neutrality Factor.

Proposed FY 2010 0.991690..................... 0.991690..................... 0.991690..................... 0.991690.

Reclassification Budget

Neutrality Factor.

Proposed FY 2010 Outlier 0.948996..................... 0.948996..................... 0.948996..................... 0.948996.

Factor.

Proposed Rural Demonstration 0.999790..................... 0.999790..................... 0.999790..................... 0.999790.

Budget Neutrality Factor.

Proposed FY 2010 0.967........................ 0.967........................ 0.967........................ 0.967.

Documentation and Coding

Adjustment and Actual FY

2008 and FY 2009 Adjustment

and Additional Adjustment

for FY 2008.

Proposed Rate for FY 2010.... Labor: $3,441.26............. Labor: $3,179.71............. Labor: $3,373.85............. Labor: $3,117.42.

Nonlabor: $1,687.30.......... Nonlabor: $1,948.85.......... Nonlabor: $1,654.25.......... Nonlabor: $1,910.68.

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Under section 1886(d)(9)(A)(ii) of the Act, the Federal portion of

the Puerto Rico payment rate is based on the discharge-weighted average

of the national standardized amount (as set forth in Table 1A of this

Addendum). The labor-related and nonlabor-related portions of the

national average standardized amounts for Puerto Rico hospitals are set

forth in Table 1C of this Addendum. This table also includes the Puerto

Rico standardized amounts. The proposed labor-related share applied to

the Puerto Rico standardized amount is 60.3 percent, or 62 percent,

depending on which results in higher payments to the hospital. (Section

1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Pub. L.

108-173, provides that the labor-related share for hospitals in Puerto

Rico will be 62 percent, unless the application of that percentage

would result in lower payments to the hospital.)

B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as set forth in this Addendum, contain the

proposed labor-related and nonlabor-related shares that we are using to

calculate the proposed prospective payment rates for hospitals located

in the 50 States, the District of Columbia, and Puerto Rico for FY

2010. This section addresses two types of adjustments to the

standardized amounts that are made in determining the proposed

prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require

that we make an adjustment to the labor-related portion of the national

and Puerto Rico prospective payment rates, respectively, to account for

area differences in hospital wage levels. This adjustment is made by

multiplying the labor-related portion of the adjusted standardized

amounts by the appropriate wage index for the area in which the

hospital is located. In section III. of the preamble to this proposed

rule, we discuss the data and methodology for the proposed FY 2010 wage

index.

2. Proposed Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act authorizes the Secretary to make

an adjustment to take into account the unique circumstances of

hospitals in Alaska and Hawaii. Higher labor-related costs for these

two States are taken into account in the adjustment for area wages

described above. For FY 2010, we are proposing to adjust the payments

for hospitals in Alaska and Hawaii by multiplying the nonlabor-related

portion of the standardized amount by the applicable adjustment factor

contained in the table below. These proposed factors were obtained from

the U.S. Office of Personnel Management (OPM) and are currently also

used under the IPPS. In addition, we are proposing that if OPM releases

revised COLA factors after publication of this proposed rule, we would

use the revised factors for the development of IPPS payments for FY

2010 and publish those revised COLA factors in the final rule.

Table of Cost-of-Living Adjustment Factors: Alaska and Hawaii Hospitals

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Cost of living

Area adjustment factor

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Alaska:

City of Anchorage and 80-kilometer (50-mile) 1.23

radius by road..................................

City of Fairbanks and 80-kilometer (50-mile) 1.23

radius by road..................................

City of Juneau and 80-kilometer (50-mile) radius 1.23

by road.........................................

Rest of Alaska................................... 1.25

[[Page 24250]]

Hawaii:

City and County of Honolulu...................... 1.25

County of Hawaii................................. 1.18

County of Kauai.................................. 1.25

County of Maui and County of Kalawao............. 1.25

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(The above factors are based on data obtained from the U.S. Office of

Personnel Management Web site at: http://www.opm.gov/oca/cola/

rates.asp.)

C. Proposed MS-DRG Relative Weights

As discussed in section II.H. of the preamble of this proposed

rule, we have developed proposed relative weights for each MS-DRG that

reflect the resource utilization of cases in each MS-DRG relative to

Medicare cases in other MS-DRGs. Table 5 of this Addendum contains the

proposed relative weights that we would apply to discharges occurring

in FY 2010. These factors have been recalibrated as explained in

section II. of the preamble of this proposed rule.

D. Calculation of the Proposed Prospective Payment Rates

General Formula for Calculation of the Proposed Prospective Payment

Rates for FY 2010

In general, the operating prospective payment rate for all

hospitals paid under the IPPS located outside of Puerto Rico, except

SCHs and MDHs, for FY 2010 equals the Federal rate.

Currently, SCHs are paid based on whichever of the following rates

yields the greatest aggregate payment: the Federal national rate; the

updated hospital-specific rate based on FY 1982 costs per discharge;

the updated hospital-specific rate based on FY 1987 costs per

discharge; the updated hospital-specific rate based on FY 1996 costs

per discharge; or for cost reporting periods beginning on or after

January 1, 2009, the updated hospital-specific rate based on the FY

2006 costs per discharge to determine the rate that yields the greatest

aggregate payment.

The prospective payment rate for SCHs for FY 2010 equals the higher

of the applicable Federal rate, or the hospital-specific rate as

described below. The prospective payment rate for MDHs for FY 2010

equals the higher of the Federal rate, or the Federal rate plus 75

percent of the difference between the Federal rate and the hospital-

specific rate as described below. The prospective payment rate for

hospitals located in Puerto Rico for FY 2010 equals 25 percent of the

Puerto Rico rate plus 75 percent of the applicable national rate.

1. Federal Rate

The Federal rate is determined as follows:

Step 1--Select the applicable average standardized amount depending

on whether the hospital submitted qualifying quality data (full update

for qualifying hospitals, update minus 2.0 percentage points for

nonqualifying hospitals).

Step 2--Multiply the labor-related portion of the standardized

amount by the applicable wage index for the geographic area in which

the hospital is located or the area to which the hospital is

reclassified.

Step 3--For hospitals in Alaska and Hawaii, multiply the nonlabor-

related portion of the standardized amount by the applicable cost-of-

living adjustment factor.

Step 4--Add the amount from Step 2 and the nonlabor-related portion

of the standardized amount (adjusted, if applicable, under Step 3).

Step 5--Multiply the final amount from Step 4 by the relative

weight corresponding to the applicable MS-DRG (see Table 5 of this

Addendum).

The Federal rate as determined in Step 5 may then be further

adjusted if the hospital qualifies for either the IME or DSH

adjustment. In addition, for hospitals that qualify for a low-volume

payment adjustment under section 1886(d)(12) of the Act and 42 CFR

412.101(b), the payment in Step 5 would be increased by 25 percent.

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that, for cost reporting

periods beginning prior to January 1, 2009, SCHs are paid based on

whichever of the following rates yields the greatest aggregate payment:

the Federal rate; the updated hospital-specific rate based on FY 1982

costs per discharge; the updated hospital-specific rate based on FY

1987 costs per discharge; the updated hospital-specific rate based on

FY 1996 costs per discharge; or for cost reporting periods beginning on

or after January 1, 2009, the updated hospital-specific rate based on

the FY 2006 costs per discharge to determine the rate that yields the

greatest aggregate payment.

As discussed previously, we are required to rebase MDHs hospital-

specific rates to their FY 2002 cost reports if doing so results in

higher payments. In addition, effective for discharges occurring on or

after October 1, 2006, MDHs are to be paid based on the Federal

national rate or, if higher, the Federal national rate plus 75 percent

(changed from 50 percent) of the difference between the Federal

national rate and the greater of the updated hospital-specific rates

based on either FY 1982, FY 1987 or FY 2002 costs per discharge.

Further, MDHs are no longer subject to the 12-percent cap on their DSH

payment adjustment factor.

Hospital-specific rates have been determined for each of these

hospitals based on the FY 1982 costs per discharge, the FY 1987 costs

per discharge, or, for SCHs, the FY 1996 costs per discharge or the FY

2006 costs per discharge, and for MDHs, the FY 2002 cost per discharge.

For a more detailed discussion of the calculation of the hospital-

specific rates, we refer the reader to the FY 1984 IPPS interim final

rule (48 FR 39772); the April 20, 1990 final rule with comment (55 FR

15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS

final rule (65 FR 47082). In addition, for both SCHs and MDHs, the

hospital-specific rate is adjusted by the budget neutrality adjustment

factor as discussed in section III. of this Addendum. The resulting

rate will be used in determining the payment rate an SCH or MDH will

receive for its discharges beginning on or after October 1, 2009.

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002, and FY 2006

Hospital-Specific Rates for FY 2010

We are proposing to increase the hospital-specific rates by 2.1

percent (the proposed hospital market basket percentage increase) for

FY 2010 for those SCHs and MDHs that submit qualifying quality data and

by 0.1

[[Page 24251]]

percent for SCHs and MDHs that fail to submit qualifying quality data.

Section 1886(b)(3)(C)(iv) of the Act provides that the update factor

applicable to the hospital-specific rates for SCHs is equal to the

update factor provided under section 1886(b)(3)(B)(iv) of the Act,

which, for SCHs in FY 2009, is the market basket percentage increase

for hospitals that submit qualifying quality data and the market basket

percentage increase minus 2 percent for hospitals that fail to submit

qualifying quality data. Section 1886(b)(3)(D) of the Act provides that

the update factor applicable to the hospital-specific rates for MDHs

also equals the update factor provided for under section

1886(b)(3)(B)(iv) of the Act, which, for FY 2009, is the market basket

percentage increase for hospitals that submit qualifying quality data

and the market basket percentage increase minus 2 percent for hospitals

that fail to submit qualifying quality data.

3. General Formula for Calculation of Proposed Prospective Payment

Rates for Hospitals Located in Puerto Rico Beginning On or After

October 1, 2009, and Before October 1, 2010

Section 1886(d)(9)(E)(iv) of the Act provides that, effective for

discharges occurring on or after October 1, 2004, hospitals located in

Puerto Rico are paid based on a blend of 75 percent of the national

prospective payment rate and 25 percent of the Puerto Rico-specific

rate.

a. Puerto Rico Rate

The Puerto Rico prospective payment rate is determined as follows:

Step 1--Select the applicable average standardized amount

considering the applicable wage index (Table 1C of this Addendum).

Step 2--Multiply the labor-related portion of the standardized

amount by the applicable Puerto Rico-specific wage index.

Step 3--Add the amount from Step 2 and the nonlabor-related portion

of the standardized amount.

Step 4--Multiply the amount from Step 3 by the applicable MS-DRG

relative weight (Table 5 of this Addendum).

Step 5--Multiply the result in Step 4 by 25 percent.

b. National Rate

The national prospective payment rate is determined as follows:

Step 1--Select the applicable average standardized amount.

Step 2--Multiply the labor-related portion of the standardized

amount by the applicable wage index for the geographic area in which

the hospital is located or the area to which the hospital is

reclassified.

Step 3--Add the amount from Step 2 and the nonlabor-related portion

of the national average standardized amount.

Step 4--Multiply the amount from Step 3 by the applicable MS-DRG

relative weight (Table 5 of this Addendum).

Step 5--Multiply the result in Step 4 by 75 percent.

The sum of the Puerto Rico rate and the national rate computed

above equals the prospective payment for a given discharge for a

hospital located in Puerto Rico. This rate would then be further

adjusted if the hospital qualifies for either the IME or DSH

adjustment.

III. Proposed Changes to Payment Rates for Acute Care Hospital

Inpatient Capital-Related Costs for FY 2010

The PPS for acute care hospital inpatient capital-related costs was

implemented for cost reporting periods beginning on or after October 1,

1991. Effective with that cost reporting period, hospitals were paid

during a 10-year transition period (which extended through FY 2001) to

change the payment methodology for Medicare acute care hospital

inpatient capital-related costs from a reasonable cost-based

methodology to a prospective methodology (based fully on the Federal

rate).

The basic methodology for determining Federal capital prospective

rates is set forth in the regulations at 42 CFR 412.308 through

412.352. Below we discuss the factors that we are proposing to use to

determine the capital Federal rate for FY 2010, which would be

effective for discharges occurring on or after October 1, 2009.

The 10-year transition period ended with hospital cost reporting

periods beginning on or after October 1, 2001 (FY 2002). Therefore, for

cost reporting periods beginning in FY 2002, all hospitals (except

``new'' hospitals under Sec. 412.304(c)(2)) are paid based on the

capital Federal rate. For FY 1992, we computed the standard Federal

payment rate for capital-related costs under the IPPS by updating the

FY 1989 Medicare inpatient capital cost per case by an actuarial

estimate of the increase in Medicare inpatient capital costs per case.

Each year after FY 1992, we update the capital standard Federal rate,

as provided at Sec. 412.308(c)(1), to account for capital input price

increases and other factors. The regulations at Sec. 412.308(c)(2)

provide that the capital Federal rate be adjusted annually by a factor

equal to the estimated proportion of outlier payments under the capital

Federal rate to total capital payments under the capital Federal rate.

In addition, Sec. 412.308(c)(3) requires that the capital Federal rate

be reduced by an adjustment factor equal to the estimated proportion of

payments for (regular and special) exceptions under Sec. 412.348.

Section 412.308(c)(4)(ii) requires that the capital standard Federal

rate be adjusted so that the effects of the annual DRG reclassification

and the recalibration of DRG weights and changes in the geographic

adjustment factor (GAF) are budget neutral.

For FYs 1992 through 1995, Sec. 412.352 required that the capital

Federal rate also be adjusted by a budget neutrality factor so that

aggregate payments for inpatient hospital capital costs were projected

to equal 90 percent of the payments that would have been made for

capital-related costs on a reasonable cost basis during the respective

fiscal year. That provision expired in FY 1996. Section 412.308(b)(2)

describes the 7.4 percent reduction to the capital Federal rate that

was made in FY 1994, and Sec. 412.308(b)(3) describes the 0.28 percent

reduction to the capital Federal rate made in FY 1996 as a result of

the revised policy for paying for transfers. In FY 1998, we implemented

section 4402 of Public Law 105-33, which required that, for discharges

occurring on or after October 1, 1997, the budget neutrality adjustment

factor in effect as of September 30, 1995, be applied to the unadjusted

capital standard Federal rate and the unadjusted hospital-specific

rate. That factor was 0.8432, which was equivalent to a 15.68 percent

reduction to the unadjusted capital payment rates. An additional 2.1

percent reduction to the rates was effective from October 1, 1997

through September 30, 2002, making the total reduction 17.78 percent.

As we discussed in the FY 2003 IPPS final rule (67 FR 50102) and

implemented in Sec. 412.308(b)(6), the 2.1 percent reduction was

restored to the unadjusted capital payment rates effective October 1,

2002.

To determine the appropriate budget neutrality adjustment factor

and the regular exceptions payment adjustment during the 10-year

transition period, we developed a dynamic model of Medicare inpatient

capital-related costs; that is, a model that projected changes in

Medicare inpatient capital-related costs over time. With the expiration

of the budget neutrality provision, the capital cost model was only

used to estimate the regular exceptions payment adjustment and other

factors during the transition period. As we explained in the FY 2002

IPPS final rule (66 FR 39911), beginning in FY 2002, an adjustment for

regular exception

[[Page 24252]]

payments is no longer necessary because regular exception payments were

only made for cost reporting periods beginning on or after October 1,

1991, and before October 1, 2001 (see Sec. 412.348(b)). Because

payments are no longer made under the regular exception policy

effective with cost reporting periods beginning in FY 2002, we

discontinued use of the capital cost model. The capital cost model and

its application during the transition period are described in Appendix

B of the FY 2002 IPPS final rule (66 FR 40099).

Section 412.374 provides for blended payments to hospitals located

in Puerto Rico under the IPPS for acute care hospital inpatient

capital-related costs. Accordingly, under the capital PPS, we compute a

separate payment rate specific to hospitals located in Puerto Rico

using the same methodology used to compute the national Federal rate

for capital-related costs. In accordance with section 1886(d)(9)(A) of

the Act, under the IPPS for acute care hospital operating costs,

hospitals located in Puerto Rico are paid for operating costs under a

special payment formula. Prior to FY 1998, hospitals located in Puerto

Rico were paid a blended operating rate that consisted of 75 percent of

the applicable standardized amount specific to Puerto Rico hospitals

and 25 percent of the applicable national average standardized amount.

Similarly, prior to FY 1998, hospitals located in Puerto Rico were paid

a blended capital rate that consisted of 75 percent of the applicable

capital Puerto Rico-specific rate and 25 percent of the applicable

capital Federal rate. However, effective October 1, 1997, in accordance

with section 4406 of Pulic. Law 105-33, the methodology for operating

payments made to hospitals located in Puerto Rico under the IPPS was

revised to make payments based on a blend of 50 percent of the

applicable standardized amount specific to Puerto Rico hospitals and 50

percent of the applicable national average standardized amount. In

conjunction with this change to the operating blend percentage,

effective with discharges occurring on or after October 1, 1997, we

also revised the methodology for computing capital payments to

hospitals located in Puerto Rico to be based on a blend of 50 percent

of the Puerto Rico capital rate and 50 percent of the national capital

Federal rate.

As we discussed in the FY 2005 IPPS final rule (69 FR 49185),

section 504 of Public Law 108-173 increased the national portion of the

operating IPPS payments for hospitals located in Puerto Rico from 50

percent to 62.5 percent and decreased the Puerto Rico portion of the

operating IPPS payments from 50 percent to 37.5 percent for discharges

occurring on or after April 1, 2004 through September 30, 2004 (refer

to the March 26, 2004 One-Time Notification (Change Request 3158)). In

addition, section 504 of Public Law 108-173 provided that the national

portion of operating IPPS payments for hospitals located in Puerto Rico

is equal to 75 percent and the Puerto Rico-specific portion of

operating IPPS payments is equal to 25 percent for discharges occurring

on or after October 1, 2004. Consistent with that change in operating

IPPS payments to hospitals located in Puerto Rico, for FY 2005 (as we

discussed in the FY 2005 IPPS final rule), we revised the methodology

for computing capital payments to hospitals located in Puerto Rico to

be based on a blend of 25 percent of the Puerto Rico-specific capital

rate and 75 percent of the national capital Federal rate for discharges

occurring on or after October 1, 2004.

A. Determination of Proposed Federal Hospital Inpatient Capital-Related

Prospective Payment Rate Update

In the Federal Register notice setting out the final wage indices

for FY 2009 (73 FR 57892), we established the final capital Federal

rate of $424.17 for FY 2009. In the discussion that follows, we explain

the factors that we are proposing to use to determine the proposed

capital Federal rate for FY 2010. In particular, we explain why the

proposed FY 2010 capital Federal rate would decrease approximately 0.8

percent, compared to the FY 2009 capital Federal rate. Furthermore, we

estimate that aggregate capital payments would decrease during this

same period (approximately $393 million), primarily due to the

estimated decrease in capital IME payments in FY 2010 as compared to FY

2009 provided under current law, in addition to the proposed decrease

in the capital Federal rate. Total payments to hospitals under the IPPS

are relatively unaffected by changes in the capital prospective

payments. Because capital payments constitute about 10 percent of

hospital payments, a 1-percent change in the capital Federal rate

yields only about a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under Sec. 412.308(c)(1), the capital standard Federal rate is

updated on the basis of an analytical framework that takes into account

changes in a capital input price index (CIPI) and several other policy

adjustment factors. Specifically, we have adjusted the projected CIPI

rate-of-increase as appropriate each year for case-mix index-related

changes, for intensity, and for errors in previous CIPI forecasts. The

proposed update factor for FY 2010 under that framework is 1.20 percent

based on the best data available at this time. The proposed update

factor under that framework is based on a projected 1.2 percent

increase in the CIPI, a 0.0 percent adjustment for intensity, a 0.0

percent adjustment for case-mix, a 0.0 percent adjustment for the FY

2008 DRG reclassification and recalibration, and a forecast error

correction of 0.0 percent. As discussed below in section III.C. of this

Addendum, we continue to believe that the CIPI is the most appropriate

input price index for capital costs to measure capital price changes in

a given year. We also explain the basis for the FY 2010 CIPI projection

in that same section of this Addendum. In addition, as also noted

below, the proposed capital rates would be further adjusted to account

for changes in documentation and coding under the MS-DRGs that do not

correspond to changes in real increases in patients' severity of

illness, discussed in section II.D. of the preamble of this proposed

rule. Below we describe the policy adjustments that we are proposing to

apply in the update framework for FY 2010.

The case-mix index is the measure of the average DRG weight for

cases paid under the IPPS. Because the DRG weight determines the

prospective payment for each case, any percentage increase in the case-

mix index corresponds to an equal percentage increase in hospital

payments.

The case-mix index can change for any of several reasons:

The average resource use of Medicare patients changes

(``real'' case-mix change);

Changes in hospital documentation and coding of patient

records result in higher weight DRG assignments (``coding effects'');

and

The annual DRG reclassification and recalibration changes

may not be budget neutral (``reclassification effect'').

We define real case-mix change as actual changes in the mix (and

resource requirements) of Medicare patients as opposed to changes in

documentation and coding behavior that result in assignment of cases to

higher weighted DRGs but do not reflect higher resource requirements.

The capital update framework includes the same case-mix index

adjustment used in the former operating IPPS update framework (as

[[Page 24253]]

discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR

28816)). (We no longer use an update framework to make a recommendation

for updating the operating IPPS standardized amounts as discussed in

section II. of Appendix B in the FY 2006 IPPS final rule (70 FR

47707).)

Absent the projected increase in case-mix resulting from changes in

documentation and coding due to the adoption of the MS-DRGs, for FY

2010, we are projecting a 1.0 percent total increase in the case-mix

index. We estimate that the real case-mix increase will also equal 1.0

percent for FY 2010. The net adjustment for change in case-mix is the

difference between the projected real increase in case-mix and the

projected total increase in case-mix. Therefore, the proposed net

adjustment for case-mix change in FY 2010 is 0.0 percentage points.

The capital update framework also contains an adjustment for the

effects of DRG reclassification and recalibration. This adjustment is

intended to remove the effect on total payments of prior year's changes

to the DRG classifications and relative weights, in order to retain

budget neutrality for all case-mix index-related changes other than

those due to patient severity. Due to the lag time in the availability

of data, there is a 2-year lag in data used to determine the adjustment

for the effects of DRG reclassification and recalibration. For example,

we are adjusting for the effects of the FY 2008 DRG reclassification

and recalibration as part of our proposed update for FY 2010. To adjust

for reclassification and recalibration effects, we run the FY 2008

cases through the FY 2007 GROUPER and through the FY 2008 GROUPER. The

resulting ratio of the case-mix indices should equate to 1.0. If not,

in the update framework for FY 2010, we would make an adjustment to

adjust for the reclassification and recalibration effects in FY 2008.

As discussed in detail in section II.B. of the preamble, however, when

we adopted the MS-DRGs for FY 2008 to better recognize severity of

illness in Medicare payment rates, we also recognized that changes in

documentation and coding could potentially lead to increases in

aggregate payments without a corresponding increase in patients'

severity of illness (that is, increased case-mix index other than real

case-mix index increase). To maintain budget neutrality for the

adoption of the MS-DRGs as discussed in greater detail in section II.D.

of the preamble of this proposed rule, we are proposing to make an

adjustment to the proposed capital Federal rates based on actuarial

estimates of the documentation and coding effects that occurred in FY

2008 (based on FY 2008 claims data). Therefore, we are not adjusting

for reclassification and recalibration effects from FY 2008 in the

update framework for FY 2010 because we have already accounted for it

in the proposed documentation and coding adjustment to the proposed

capital Federal rates. Therefore, we are proposing a 0.0 percent

adjustment for DRG reclassification in the proposed update for FY 2010,

as discussed above.

The capital update framework also contains an adjustment for

forecast error. The input price index forecast is based on historical

trends and relationships ascertainable at the time the update factor is

established for the upcoming year. In any given year, there may be

unanticipated price fluctuations that may result in differences between

the actual increase in prices and the forecast used in calculating the

update factors. In setting a prospective payment rate under the

framework, we make an adjustment for forecast error only if our

estimate of the change in the capital input price index for any year is

off by 0.25 percentage points or more. There is a 2-year lag between

the forecast and the availability of data to develop a measurement of

the forecast error. A forecast error of 0.1 percentage point was

calculated for the FY 2010 update. That is, current historical data

indicate that the forecasted FY 2008 CIPI (1.3 percent) used in

calculating the FY 2008 update factor slightly understated the actual

realized price increases (1.4 percent) by 0.1 percentage point. This

slight underprediction was mostly due to the incorporation of newly

available source data for fixed asset prices and moveable asset prices

into the market basket. However, because this estimation of the change

in the CIPI is less than 0.25 percentage points, it is not reflected in

the update recommended under this framework. Therefore, we are

proposing to make a 0.0 percent adjustment for forecast error in the

update for FY 2010.

Under the capital IPPS update framework, we also make an adjustment

for changes in intensity. We calculate this adjustment using the same

methodology and data that were used in the past under the framework for

operating IPPS. The intensity factor for the operating update framework

reflects how hospital services are utilized to produce the final

product, that is, the discharge. This component accounts for changes in

the use of quality-enhancing services, for changes within DRG severity,

and for expected modification of practice patterns to remove noncost-

effective services.

We calculate case-mix constant intensity as the change in total

charges per admission, adjusted for price level changes (the CPI for

hospital and related services) and changes in real case-mix. The use of

total charges in the calculation of the intensity factor makes it a

total intensity factor; that is, charges for capital services are

already built into the calculation of the factor. Therefore, we have

incorporated the intensity adjustment from the operating update

framework into the capital update framework. Without reliable estimates

of the proportions of the overall annual intensity increases that are

due, respectively, to ineffective practice patterns and the combination

of quality-enhancing new technologies and complexity within the DRG

system, we assume that one-half of the annual increase is due to each

of these factors. The capital update framework thus provides an add-on

to the input price index rate of increase of one-half of the estimated

annual increase in intensity, to allow for increases within DRG

severity and the adoption of quality-enhancing technology.

We have developed a Medicare-specific intensity measure based on a

5-year average. Past studies of case-mix change by the RAND Corporation

(Has DRG Creep Crept Up? Decomposing the Case Mix Index Change Between

1987 and 1988 by G.M. Carter, J.P. Newhouse, and D.A. Relles, R-4098-

HCFA/ProPAC (1991)) suggest that real case-mix change was not dependent

on total change, but was usually a fairly steady increase of 1.0 to 1.5

percent per year. However, we used 1.4 percent as the upper bound

because the RAND study did not take into account that hospitals may

have induced doctors to document medical records more completely in

order to improve payment.

As we noted above, in accordance with Sec. 412.308(c)(1)(ii), we

began updating the capital standard Federal rate in FY 1996 using an

update framework that takes into account, among other things, allowable

changes in the intensity of hospital services. For FYs 1996 through

2001, we found that case-mix constant intensity was declining, and we

established a 0.0 percent adjustment for intensity in each of those

years. For FYs 2002 and 2003, we found that case-mix constant intensity

was increasing, and we established a 0.3 percent adjustment and 1.0

percent adjustment for intensity, respectively. For FYs 2004 and 2005,

we found that the charge data appeared to be skewed (as discussed in

greater detail below) as a result of hospitals attempting to maximize

outlier payments, while lessening costs, and we

[[Page 24254]]

established a 0.0 percent adjustment in each of those years.

Furthermore, we stated that we would continue to apply a 0.0 percent

adjustment for intensity until any increase in charges can be tied to

intensity rather than attempts to maximize outlier payments.

On June 9, 2003, we published in the Federal Register revisions to

our outlier policy for determining the additional payment for

extraordinarily high-cost cases (68 FR 34494 through 34515). These

revised policies were effective on August 8, 2003, and October 1, 2003.

While it does appear that a response to these policy changes is

beginning to occur, that is, the increase in charges for FYs 2004 and

2005 are somewhat less than the previous 4 years, they still show a

significant annual increase in charges without a corresponding increase

in hospital case-mix. Specifically, the percent change in hospitals'

charges in FY 2004 is approximately 12 percent, which is similar in

magnitude to the large increases in charges that we found in the 4

years prior to FY 2004 and before our revisions to the outlier policy

in FY 2003. For FY 2005, there is approximately an 8 percent change in

charges, which is somewhat lower than the percent change in FY 2004.

Nevertheless, the percent change in charges in both FYs 2004 and 2005

are still relatively high as compared to the change in charges prior to

FY 2001. Moreover, the percent change in hospitals' case-mix in those

years is not in proportion to the higher charges. The remaining 3 years

in the 5-year average indicate that the change in hospitals' charges

appears to be slightly moderating, and is lower than FYs 2004 and 2005.

(We refer readers to a discussion regarding the intensity factor in the

FY 2004 IPPS final rule (68 FR 45482), the FY 2005 IPPS final rule (69

FR 49285), the FY 2006 IPPS final rule (70 FR 47500), the FY 2007 IPPS

final rule (72 FR 47500), the FY 2008 IPPS final rule with comment

period (72 FR 47426), and the FY 2009 IPPS final rule (73 FR 48771.)

Our intensity measure is based on a 5-year average, and therefore,

the proposed intensity adjustment for FY 2010 is based on data from the

5-year period beginning with FY 2004 and extending through FY 2008.

Based on the increases in charges for FYs 2004 through 2005 that remain

in the 5-year average used for the intensity adjustment, we believe

residual effects of hospitals' charge practices prior to the

implementation of the outlier policy revisions established in the June

9, 2003 final rule continue to appear in the data, as it may have taken

hospitals some time to adopt changes in their behavior in response to

the new outlier policy. Thus, we believe that the FY 2004 and possibly

the FY 2005 charge data may still be skewed.

The change in hospitals' charges for FY 2004 and to a somewhat

lesser extent, FY 2005, remains similar to the considerable increase in

hospitals' charges that we found when examining hospitals' charge data

in determining the intensity factor in the update recommendations for

the past few years. If hospitals were treating new or different types

of cases, which would result in an appropriate increase in charges per

discharge, then we would expect hospitals' case-mix to increase

proportionally, and it did not.

Although it appears that the change in hospitals' charges is more

reasonable compared to data used in recent past rulemaking, using a 5-

year average of the data tends to smooth out what might otherwise be

more obvious effects of particular years such as FYs 2004 and 2005.

Therefore, notwithstanding the gradual effect of the outlier policy

over time, we believe the effect from hospitals attempting to maximize

outlier payments prior to the implementation of the outlier policy

continues, albeit to a smaller degree, to skew the charge data used in

determining the intensity adjustment.

As we discussed most recently in the FY 2009 IPPS final rule (73 FR

48771), because our intensity calculation relies heavily upon charge

data and we believe that these charge data for at least 1 if not 2

years of the 5-year average may be inappropriately skewed, we are

proposing to establish a 0.0 percent adjustment for intensity for FY

2010, just as we did for FYs 2004 through 2009.

In the past (FYs 1996 through 2001) when we found intensity to be

declining, we believed a zero (rather than negative) intensity

adjustment was appropriate. Similarly, we believe that it is

appropriate to apply a zero intensity adjustment for FY 2010 until any

increase in charges during the 5-year period upon which the intensity

adjustment is based can be tied to intensity rather than to attempts to

maximize outlier payments.

Above, we described the basis of the components used to develop the

proposed 1.2 percent capital update factor under the capital update

framework for FY 2010 as shown in the table below.

CMS FY 2010 Proposed Update Factor to the Capital Federal Rate

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Capital Input Price Index....................................... 1.2

Intensity....................................................... 0.0

Case-Mix Adjustment Factors:

Real Across DRG Change........................................ -1.0

Projected Case-Mix Change..................................... 1.0

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Subtotal.................................................... 1.2

Effect of FY 2008 Reclassification and Recalibration............ 0.0

Forecast Error Correction....................................... 0.0

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Total Update................................................ 1.2

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b. Comparison of CMS and MedPAC Update Recommendation

In its March 2009 Report to Congress, MedPAC did not make a

specific update recommendation for capital IPPS payments for FY 2010.

However, in that same report, in assessing the adequacy of current

payments and costs, MedPAC recommended an update to the hospital

inpatient and outpatient PPS rates equal to the increase in the

hospital market basket in FY 2010, concurrent with a quality incentive

program. (MedPAC's Report to the Congress: Medicare Payment Policy,

March 2009, Section 2A.)

2. Proposed Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment

methodology for inpatient operating and inpatient capital-related

costs. A single set of thresholds is used to identify outlier cases for

both inpatient operating and inpatient capital-related payments.

Section 412.308(c)(2) provides that the standard Federal rate for

inpatient capital-related costs be reduced by an adjustment factor

equal to the estimated proportion of capital-related outlier payments

to total inpatient capital-related PPS payments. The outlier thresholds

are set so that operating outlier payments are projected to be 5.1

percent of total operating IPPS DRG payments.

In the Federal Register notice setting out the final wage indices

for FY 2009 (73 FR 57891), we estimated that outlier payments for

capital will equal 5.35 percent of inpatient capital-related payments

based on the capital Federal rate in FY 2009. Based on the proposed

thresholds as set forth in section II.A. of this Addendum, we estimate

that outlier payments for capital-related costs would equal 5.46

percent for inpatient capital-related payments based on the proposed

capital Federal rate in FY 2010. Therefore, we are proposing to apply

an outlier adjustment factor of 0.9454 in

[[Page 24255]]

determining the proposed capital Federal rate. Thus, we estimate that

the percentage of capital outlier payments to total capital standard

payments for FY 2010 would be higher than the percentage for FY 2009.

This increase in capital outlier payments is primarily due to the

proposed decrease in estimated aggregate capital IPPS payments. That

is, because overall payments are projected to be lower in FY 2010

compared to FY 2009, as discussed in section VIII. of Appendix A to

this proposed rule, even more cases would qualify for outlier payments.

The outlier reduction factors are not built permanently into the

capital rates; that is, they are not applied cumulatively in

determining the capital Federal rate. The proposed FY 2010 outlier

adjustment of 0.9454 is a -0.12 percent change from the FY 2009 outlier

adjustment of 0.9465. Therefore, the net change in the outlier

adjustment to the proposed capital Federal rate for FY 2010 is 0.9988

(0.9454/0.9465). Thus, the proposed outlier adjustment decreases the

proposed FY 2010 capital Federal rate by 0.12 percent compared with the

FY 2009 outlier adjustment.

3. Proposed Budget Neutrality Adjustment Factor for Changes in DRG

Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be

adjusted so that aggregate payments for the fiscal year based on the

capital Federal rate after any changes resulting from the annual DRG

reclassification and recalibration and changes in the GAF are projected

to equal aggregate payments that would have been made on the basis of

the capital Federal rate without such changes. Because we implemented a

separate GAF for Puerto Rico, we apply separate budget neutrality

adjustments for the national GAF and the Puerto Rico GAF. We apply the

same budget neutrality factor for DRG reclassifications and

recalibration nationally and for Puerto Rico. Separate adjustments were

unnecessary for FY 1998 and earlier because the GAF for Puerto Rico was

implemented in FY 1998.

In the past, we used the actuarial capital cost model (described in

Appendix B of the FY 2002 IPPS final rule (66 FR 40099)) to estimate

the aggregate payments that would have been made on the basis of the

capital Federal rate with and without changes in the DRG

classifications and weights and in the GAF to compute the adjustment

required to maintain budget neutrality for changes in DRG weights and

in the GAF. During the transition period, the capital cost model was

also used to estimate the regular exception payment adjustment factor.

As we explain in section III.A. of this Addendum, beginning in FY 2002,

an adjustment for regular exception payments is no longer necessary.

Therefore, we no longer use the capital cost model. Instead, we are

using historical data based on hospitals' actual cost experiences to

determine the exceptions payment adjustment factor for special

exceptions payments.

To determine the proposed factors for FY 2010, we compared

(separately for the national capital rate and the Puerto Rico capital

rate) estimated aggregate capital Federal rate payments based on the FY

2009 MS-DRG classifications and relative weights and the FY 2009 GAF to

estimated aggregate capital Federal rate payments based on the proposed

FY 2010 MS-DRG classifications and relative weights and the proposed FY

2010 GAFs. In making the comparison, we set the exceptions reduction

factor to 1.00. To achieve budget neutrality for the proposed changes

in the national GAFs, based on calculations using updated data, we are

proposing to apply an incremental budget neutrality adjustment of

0.9999 for FY 2010 to the previous cumulative FY 2009 adjustment of

0.9917, yielding a proposed adjustment of 0.9916, through FY 2010. For

the Puerto Rico GAFs, we are proposing to apply an incremental budget

neutrality adjustment of 1.0015 for FY 2010 to the previous cumulative

FY 2009 adjustment of 0.9960 (calculated with unrounded numbers),

yielding a proposed cumulative adjustment of 0.9975 through FY 2010.

We then compared estimated aggregate capital Federal rate payments

based on the FY 2009 DRG relative weights and the proposed FY 2010 GAFs

to estimated aggregate capital Federal rate payments based on the

cumulative effects of the proposed FY 2010 MS-DRG classifications and

relative weights and the proposed FY 2010 GAFs. The proposed

incremental adjustment for proposed DRG classifications and proposed

changes in relative weights is 0.9995 both nationally and for Puerto

Rico. The proposed cumulative adjustments for MS-DRG classifications

and changes in relative weights and for proposed changes in the GAFs

through FY 2010 are 0.9911 (calculated with unrounded numbers)

nationally and 0.9969 for Puerto Rico. The following table summarizes

the adjustment factors for each fiscal year:

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[[Page 24256]]

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[[Page 24257]]

The methodology used to determine the recalibration and geographic

adjustment factor (DRG/GAF) budget neutrality adjustment is similar to

the methodology used in establishing budget neutrality adjustments

under the IPPS for operating costs. One difference is that, under the

operating IPPS, the budget neutrality adjustments for the effect of

geographic reclassifications are determined separately from the effects

of other changes in the hospital wage index and the DRG relative

weights. Under the capital IPPS, there is a single DRG/GAF budget

neutrality adjustment factor (the national capital rate and the Puerto

Rico capital rate are determined separately) for changes in the GAF

(including geographic reclassification) and the DRG relative weights.

In addition, there is no adjustment for the effects that geographic

reclassification has on the other payment parameters, such as the

payments for DSH or IME.

For FY 2009, we calculated a final GAF/DRG budget neutrality factor

of 1.0015 (73 FR 57892). For FY 2010, we are proposing to establish a

GAF/DRG budget neutrality factor of 0.9994. The GAF/DRG budget

neutrality factors are built permanently into the capital rates; that

is, they are applied cumulatively in determining the capital Federal

rate. This follows the requirement that estimated aggregate payments

each year be no more or less than they would have been in the absence

of the annual DRG reclassification and recalibration and changes in the

GAFs. The incremental change in the proposed adjustment from FY 2009 to

FY 2010 is 0.9994. The cumulative change in the proposed capital

Federal rate due to this proposed adjustment is 0.9911 (the product of

the incremental factors for FYs 1995 though 2009 and the proposed

incremental factor of 0.9994 for FY 2010). (We note that averages of

the incremental factors that were in effect during FYs 2005 and 2006,

respectively, were used in the calculation of the proposed cumulative

adjustment of 0.9911 for FY 2010.)

The proposed factor accounts for the proposed MS-DRG

reclassifications and recalibration and for proposed changes in the

GAFs. It also incorporates the effects on the proposed GAFs of FY 2010

geographic reclassification decisions made by the MGCRB compared to FY

2009 decisions. However, it does not account for changes in payments

due to changes in the DSH and IME adjustment factors.

4. Exceptions Payment Adjustment Factor

Section 412.308(c)(3) of our regulations requires that the capital

standard Federal rate be reduced by an adjustment factor equal to the

estimated proportion of additional payments for both regular exceptions

and special exceptions under Sec. 412.348 relative to total capital

PPS payments. In estimating the proportion of regular exception

payments to total capital PPS payments during the transition period, we

used the actuarial capital cost model originally developed for

determining budget neutrality (described in Appendix B of the FY 2002

IPPS final rule (66 FR 40099)) to determine the exceptions payment

adjustment factor, which was applied to both the Federal and hospital-

specific capital rates.

An adjustment for regular exception payments is no longer necessary

in determining the proposed FY 2010 capital Federal rate because, in

accordance with Sec. 412.348(b), regular exception payments were only

made for cost reporting periods beginning on or after October 1, 1991

and before October 1, 2001. Accordingly, as we explained in the FY 2002

IPPS final rule (66 FR 39949), in FY 2002 and subsequent fiscal years,

no payments are made under the regular exceptions provision. However,

in accordance with Sec. 412.308(c), we still need to compute a budget

neutrality adjustment for special exception payments under Sec.

412.348(g). We describe our methodology for determining the proposed

exceptions adjustment used in calculating the FY 2010 capital Federal

rate below.

Under the special exceptions provision specified at Sec.

412.348(g)(1), eligible hospitals include SCHs, urban hospitals with at

least 100 beds that have a disproportionate share percentage of at

least 20.2 percent or qualify for DSH payments under Sec.

412.106(c)(2), and hospitals with a combined Medicare and Medicaid

inpatient utilization of at least 70 percent. An eligible hospital may

receive special exceptions payments if it meets the following criteria:

(1) A project need requirement as described at Sec. 412.348(g)(2),

which, in the case of certain urban hospitals, includes an excess

capacity test as described at Sec. 412.348(g)(4); (2) an age of assets

test as described at Sec. 412.348(g)(3); and (3) a project size

requirement as described at Sec. 412.348(g)(5).

Based on information compiled from our fiscal intermediaries and

MACs, six hospitals have qualified for special exceptions payments

under Sec. 412.348(g). One of these hospitals closed in May 2005.

Because we have cost reports ending in FY 2006 for all five of these

hospitals, we calculated the adjustment based on actual cost

experience. Using data from cost reports ending in FY 2006 from the

December 2008 update of the HCRIS data, we divided the capital special

exceptions payment amounts for the five hospitals that qualified for

special exceptions by the total capital PPS payment amounts (including

special exception payments) for all hospitals. Based on the data from

cost reports ending in FY 2006, this ratio is rounded to 0.0001. We

also computed the ratio for FY 2005, which rounds to 0.0002, and the

ratio for FY 2004, which rounds to 0.0003. Based on these data, we are

proposing to make an adjustment of 0.0001. Because special exceptions

are budget neutral, we are proposing to offset the proposed capital

Federal rate by 0.01 percent for special exceptions payments for FY

2010. Therefore, the proposed exceptions adjustment factor is equal to

0.0001 (1-0.9999) to account for special exceptions payments in FY

2009.

In the FY 2009 IPPS final rule (73 FR 48773), we estimated that

total (special) exceptions payments for FY 2009 would equal 0.01

percent of aggregate payments based on the proposed capital Federal

rate. Therefore, we applied an exceptions adjustment factor of 0.9999

(1-0.0001) to determine the FY 2009 capital Federal rate. As we stated

above, we estimate that exceptions payments in FY 2010 would equal 0.01

percent of aggregate payments based on the proposed FY 2010 capital

Federal rate. Therefore, we are proposing to apply an exceptions

payment adjustment factor of 0.9999 to the proposed capital Federal

rate for FY 2010. The proposed exceptions adjustment factor for FY 2010

is the same as the factor used in determining the FY 2009 capital

Federal rate as established in the FY 2009 IPPS final rule. The

exceptions reduction factors are not built permanently into the capital

rates; that is, the factors are not applied cumulatively in determining

the capital Federal rate. Therefore, the net change in the proposed

exceptions adjustment factor used in determining the proposed FY 2010

capital Federal rate is 1.0000 (0.9999/0.9999).

5. Proposed Capital Standard Federal Rate for FY 2010

For FY 2009, we established a final capital Federal rate of $424.17

(73 FR 57891). We are proposing an update of 1.2 percent in determining

the proposed FY 2010 capital Federal rate for all hospitals. However,

as discussed in greater detail in section III.E.1. of the preamble of

this proposed rule, under the statutory authority at section 1886(g) of

the Act, in conjunction with section 1886(d)(3)(A)(vi) of the Act and

section 7(b) of Public Law 110-90, we are proposing an additional 1.9

percent

[[Page 24258]]

reduction to the national capital Federal payment rate in FY 2010. The

proposed 1.9 percent reduction is based on our Actuary's analysis of

the effect of changes in case-mix resulting from documentation and

coding changes that do not reflect real changes in the case-mix in

light of the adoption of MS-DRGs. Accordingly, we are proposing to

apply a cumulative documentation and coding adjustment of -3.4 percent

(that is, the existing -1.5 percent adjustment plus the proposed

additional -1.9 percent adjustment) by applying a factor of 0.967 (that

is 1 divided by 1.034) in determining the national capital Federal rate

for FY 2010. (As also discussed in greater detail in section III.E.2.

of the preamble of this proposed rule, under the statutory authority at

section 1886(g) of the Act, in conjunction with section

1886(d)(3)(A)(vi) of the Act and section 7(b) of Pub. L. 110-90, based

on an analysis of the change in case-mix after the implementation of

the MS-DRGs for hospitals located in Puerto Rico, we are proposing to

apply a 1.1 percent reduction in developing the proposed FY 2010 Puerto

Rico-specific capital rate.) As a result of the proposed 1.2 percent

update and other proposed budget neutrality factors discussed above, we

are proposing to establish a national capital Federal rate of $420.67

for FY 2010. The proposed national capital Federal rate for FY 2010 was

calculated as follows:

The proposed FY 2010 update factor is 1.0120, that is, the

update is 1.2 percent.

The proposed FY 2010 budget neutrality adjustment factor

that is applied to the capital standard Federal payment rate for

proposed changes in the MS-DRG classifications and relative weights and

proposed changes in the GAFs is 0.9994.

The proposed FY 2010 outlier adjustment factor is 0.9454.

The proposed FY 2010 (special) exceptions payment

adjustment factor is 0.9999.

The proposed FY 2010 adjustment factor applied to the

national capital Federal rate for changes in documentation and coding

under the MS-DRGs is 0.967.

Because the proposed capital Federal rate has already been adjusted

for differences in case-mix, wages, cost-of-living, indirect medical

education costs, and payments to hospitals serving a disproportionate

share of low-income patients, we are not proposing to make additional

adjustments in the capital standard Federal rate for these factors,

other than the budget neutrality factor for proposed changes in the MS-

DRG classifications and relative weights and for proposed changes in

the GAFs.

We are providing the following chart that shows how each of the

proposed factors and adjustments for FY 2010 affected the computation

of the proposed FY 2010 national capital Federal rate in comparison to

the FY 2009 national capital Federal rate. The proposed FY 2010 update

factor has the effect of increasing the proposed capital Federal rate

by 1.2 percent compared to the FY 2009 capital Federal rate. The

proposed GAF/DRG budget neutrality factor has the effect of decreasing

the proposed capital Federal rate by 0.06 percent. The proposed FY 2010

outlier adjustment factor has the effect of decreasing the proposed

capital Federal rate by 0.12 percent compared to the FY 2009 capital

Federal rate. The proposed FY 2010 exceptions payment adjustment factor

has no net effect on the proposed capital Federal rate. Furthermore, as

shown in the chart below, the resulting cumulative adjustment for

changes in documentation and coding that do not reflect real changes in

patients' severity of illness (that is, the proposed cumulative

adjustment factor of 0.967) has the net effect of decreasing the

proposed FY 2010 national capital Federal rate by 1.83 percent as

compared to the FY 2009 national capital Federal rate. (As discussed in

section VI.E.1. of the preamble of this proposed rule, a cumulative

adjustment of -1.5 percent (that is, a factor of 0.985) was applied to

the FY 2009 capital Federal rate for changes in documentation and

coding that do not reflect real changes in patients' severity of

illness.) The combined effect of all the proposed changes would

decrease the national capital Federal rate by approximately 0.83

percent compared to the FY 2009 national capital Federal rate.

Comparison of Factors and Adjustments: FY 2009 Capital Federal Rate and Proposed FY 2010 Capital Federal Rate

----------------------------------------------------------------------------------------------------------------

FY 2009 FY 2010 Change Percent change

----------------------------------------------------------------------------------------------------------------

Update Factor \1\............................... 1.0090 1.0120 1.0120 1.20

GAF/DRG Adjustment Factor \1\................... 1.0015 0.9994 0.9994 -0.06

Outlier Adjustment Factor \2\................... 0.9465 0.9454 0.9988 -0.12

Exceptions Adjustment Factor \2\................ 0.9999 0.9999 1.0000 0.00

MS-DRG Documentation and Coding Adjustment 0.985 0.967 0.9817 -1.83

Factor.........................................

Capital Federal Rate............................ $424.17 $420.67 0.9917 -0.83

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\1\ The update factor and the GAF/DRG budget neutrality factors are built permanently into the capital rates.

Thus, for example, the incremental change from FY 2009 to FY 2010 resulting from the application of the

proposed 0.9994 GAF/DRG budget neutrality factor for FY 2010 is 0.9994.

\2\ The outlier reduction factor and the exceptions adjustment factor are not built permanently into the capital

rates; that is, these factors are not applied cumulatively in determining the capital rates. Thus, for

example, the net change resulting from the application of the proposed FY 2010 outlier adjustment factor is

0.9454/0.9465, or 0.9988.

6. Proposed Special Capital Rate for Puerto Rico Hospitals

Section 412.374 provides for the use of a blended payment system

for payments to hospitals located in Puerto Rico under the PPS for

acute care hospital inpatient capital-related costs. Accordingly, under

the capital PPS, we compute a separate payment rate specific to

hospitals located in Puerto Rico using the same methodology used to

compute the national Federal rate for capital-related costs. Under the

broad authority of section 1886(g) of the Act, as discussed in section

VI. of the preamble of this proposed rule, beginning with discharges

occurring on or after October 1, 2004, capital payments to hospitals

located in Puerto Rico are based on a blend of 25 percent of the Puerto

Rico capital rate and 75 percent of the capital Federal rate. The

Puerto Rico capital rate is derived from the costs of Puerto Rico

hospitals only, while the capital Federal rate is derived from the

costs of all acute care hospitals participating in the IPPS (including

Puerto Rico).

To adjust hospitals' capital payments for geographic variations in

capital

[[Page 24259]]

costs, we apply a GAF to both portions of the blended capital rate. The

GAF is calculated using the operating IPPS wage index, and varies

depending on the labor market area or rural area in which the hospital

is located. We use the Puerto Rico wage index to determine the GAF for

the Puerto Rico part of the capital-blended rate and the national wage

index to determine the GAF for the national part of the blended capital

rate.

Because we implemented a separate GAF for Puerto Rico in FY 1998,

we also apply separate budget neutrality adjustments for the national

GAF and for the Puerto Rico GAF. However, we apply the same budget

neutrality factor for DRG reclassifications and recalibration

nationally and for Puerto Rico. As we stated in section III.A.4. of

this Addendum, the proposed national GAF budget neutrality factor is

0.9999, while the DRG adjustment is 0.9995, for a combined proposed

cumulative adjustment of 0.9994.

In computing the payment for a particular Puerto Rico hospital, the

Puerto Rico portion of the capital rate (25 percent) is multiplied by

the Puerto Rico-specific GAF for the labor market area in which the

hospital is located, and the national portion of the capital rate (75

percent) is multiplied by the national GAF for the labor market area in

which the hospital is located (which is computed from national data for

all hospitals in the United States and Puerto Rico). In FY 1998, we

implemented a 17.78 percent reduction to the Puerto Rico capital rate

as a result of Public Law 105-33. In FY 2003, a small part of that

reduction was restored.

For FY 2009, before application of the GAF, the special capital

rate for hospitals located in Puerto Rico is $198.77 for discharges

occurring on or after October 1, 2008, through September 30, 2009 (73

FR 57893). Consistent with our development of the FY 2009 Puerto Rico-

specific operating standardized amount, we did not apply the additional

-0.9 percent documentation and coding adjustment (or the cumulative -

1.5 percent adjustment) to the FY 2009 Puerto Rico-specific capital

rate. We also noted in the FY 2009 IPPS final rule (73 FR 48449 through

48550) that we may propose to apply such an adjustment to the Puerto

Rico operating and capital rates in the future.

With the changes we are proposing to make to the other factors used

to determine the proposed capital rate, the proposed FY 2010 special

capital rate for hospitals in Puerto Rico is $201.91. As discussed in

greater detail in section VI.E.1. of the preamble of this proposed

rule, consistent with our development of the proposed Puerto Rico-

specific operating standardized amount, we are proposing to reduce the

Puerto Rico-specific capital rate by 1.1 percent to account for changes

in documentation and coding as a result of the adoption of the MS-DRGs

by applying a factor of 0.989 (that is, 1 divided by 1.011) in

determining the proposed FY 2010 Puerto Rico-specific capital rate.

B. Calculation of the Proposed Inpatient Capital-Related Prospective

Payments for FY 2010

Because the 10-year capital PPS transition period ended in FY 2001,

all hospitals (except ``new'' hospitals under Sec. 412.324(b) and

under Sec. 412.304(c)(2)) are paid based on 100 percent of the capital

Federal rate in FY 2010.

For purposes of calculating proposed payments for each discharge

during FY 2010, the capital standard Federal rate is adjusted as

follows: (Standard Federal Rate) x (DRG weight) x (GAF) x (COLA for

hospitals located in Alaska and Hawaii) x (1 + DSH Adjustment Factor,

if applicable). The result is the adjusted capital Federal rate. (As

discussed above, under current law, there will no longer be an

adjustment for IME under the capital IPPS beginning in FY 2010 (Sec.

412.322(d).)

Hospitals also may receive outlier payments for those cases that

qualify under the thresholds established for each fiscal year. Section

412.312(c) provides for a single set of thresholds to identify outlier

cases for both inpatient operating and inpatient capital-related

payments. The proposed outlier thresholds for FY 2010 are in section

II.A. of this Addendum. For FY 2010, a case would qualify as a cost

outlier if the cost for the case plus the (operating) IME and DSH

payments is greater than the prospective payment rate for the MS-DRG

plus the proposed fixed-loss amount of $24,240.

An eligible hospital may also qualify for a special exceptions

payment under Sec. 412.348(g) up through the 10th year beyond the end

of the capital transition period if it meets the following criteria:

(1) A project need requirement described at Sec. 412.348(g)(2), which

in the case of certain urban hospitals includes an excess capacity test

as described at Sec. 412.348(g)(4); and (2) a project size requirement

as described at Sec. 412.348(g)(5). Eligible hospitals include SCHs,

urban hospitals with at least 100 beds that have a DSH patient

percentage of at least 20.2 percent or qualify for DSH payments under

Sec. 412.106(c)(2), and hospitals that have a combined Medicare and

Medicaid inpatient utilization of at least 70 percent. Under Sec.

412.348(g)(8), the amount of a special exceptions payment is determined

by comparing the cumulative payments made to the hospital under the

capital PPS to the cumulative minimum payment level. This amount is

offset by: (1) Any amount by which a hospital's cumulative capital

payments exceed its cumulative minimum payment levels applicable under

the regular exceptions process for cost reporting periods beginning

during which the hospital has been subject to the capital PPS; and (2)

any amount by which a hospital's current year operating and capital

payments (excluding 75 percent of operating DSH payments) exceed its

operating and capital costs. Under Sec. 412.348(g)(6), the minimum

payment level is 70 percent for all eligible hospitals.

Currently, as provided in Sec. 412.304(c)(2), we pay a new

hospital 85 percent of its reasonable costs during the first 2 years of

operation unless it elects to receive payment based on 100 percent of

the capital Federal rate. Effective with the third year of operation,

we pay the hospital based on 100 percent of the capital Federal rate

(that is, the same methodology used to pay all other hospitals subject

to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index

(CIPI) is a fixed-weight price index that measures the price changes

associated with capital costs during a given year. The CIPI differs

from the operating input price index in one important aspect--the CIPI

reflects the vintage nature of capital, which is the acquisition and

use of capital over time. Capital expenses in any given year are

determined by the stock of capital in that year (that is, capital that

remains on hand from all current and prior capital acquisitions). An

index measuring capital price changes needs to reflect this vintage

nature of capital. Therefore, the CIPI was developed to capture the

vintage nature of capital by using a weighted-average of past capital

purchase prices up to and including the current year.

We periodically update the base year for the operating and capital

input price indexes to reflect the changing composition of inputs for

operating and capital expenses. In this proposed rule, we are proposing

to rebase and revise the CIPI to a FY 2006 base year to reflect the

more current structure of capital costs in hospitals. A complete

[[Page 24260]]

discussion of this rebasing is provided in section IV.D. of the

preamble of this proposed rule. The CIPI was last rebased to FY 2002 in

the FY 2006 IPPS final rule (70 FR 47387).

2. Forecast of the CIPI for FY 2010

Based on the latest forecast by IHS Global Insight, Inc. (first

quarter of 2009), we are forecasting the proposed FY 2006-based CIPI to

increase 1.2 percent in FY 2010. This reflects a projected 1.7 percent

increase in vintage-weighted depreciation prices (building and fixed

equipment, and movable equipment), and a 2.2 percent increase in other

capital expense prices in FY 2010, partially offset by a 1.7 percent

decline in vintage-weighted interest expenses in FY 2010. The weighted

average of these three factors produces the 1.2 percent increase for

the proposed FY 2006-based CIPI as a whole in FY 2010.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-

Increase Percentages

Historically, hospitals and hospital units excluded from the

prospective payment system received payment for inpatient hospital

services they furnished on the basis of reasonable costs, subject to a

rate-of-increase ceiling. An annual per discharge limit (the target

amount as defined in Sec. 413.40(a)) was set for each hospital or

hospital unit based on the hospital's own cost experience in its base

year. The target amount was multiplied by the Medicare discharges and

applied as an aggregate upper limit (the ceiling as defined in Sec.

413.40(a)) on total inpatient operating costs for a hospital's cost

reporting period. Prior to October 1, 1997, these payment provisions

applied consistently to all categories of excluded providers

(rehabilitation hospitals and units (now referred to as IRFs),

psychiatric hospitals and units (now referred to as IPFs), LTCHs,

children's hospitals, and cancer hospitals).

Payments for services furnished in children's hospitals and cancer

hospitals that are excluded from the IPPS continue to be subject to the

rate-of-increase ceiling based on the hospital's own historical cost

experience. (We note that, in accordance with Sec. 403.752(a), RNHCIs

are also subject to the rate-of-increase limits established under Sec.

413.40 of the regulations.)

We are proposing that the FY 2010 rate-of-increase percentage for

cancer and children's hospitals and RNHCIs be the estimated percentage

increase in the FY 2010 IPPS operating market basket, estimated to be

2.1 percent, in accordance with applicable regulations at Sec. 413.40.

We are proposing to use the most recent data available to determine the

estimated FY 2010 IPPS operating market basket based on IHS Global

Insight, Inc.'s first quarter 2009 forecast of the IPPS operating

market basket increase, which is estimated to be 2.1 percent. (We are

proposing to use more recent data when determining the estimated

percentage increase for the FY 2010 IPPS operating market basket for

the final rule, to the extent these data are available.)

IRFs, IPFs, and LTCHs were previously paid under the reasonable

cost methodology. However, the statute was amended to provide for the

implementation of prospective payment systems for IRFs, IPFs, and

LTCHs. In general, the prospective payment systems for IRFs, IPFs, and

LTCHs provide transitioning periods of varying lengths of time during

which a portion of the prospective payment is based on cost-based

reimbursement rules under 42 CFR Part 413 (certain providers do not

receive a transitioning period or may elect to bypass the transition as

applicable under 42 CFR Part 412, Subparts N, O, and P). We note that

all of the various transitioning periods provided for under the IRF

PPS, the IPF PPS, and the LTCH PPS have ended.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We

refer readers to section VIII. of the preamble and section V. of the

Addendum to this proposed rule for the proposed update changes to the

Federal payment rates for LTCHs under the LTCH PPS for RY 2010. The

annual updates for the IRF PPS and the IPF PPS are issued by the agency

in separate Federal Register documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for RY 2010

A. Proposed LTCH PPS Standard Federal Rate for FY 2010

1. Background

In section VIII. of the preamble of this proposed rule, we discuss

our proposed changes to the payment rates, factors, and specific

policies under the LTCH PPS for RY 2010. At Sec. 412.523(c)(3)(ii) of

the regulations, for LTCH PPS rate years beginning RY 2004 through RY

2006, we updated the standard Federal rate by a rate increase factor to

adjust for the most recent estimate of the increases in prices of an

appropriate market basket of goods and services for LTCHs. We

established that policy of annually updating the standard Federal rate

because, at that time, we believed that was the most appropriate method

for updating the LTCH PPS standard Federal rate annually for years

after the initial implementation of the LTCH PPS in FY 2003. When we

moved the date of the annual update of the LTCH PPS from October 1 to

July 1 in the RY 2004 LTCH PPS final rule (68 FR 34138), we revised

Sec. 412.523(c)(3) to specify that, for LTCH PPS rate years beginning

on or after July 1, 2003, the annual update to the standard Federal

rate for the LTCH PPS would be equal to the previous rate year's

Federal rate updated by the most recent estimate of increases in the

appropriate market basket of goods and services included in covered

inpatient LTCH services. At that time, we believed that was the most

appropriate method for updating the LTCH PPS standard Federal rate

annually for years after RY 2004.

In the RY 2007 LTCH PPS final rule (71 FR 27818), we explained that

rather than solely using the most recent estimate of the LTCH PPS

market basket as the basis of the update factor for the standard

Federal rate for RY 2007, we believed that, based on our ongoing

monitoring activity, it was appropriate to adjust the standard Federal

rate to account for the changes in documentation and coding practices

(rather than patient severity of illness). We established regulations

at Sec. 412.523(c)(3)(iii) to specify that the update to the standard

Federal rate for the 2007 LTCH PPS rate year is zero percent. This was

based on the most recent estimate of the LTCH PPS market basket at the

time, which was offset by an adjustment to account for changes in case-

mix in prior periods due to changes in documentation and coding rather

than increased patient severity of illness in FY 2004. For the

following year, we also considered changes in documentation and coding

practices rather than patient severity of illness in establishing the

update to the standard Federal rate for the 2008 LTCH PPS rate year. In

the RY 2008 LTCH PPS final rule (72 FR 26887 through 27890), we

adjusted the standard Federal rate based on the most recent estimate of

the increase in the market basket (3.2 percent) and an adjustment to

account for changes in documentation and coding practices (2.49

percent) in FY 2005. Accordingly, we established regulations at Sec.

412.523(c)(3)(iv) to specify that the update to the standard Federal

rate for RY 2008 was 0.71 percent.

However, Public Law 110-173 (MMSEA), enacted on December 29, 2007,

contained a provision that addressed the standard Federal rate for RY

2008. Specifically, section 114(e)(1) of Public Law 110-173 provided

that under the added section 1886(m)(2) of

[[Page 24261]]

the Act, the standard Federal rate for RY 2008 shall be the same as the

standard Federal rate for RY 2007. In addition, section 114(e)(2) of

Public Law 110-173 specifically stated that the revised standard

Federal rate provided for under section 114(e)(1) ``shall not apply to

discharges occurring on or after July 1, 2007, and before April 1,

2008,'' effectively resulting in a delay of the application of the

updated standard Federal rate for RY 2007 established in the LTCH PPS

RY 2008 final rule (72 FR 26890). We implemented these statutory

provisions in an interim final rule with comment period (73 FR 24875

through 24877). Accordingly, we revised Sec. 412.523(c)(iv) to provide

that: (1) The standard Federal rate for the LTCH PPS RY 2008 is the

same as the standard Federal rate for the previous LTCH PPS RY, which

is RY 2007; and (2) for discharges occurring on or after July 1, 2007,

and before April 1, 2008, payments are based on the standard Federal

rate for LTCH PPS RY 2007, updated by 0.71 percent. Thus, effectively,

the standard Federal rate used to determine LTCH PPS payments for

discharges occurring on or after July 1, 2007, through March 31, 2008

is the standard Federal rate for RY 2007 updated by 0.71 percent, while

LTCH PPS payments for discharges occurring from April 1, 2008, through

June 30, 2008, are determined based on the standard Federal rate set

forth in section 114(e)(1) of Public Law 110-173 (that is, the same

standard Federal rate as the previous rate year (RY 2007)).

Consistent with our historical practice, in the RY 2009 LTCH PPS

final rule (73 FR 26806), we updated the standard Federal rate from the

previous year (that is, the standard Federal rate for RY 2008 as

established by section 1886(m)(2) of the Act) to determine the standard

Federal rate for RY 2009. In that same final rule, under the broad

authority conferred upon the Secretary by section 123 of the BBRA as

amended by section 307(b) of the BIPA, we established an annual update

to the standard Federal rate for RY 2009 based on the most recent

estimate of the increase in the LTCH PPS market basket of 3.6 percent

(for the 15-month rate year, which was based on the best available data

at that time) and an adjustment of -0.9 percent to account for the

increase in case-mix in a prior period (FY 2006) due to changes in

documentation and coding practices rather than an increase in patient

severity of illness. (As noted above, we established a 15-month period

for RY 2009 (July 1, 2008 through September 30, 2009) in order to move

the LTCH PPS annual rate update to an October 1 effective date

beginning October 1, 2009. We refer readers to 73 FR 26797 through

26798).) Accordingly, we established regulations at Sec.

412.523(c)(3)(v) to specify that the update to the standard Federal

rate for the 2009 LTCH PPS rate year is 2.7 percent.

2. Development of the Proposed RY 2010 LTCH PPS Standard Federal Rate

As noted above and as discussed in greater detail in the RY 2007,

RY 2008, and RY 2009 LTCH PPS final rules (71 FR 27819 through 27827,

72 FR 26887 through 2689, and 73 FR 26805 through 26812, respectively),

while we continue to believe that an update to the LTCH PPS standard

Federal rate should be based on the most recent estimate of the

increase in the LTCH PPS market basket, we also believe it is

appropriate that the standard Federal rate be offset by an adjustment

to account for any changes in documentation and coding practices that

do not reflect increased patient severity of illness. Such an

adjustment protects the integrity of the Medicare Trust Funds by

ensuring that the LTCH PPS payment rates better reflect the true costs

of treating LTCH patients. Furthermore, as we discussed most recently

in the RY 2009 final rule (73 FR 26805), we did not establish a case-

mix budget neutrality factor (that is, a documentation and coding

adjustment for changes in case-mix that are not due to changes in

patient severity of illness) for the adoption of the severity adjusted

MS-LTC-DRG patient classification system. Rather, we noted that,

consistent with past LTCH payment policy, we would continue to monitor

LTCH data and we could propose to make adjustments when updating the

LTCH PPS standard Federal rate in the future to account for changes in

documentation and coding that do not reflect any real changes in case-

mix during these years that we are implementing MS-LTC-DRGs.

As we discussed in greater detail in section VIII.C.3. of the

preamble of this proposed rule, we performed a case-mix index (CMI)

analysis using the most recent available LTCH claims data under both

the current MS-LTC-DRG and former CMS LTC-DRG patient classification

systems. Based on this evaluation, we have determined that there was a

total increase in LTCH CMI of 1.8 percent due to changes in

documentation and coding that did not reflect real changes in patient

severity of illness for LTCH discharges occurring in FY 2007 and FY

2008. Specifically, our analysis showed an increase in CMI of 0.5

percent in FY 2007 and 1.3 percent in FY 2008 due to changes in

documentation and coding that did not reflect increased patient

severity of illness (or costs).

At this time, the most recent estimate of the proposed increase in

the LTCH PPS market basket (that is, the FY 2002-based RPL market

basket) for RY 2010 is 2.4 percent, as discussed in section VIII.B.2.

of the preamble of this proposed rule. Consistent with our historical

practice, in this proposed rule, we are proposing to update the LTCH

PPS standard Federal rate for RY 2010 based on the full proposed LTCH

PPS market basket increase estimate of 2.4 percent and a proposed

adjustment to account for the increase in case-mix in prior periods

(FYs 2007 and 2008) that resulted from changes in documentation and

coding practices of 1.8 percent. Therefore, the proposed update factor

to the standard Federal rate for RY 2010 is 0.6 percent (that is, we

are proposing to apply a factor of 1.006 in determining the proposed

LTCH PPS standard Federal rate for RY 2010, calculated as 1.024 x 1

divided by 1.018 = 1.006 or 0.6 percent). That is, under the broad

authority conferred upon the Secretary under the BBRA and the BIPA to

determine appropriate updates under the LTCH PPS, we are proposing to

specify under Sec. 412.523(c)(3)(vi) that, for LTCH discharges

occurring on or after October 1, 2009, and on or before September 30,

2010, the standard Federal rate from the previous year would be updated

by 0.6 percent. In determining the proposed standard Federal rate for

RY 2010, we are applying the proposed 1.006 update factor to the RY

2009 Federal rate of $39,114.36 (as established in the RY 2009 LTCH PPS

final rule (73 FR 26812)). Consequently, the proposed standard Federal

rate for RY 2010 is $39,349.05. We also are proposing that if more

recent data become available, we would use that data, if appropriate,

to determine the update to the standard Federal rate for RY 2010 in the

final rule, and, thus, the standard Federal rate update noted in the

proposed regulation text at Sec. 412.523(c)(3)(vi) could change.

B. Proposed Adjustment for Area Wage Levels under the LTCH PPS for RY

2010

1. Background

Under the authority of section 123 of the BBRA as amended by

section 307(b) of the BIPA, we established an adjustment to the LTCH

PPS standard Federal rate to account for differences in LTCH area wage

levels at Sec. 412.525(c). The labor-related share of the LTCH PPS

standard Federal rate (discussed in greater detail in section VIII.C.2.

of the

[[Page 24262]]

preamble of this proposed rule), is adjusted to account for geographic

differences in area wage levels by applying the applicable LTCH PPS

wage index. The applicable LTCH PPS wage index is computed using wage

data from inpatient acute care hospitals without regard to

reclassification under section 1886(d)(8) or section 1886(d)(10) of the

Act.

As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR

56015), when we implemented the LTCH PPS, we established a 5-year

transition to the full wage index adjustment. The wage index adjustment

was completely phased-in for cost reporting periods beginning in FY

2007. Therefore, for cost reporting periods beginning on or after

October 1, 2006, the applicable LTCH wage index values are the full

(five-fifths) LTCH PPS wage index values calculated based on acute care

hospital inpatient wage index data without taking into account

geographic reclassification under section 1886(d)(8) and section

1886(d)(10) of the Act. For additional information on the phase-in of

the wage index adjustment under the LTCH PPS, we refer readers to the

August 30, 2002 LTCH PPS final rule (67 FR 56017 through 56019) and the

RY 2008 LTCH PPS final rule (72 FR 26891).

2. Proposed Updates to the Geographic Classifications/Labor Market Area

Definitions

a. Background

As discussed in the August 30, 2002 LTCH PPS final rule, which

implemented the LTCH PPS (67 FR 56015 through 56019), in establishing

an adjustment for area wage levels under Sec. 412.525(c), the labor-

related portion of a LTCH's Federal prospective payment is adjusted by

using an appropriate wage index based on the labor market area in which

the LTCH is located. In the RY 2006 LTCH PPS final rule (70 FR 24184

through 24185), in regulations at Sec. 412.525(c), we revised the

labor market area definitions used under the LTCH PPS effective for

discharges occurring on or after July 1, 2005, based on the Executive

OMB's CBSA designations which are based on 2000 Census data. We made

this revision because we believe that the CBSA-based labor market area

definitions will ensure that the LTCH PPS wage index adjustment most

appropriately accounts for and reflects the relative hospital wage

levels in the geographic area of the hospital as compared to the

national average hospital wage level. We note that these are the same

CBSA-based designations implemented for acute care hospitals under the

IPPS at Sec. 412.64(b), effective October 1, 2004 (69 FR 49026 through

49034). (For further discussion of the CBSA-based labor market area

(geographic classification) definitions currently used under the LTCH

PPS, we refer readers to the RY 2006 LTCH PPS final rule (70 FR 24182

through 24191).)

In the RY 2009 LTCH PPS final rule (73 FR 26814), we codified the

definitions of ``urban'' and ``rural'' in 42 CFR Part 412, Subpart O

(the subpart of the regulations specific to the LTCH PPS). Prior to

this codification, the application of the wage index adjustment under

Sec. 412.525(c)(2) was made on the basis of the location of the

facility in either an urban area or a rural area as defined in Sec.

412.64(b)(1)(ii)(A) through (C) of the regulations, which apply

specifically to the IPPS. Under that regulatory construction, existing

Sec. 412.525(c) indicated that the terms ``rural area'' and ``urban

area'' were defined according to the definitions of those terms under

the IPPS in 42 CFR Part 412, Subpart D. In that same final rule, we

revised Sec. 412.525(c) to specify that the application of the LTCH

PPS wage index adjustment is made on the basis of the location of the

LTCH in either an urban area or a rural area as defined in Sec.

412.503 because we believe it is administratively simpler to have the

LTCH PPS urban and rural labor market area definitions self-contained

in the regulations of the subpart specific to the LTCH PPS (Sec.

412.503) rather than specifying a cross-reference to the definitions of

urban area and rural area in the IPPS regulations in 42 CFR Part 412,

Subpart D. Thus, under Sec. 412.503, for discharges occurring on or

after July 1, 2008, an ``urban area'' under the LTCH PPS is defined as

a Metropolitan Statistical Area, as defined by OMB and a ``rural area''

is defined as any area outside of an urban area.

In addition, in the RY 2009 final rule (73 FR 26813 through 26814),

we clarified the change regarding the treatment of Litchfield County,

Connecticut (CT), and Merrimack County, New Hampshire (NH) CBSA-based

labor market area definitions. Specifically, we discussed that,

effective for LTCH PPS discharges occurring on or after July 1, 2008,

Litchfield County, CT, and Merrimack County, NH, are considered

``rural'' and are no longer considered as being part of urban CBSA

25540 (Hartford-West Hartford-East Hartford, CT) and urban CBSA 31700

(Manchester-Nashua, NH), respectively, as these areas had been in the

past as a result of a change to the regulations at Sec.

412.64(b)(1)(ii)(B) established in the FY 2008 IPPS final rule with

comment period (72 FR 47337 through 47338). In making this

clarification, we noted that this policy is consistent with our policy

of not taking into account IPPS geographic reclassifications in

determining payments under the LTCH PPS.

b. Update to the CBSA-Based Labor Market Area Definitions

The CBSA-based labor market area definitions used under the LTCH

PPS were last updated in the RY 2009 LTCH PPS final rule (73 FR 26812

through 26813) based on the most recent OMB bulletin available at that

time (December 18, 2006; OMB Bulletin No. 07-01). Since that time,

there have been two OMB bulletins announcing revisions to the CBSA

designations. First, on November 20, 2007, OMB announced the revision

of titles for eight urban areas (OMB Bulletin No. 08-01). This OMB

bulletin is available on the OMB Web site at: http://

www.whitehouse.gov/omb/assets/omb/bulletins/fy2008/b08-01.pdf. The

revised titles are as follows:

Hammonton, New Jersey qualifies as a new principal city of

the Atlantic City, New Jersey CBSA. The new title is Atlantic City-

Hammonton, New Jersey CBSA (CBSA 12100).

New Brunswick, New Jersey, located in the Edison, New

Jersey Metropolitan Division, qualifies as a new principal city of the

New York-Northern New Jersey-Long Island, New York, New Jersey,

Pennsylvania CBSA. The new title for the Metropolitan Division is

Edison-New Brunswick, New Jersey CBSA (CBSA 20764).

Summerville, South Carolina qualifies as a new principal

city of the Charleston-North Charleston, South Carolina CBSA. The new

title is Charleston-North Charleston-Summerville, South Carolina (CBSA

16700).

Winter Haven, Florida qualifies as a new principal city of

the Lakeland, Florida CBSA. The new title is Lakeland-Winter Haven,

Florida (CBSA 29460).

Bradenton, Florida replaces Sarasota, Florida as the most

populous principal city of the Sarasota-Bradenton-Venice, Florida CBSA

(currently CBSA 42260). The new title is Bradenton-Sarasota-Venice,

Florida. The new CBSA code is 14600.

Frederick, Maryland replaces Gaithersburg, Maryland as the

second most populous principal city in the Bethesda-Gaithersburg-

Frederick, Maryland CBSA. The new title is Bethesda-Frederick-

Gaithersburg, Maryland (CBSA 13644).

North Myrtle Beach, South Carolina replaces Conway, South

Carolina as the

[[Page 24263]]

second most populous principal city of the Myrtle Beach-Conway-North

Myrtle Beach, South Carolina CBSA. The new title is Myrtle Beach-North

Myrtle Beach-Conway, South Carolina (CBSA 34820).

Pasco, Washington replaces Richland, Washington as the

second most populous principal city of the Kennewick-Richland-Pasco,

Washington CBSA. The new title is Kennewick-Pasco-Richland, Washington

(CBSA 28420).

In this proposed rule, under the broad authority conferred upon the

Secretary by section 123 of the BBRA, as amended by section 307(b) of

BIPA to determine appropriate adjustments under the LTCH PPS, we are

proposing to apply these changes to the current CBSA-based labor market

area definitions and geographic classifications used under the LTCH PPS

effective for discharges occurring on or after October 1, 2009 (to the

extent that they are not changed by the later OMB Bulletin No. 90-1

discussed below). We believe these revisions to the LTCH PPS CBSA-based

labor market area definitions, which are based on the most recent

available data, would ensure that the LTCH PPS wage index adjustment

most appropriately accounts for and reflects the relative hospital wage

levels in the geographic area of the hospital as compared to the

national average hospital wage level. Accordingly, the proposed RY 2010

LTCH PPS wage index values presented in Tables 12A and 12B in the

Addendum of this proposed rule reflect the proposed revisions to the

CBSA-based labor market area definitions described above. We note that

the eight CBSA title revisions announced in OMB Bulletin No.08-01 do

not change the composition (constituent counties) of the affected

CBSAs; they only revise the CBSA titles (and do not change the CBSA

codes with the exception of the change in CBSA code 42260 to 14600). We

also note that these revisions were applicable under the IPPS beginning

October 1, 2008 (73 FR 48575).

Second, on November 20, 2008, OMB announced three Micropolitan

Statistical Areas that now qualify as MSAs and changed the principal

cities and titles of a number of CBSAs and a Metropolitan Division (OMB

Bulletin No. 09-01). This OMB bulletin is available on the OMB Web site

at: http://www.whitehouse.gov/omb/assets/omb/bulletins/fy2009/09-

01.pdf. The new urban CBSAs are as follows:

Cape Girardeau-Jackson, Missouri-Illinois (CBSA 16020).

This CBSA is comprised of the principal cities of Cape Girardeau and

Jackson, Missouri; Alexander County, Illinois; Bollinger County,

Missouri, and Cape Girardeau County, Missouri.

Manhattan, Kansas (CBSA 31740). This CBSA is comprised of

the principal city of Manhattan, Kansas in Geary County, Pottawatomie

County, and Riley County.

Mankato-North Mankato, Minnesota (CBSA 31860). This CBSA

is comprised of the principal cities of Mankato and North Mankato,

Minnesota in Blue Earth County and Nicollet County.

The changes in the principal cities and the revised titles are as

follows:

Broomfield, Colorado qualifies as a new principal city of

the Denver-Aurora, Colorado CBSA. The new title is Denver-Aurora-

Broomfield, Colorado (CBSA 19740).

Chapel Hill, North Carolina qualifies as a new principal

city of the Durham, North Carolina CBSA. The new title is Durham-Chapel

Hill, North Carolina (CBSA 20500).

Chowchilla, California qualifies as a new principal city

of the Madera, California CBSA. The new title is Madera-Chowchilla,

California (CBSA 31460).

Panama City Beach, Florida qualifies as a new principal

city of the Panama City-Lynn Haven, Florida CBSA. The new title is

Panama City-Lynn Haven-Panama City Beach, Florida (CBSA 37460).

East Wenatchee, Washington qualifies as a new principal

city of the Wenatchee, Washington CBSA. The new title is Wenatchee-East

Wenatchee, Washington (CBSA 48300).

Rockville, Maryland replaces Gaithersburg, Maryland as the

third most populous city of the Bethesda-Frederick-Gaithersburg,

Maryland Metropolitan Division. The new title is Bethesda-Frederick-

Rockville, Maryland Metropolitan Division (CBSA 13644).

In this proposed rule, under the broad authority conferred upon the

Secretary by section 123 of the BBRA, as amended by section 307(b) of

BIPA, to determine appropriate adjustments under the LTCH PPS, we are

proposing to apply these changes to the current CBSA-based labor market

area definitions and geographic classifications used under the LTCH PPS

effective for discharges occurring on or after October 1, 2009. We

believe these proposed revisions to the LTCH PPS CBSA-based labor

market area definitions, which are based on the most recent available

data, would ensure that the LTCH PPS wage index adjustment most

appropriately accounts for and reflects the relative hospital wage

levels in the geographic area of the hospital as compared to the

national average hospital wage level. Accordingly, the proposed RY 2010

LTCH PPS wage index values presented in Tables 12A and 12B in the

Addendum of this proposed rule reflect the revisions to the CBSA-based

labor market area definitions described above. We note that the six

CBSA title revisions noted above do not change the composition

(constituent counties) of the affected CBSAs; they only revise the CBSA

titles (and do not change the CBSA codes). We also note that we are

currently aware of only one LTCH located in one of the three new CBSAs

(CBSA 16020). As discussed in section III.C. of the preamble of this

proposed rule, the revisions to the CBSA-based designations are also

proposed for adoption under the IPPS effective beginning October 1,

2009.

3. Proposed LTCH PPS Labor-Related Share

As noted above in this section, under the adjustment for difference

in area wage levels at Sec. 412.525(c), the labor-related share of a

LTCH's PPS payment is adjusted by the applicable wage index for the

labor market area in which the LTCH is located. Specifically, as

discussed in section VIII.C.2.d. of the preamble of this proposed rule,

the LTCH PPS labor-related share is determined by our actuaries and is

based on data for the labor-related share of operating costs and

capital costs of the FY 2002-based RPL market basket. (Additional

background information on the historical development of the labor-

related share under the LTCH PPS can be found in the RY 2009 LTCH PPS

final rule (73 FR 26815). In the RY 2007 final rule (71 FR 27829

through 27830), we established a labor-related share based on the

relative importance of the labor-related share of operating costs

(wages and salaries, employee benefits, professional fees, postal

services, and all other labor-intensive services) and capital costs of

the RPL market basket based on FY 2002 data, as they are the best

available data that reflect the cost structure of LTCHs. For the past 2

years (RYs 2008 and 2009), we updated the LTCH PPS labor-related share

annually based on the latest available data for the RPL market basket.

For RY 2009, the labor-related share is 75.662 percent, as established

in the RY 2009 LTCH PPS final rule (73 FR 26815 through 26816), based

on the sum of the relative importance of the labor-related share of

operating costs (wages and salaries, employee benefits, professional

fees, and all other labor-intensive services) and capital costs of the

FY 2002-based RPL market basket from the first quarter

[[Page 24264]]

of 2008 forecast (the most recent available data at that time).

As discussed in section VIII.C. of the preamble of this proposed

rule, we are proposing to continue to use the FY 2002-based RPL market

basket used under the LTCH PPS for RY 2010. Furthermore, for RY 2010,

we are proposing to continue to define the LTCH PPS labor-related share

as the national average proportion of operating costs that are

attributable to wages and salaries, employee benefits, the labor-

related portion of professional fees, all other labor-intensive

services, and a labor-related portion of capital based on the FY 2002-

based RPL market basket. (As noted above, additional information on the

development of the FY 2002-based RPL market basket used under the LTCH

PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27808

through 27818).) Accordingly, consistent with our historical practice

of using the best available data, we are proposing to use IHS Global

Insight Inc.'s first quarter 2009 forecast of the FY 2002-based RPL

market basket for RY 2010 to determine the proposed labor-related share

for the LTCH PPS for RY 2010 that would be effective for discharges

occurring on or after October 1, 2009, and through September 30, 2010,

as these are the most recent available data. As shown in the chart in

section VIII.C.2.d. of the preamble of this proposed rule, based on the

latest available data (and the authority set forth in section 123 of

the BBRA as amended by section 307(b) of the BIPA) we are proposing to

establish a labor-related share of 75.904 percent under the LTCH PPS

for the RY 2010. Furthermore, consistent with our historical practice

of using the best data available, we also are proposing that if more

recent data are available to determine the labor-related share used

under the LTCH PPS for RY 2010, we would use these data for determining

the RY 2010 LTCH PPS labor-related share in the final rule.

4. Proposed LTCH PPS Wage Index for RY 2010

Historically, under the LTCH PPS, we have established LTCH PPS wage

index values calculated from acute care IPPS hospital wage data without

taking into account geographic reclassification under sections

1886(d)(8) and 1886(d)(10) of the Act. As we discussed in the August

30, 2002 LTCH PPS final rule (67 FR 56019), hospitals that are excluded

from the IPPS are not required to provide wage-related information on

the Medicare cost report. Therefore, we would need to establish

instructions for the collection of these LTCH data as well as develop

some type of application and determination process before a geographic

reclassification adjustment under the LTCH PPS could be implemented.

The wage adjustment established under the LTCH PPS is based on a LTCH's

actual location without regard to the urban or rural designation of any

related or affiliated provider. Acute care hospital inpatient wage

index data are also used to establish the wage index adjustment used in

other Medicare PPSs, such as the IRF PPS, the IPF PPS, the HHA PPS, and

the SNF PPS.

In the RY 2009 LTCH PPS final rule (73 FR 26816 through 26817), we

established LTCH PPS wage index values for RY 2009 calculated from the

same data collected from cost reports submitted by IPPS hospitals for

cost reporting periods beginning during FY 2004 that were used to

compute the FY 2008 acute care hospital inpatient wage index data

without taking into account geographic reclassification under sections

1886(d)(8) and 1886(d)(10) of the Act because these were the best

available data at that time. The LTCH PPS wage index values applicable

for discharges occurring on or after July 1, 2008, through September

30, 2009, were shown in Table 1 (for urban areas) and Table 2 (for

rural areas) in the Addendum to the RY 2009 LTCH PPS final rule (73 FR

26840 through 26863).

In this proposed rule, under the broad authority conferred upon the

Secretary by section 123 of the BBRA, as amended by section 307(b) of

BIPA, to determine appropriate adjustments under the LTCH PPS for RY

2010, we are proposing to use the same data collected from cost reports

submitted by IPPS hospitals for cost reporting periods beginning during

FY 2006 that are being used to compute the proposed FY 2010 acute care

hospital inpatient wage index data without taking into account

geographic reclassification under sections 1886(d)(8) and 1886(d)(10)

of the Act to determine the proposed applicable wage index values under

the LTCH PPS in RY 2010 because these data (FY 2006) are the most

recent complete data available at this time. (We note that due to the

change in the annual LTCH PPS rate year update cycle from July 1 to

October 1, effective October 1, 2009, established in the RY 2009 LTCH

PPS final rule, there is no longer a lag-time in the availability of

the IPPS hospital wage data used to develop the respective wage indices

used under the IPPS and LTCH PPS. Consequently, because the annual

update to the LTCH PPS and the IPPS now occurs on October 1 of each

year, we are able to propose wage index values using the same wage data

to develop the proposed LTCH wage index as is used to develop the

proposed IPPS wage index in a given year. Under the previous July 1

annual LTCH PPS rate year update cycle, due to the lag-time in the

availability of data, there was a 1-year lag-time in the best available

IPPS wage data to develop the LTCH PPS wage index each year (for

example, as noted above, we established RY 2009 LTCH PPS wage index

values from the same data collected from FY 2004 IPPS hospital cost

reports that were used to compute the FY 2008 IPPS wage index). We are

proposing to continue to use IPPS wage data as a proxy to determine the

proposed LTCH wage index values for RY 2010 because both LTCHs and

acute care hospitals are required to meet the same certification

criteria set forth in section 1861(e) of the Act to participate as a

hospital in the Medicare program and they both compete in the same

labor markets, and therefore, experience similar wage-related costs.

We also note that using the IPPS wage data to determine the

proposed RY 2010 LTCH wage index values reflects our policy under the

IPPS beginning in FY 2008 that apportions the wage data for multicampus

hospitals that are located in different labor market areas (CBSAs) to

each CBSA where the campuses are located. (For additional information,

we refer readers to the FY 2008 IPPS final rule with comment (72 FR

47317 through 47320), the FY 2009 IPPS final rule (73 FR 48582), and

section III.C. of the preamble of this proposed rule.) Specifically,

for the proposed RY 2010 LTCH PPS wage index values, which are computed

from IPPS wage data submitted by hospitals for cost reporting periods

beginning in FY 2006 (which are used to determine the proposed FY 2010

IPPS wage index discussed in section III.F. of the preamble of this

proposed rule), we allocated salaries and hours to the campuses of

three multicampus hospitals with campuses that are located in different

labor areas that are located in the following States: Massachusetts,

Illinois, and Michigan. Thus, consistent with the proposed FY 2010 IPPS

wage index, the proposed RY 2010 LTCH PPS wage index values for the

following CBSAs would be affected by this policy: Boston-Quincy, MA

(CBSA 14484); Providence-New Bedford-Falls River, RI-MA (CBSA 39300);

Chicago-Naperville-Joliet, IL (CBSA 16974); Lake County-Kenosha County,

IL-WI (CBSA 29404); Detroit-Livonia-Dearborn, MI (CBSA 19804); and

Warren-Troy-Farmington-Hills, MI (CBSA 47644) (reflected in Tables 12A

[[Page 24265]]

and 12B in the Addendum of this proposed rule).

The proposed RY 2010 LTCH PPS wage index values are computed

consistent with the urban and rural geographic classifications (labor

market areas) discussed in section V.B.2. of the Addendum of this

proposed rule and consistent with the pre-reclassified IPPS wage index

policy (that is, our historical policy of not taking into account IPPS

geographic reclassifications in determining payments under the LTCH

PPS). The proposed RY 2010 wage index values also reflect our

methodology for establishing wage index values in urban and rural areas

in which there are no IPPS wage data from which to compute a wage index

value (as described above in this section).

As previously noted, in the RY 2009 LTCH PPS final rule (73 FR

26817 through 26818), we established a methodology for determining a

LTCH PPS wage index value for areas that have no IPPS wage data. Under

this methodology, we stated that each year we would determine a wage

index value for any area in which there is no IPPS wage data based on

the methodologies described in that final rule. We believe it is

appropriate to establish a methodology for determining LTCH PPS wage

index values for areas with no IPPS wage data, if necessary, because

IPPS hospitals may open or close at any time, and therefore the number

of areas without any IPPS wage data may change from year to year. Even

when an IPPS hospital opens in an area where there are currently no

IPPS hospitals, there is a lag-time between the time a hospital opens

or becomes an IPPS provider and when the hospital's cost report wage

data are available to include in calculating the area wage index. The

policies established for determining LTCH PPS wage index values for

areas with no IPPS hospital wage data are consistent with the

methodologies that have been established under other Medicare postacute

care PPSs, such as SNF and HHA, as well as the IPPS. Below we discuss

the application of our established methodology for determining a

proposed LTCH PPS wage index value for RY 2010 for any areas in which

there is no IPPS wage data for cost reporting periods beginning during

FY 2006 (that is, for the areas in which there is no data in the IPPS

wage data that we are proposing to use to compute the proposed RY 2010

LTCH PPS wage index).

In this proposed rule, we are proposing to determine RY 2010 LTCH

PPS wage index values for labor market areas in which there is no IPPS

hospital wage data from which to compute a wage index value consistent

with the methodology we established in the RY 2009 LTCH PPS final rule

(73 FR 26817). As was the case in RY 2009, there are no LTCHs located

in labor areas where there is no IPPS hospital wage data (or IPPS

hospitals) for RY 2010. However, we continue to believe it is

appropriate to propose LTCH PPS wage index values for these areas using

our established methodology in the event that in the future a LTCH

should open in one of those areas.

Therefore, we are proposing to continue to determine a LTCH PPS

wage index value for urban CBSAs with no IPPS wage data by using an

average of all of the urban areas within the State to serve as a

reasonable proxy for determining the LTCH PPS wage index for an urban

area without specific IPPS hospital wage index data. We believe that an

average of all of the urban areas within the State is a reasonable

proxy for determining the LTCH PPS wage index for an urban area in the

State with no wage data because it is based on pre-reclassified IPPS

wage data, it is easy to evaluate, and it uses the most geographically

similar relative wage-related costs data available. Furthermore, as

noted above, this methodology has been adopted by other Medicare PPSs,

such as the SNF PPS and the HHA PPS.

Based on the FY 2006 IPPS wage data that we are proposing to use to

determine the proposed RY 2010 LTCH PPS wage index values, there are no

IPPS wage data for the urban area of Hinesville-Fort Stewart, GA (CBSA

25980). Consistent with our methodology for determining a LTCH PPS wage

index value for urban areas with no IPPS wage data (discussed above),

in this proposed rule, we calculated the proposed RY 2010 wage index

value for CBSA 25980 as the average of the proposed wage index values

for all of the other urban areas within the State of Georgia (that is,

CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580,

31420, 40660, 42340, 46660 and 47580) (reflected in Table 12A of the

Addendum of this proposed rule). (As noted above, there are currently

no LTCHs located in CBSA 25980.) As discussed in the RY 2009 final rule

(73 FR 26817), as IPPS wage data are dynamic, it is possible that urban

areas without IPPS wage data will vary in the future.

We also are proposing to continue to determine a LTCH PPS wage

index value for rural areas with no IPPS wage data using the unweighted

average of the wage indices from all of the CBSAs that are contiguous

to the rural counties of the State to serve as a reasonable proxy in

determining the LTCH PPS wage index for a rural area without specific

IPPS hospital wage index data. For this purpose, we are defining

``contiguous'' as sharing a border. We are not able to apply an

averaging in rural areas with no wage data similar to what we are doing

for urban areas with no wage data because there is no rural hospital

data available for averaging on a statewide basis. We believe that

using an unweighted average of the wage indices from all of the CBSAs

that are contiguous to the rural counties of the State is a reasonable

proxy for determining the wage index for rural areas in a State with no

wage data because it is based on pre-reclassified IPPS wage data, it is

easy to evaluate, and it uses the most geographically similar relative

wage-related costs data available.

Based on the FY 2006 IPPS wage data that we are proposing to use to

determine the proposed RY 2010 LTCH PPS wage index values, there are no

IPPS wage data for the rural area of Massachusetts (CBSA code 11).

Consistent with our methodology for determining a LTCH PPS wage index

value for rural areas with no IPPS wage data (discussed above), in this

proposed rule, we calculated the proposed RY 2010 wage index value for

rural Massachusetts by computing the unweighted average of the wage

indices from all of the CBSAs that are contiguous to the rural counties

in that State. Specifically, in the case of Massachusetts, the entire

rural area consists of Dukes and Nantucket counties. We determined that

the borders of Dukes and Nantucket counties are ``contiguous'' with

Barnstable County, MA, and Bristol County, MA. Therefore, the proposed

RY 2010 LTCH PPS wage index value for rural Massachusetts is computed

as the unweighted average of the proposed RY 2010 wage indexes for

Barnstable County and Bristol County (reflected in Tables 12A and 12B

in the Addendum of this proposed rule). (There are currently no LTCHs

located in rural Massachusetts.) As discussed in the RY 2009 final rule

(73 FR 26817), as IPPS wage data are dynamic, it is possible that rural

areas without IPPS wage data will vary in the future.

The proposed RY 2010 LTCH wage index values that would be

applicable for LTCH discharges occurring on or after October 1, 2009,

through September 30, 2010, are presented in Table 12A (for urban

areas) and Table 12B (for rural areas) in the Addendum of this proposed

rule.

[[Page 24266]]

5. Proposed LTCH PPS Cost-of-Living Adjustment for LTCHs Located in

Alaska and Hawaii

In the August 30, 2002 final rule (67 FR 56022), we established,

under Sec. 412.525(b), a cost-of-living adjustment (COLA) for LTCHs

located in Alaska and Hawaii to account for the higher costs incurred

in those States. In the RY 2009 LTCH PPS final rule (73 FR 26819)

(under the broad authority conferred upon the Secretary by section 123

of the BBRA as amended by section 307(b) of BIPA to determine

appropriate adjustments under the LTCH PPS, for RY 2009, we applied a

COLA to payments to LTCHs located in Alaska and Hawaii by multiplying

the standard Federal payment rate by the factors listed in Table III of

that same rule.

For RY 2010, under the broad authority conferred upon the Secretary

by section 123 of the BBRA as amended by section 307(b) of BIPA to

determine appropriate adjustments under the LTCH PPS, we are proposing

to apply a COLA to payments to LTCHs located in Alaska and Hawaii by

multiplying the proposed standard Federal payment rate by the factors

listed in the chart below because they are the most recent available

data at this time. These proposed factors were obtained from the U.S.

Office of Personnel Management (OPM) and are also proposed to be used

under the IPPS effective October 1, 2009 (section II.B.2. of the

Addendum of this proposed rule). In addition, we are proposing that if

OPM releases revised COLA factors before publication of the final rule,

we would use the revised factors for the development of LTCH PPS

payments for RY 2010 and publish those revised COLA factors in the

final rule.

Proposed Cost-of-Living Adjustment Factors for Alaska and Hawaii

Hospitals for the 2010 LTCH PPS Rate Year

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Alaska:

City of Anchorage and 80-kilometer (50-mile) radius by road.. 1.23

City of Fairbanks and 80-kilometer (50-mile) radius by road.. 1.23

City of Juneau and 80-kilometer (50-mile) radius by road..... 1.23

All other areas of Alaska.................................... 1.25

Hawaii:

City and County of Honolulu.................................. 1.25

County of Hawaii............................................. 1.18

County of Kauai.............................................. 1.25

County of Maui and County of Kalawao......................... 1.25

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C. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. Background

Under the broad authority conferred upon the Secretary by section

123 of the BBRA as amended by section 307(b) of BIPA, in the

regulations at Sec. 412.525(a), we established an adjustment for

additional payments for outlier cases that have extraordinarily high

costs relative to the costs of most discharges. We refer to these cases

as high cost outliers (HCOs). Providing additional payments for

outliers strongly improves the accuracy of the LTCH PPS in determining

resource costs at the patient and hospital level. These additional

payments reduce the financial losses that would otherwise be incurred

when treating patients who require more costly care and, therefore,

reduce the incentives to underserve these patients. We set the outlier

threshold before the beginning of the applicable rate year so that

total estimated outlier payments are projected to equal 8 percent of

total estimated payments under the LTCH PPS. Outlier payments under the

LTCH PPS are determined consistent with the instructions issued for the

IPPS outlier policy.

Under Sec. 412.525(a) in the regulations (in conjunction with the

revised definition of ``LTC-DRG'' at Sec. 412.503), we make outlier

payments for any discharges if the estimated cost of a case exceeds the

adjusted LTCH PPS payment for the MS-LTC-DRG plus a fixed-loss amount.

Specifically, in accordance with Sec. 412.525(a)(3) (in conjunction

with the revised definition of ``LTC-DRG'' at Sec. 412.503), we pay

outlier cases 80 percent of the difference between the estimated cost

of the patient case and the outlier threshold, which is the sum of the

adjusted Federal prospective payment for the MS-LTC-DRG and the fixed-

loss amount. The fixed-loss amount is the amount used to limit the loss

that a hospital will incur under the outlier policy for a case with

unusually high costs. This results in Medicare and the LTCH sharing

financial risk in the treatment of extraordinarily costly cases. Under

the LTCH PPS HCO policy, the LTCH's loss is limited to the fixed-loss

amount and a fixed percentage (currently 80 percent) of costs above the

outlier threshold (MS-LTC-DRG payment plus the fixed-loss amount). The

fixed percentage of costs is called the marginal cost factor. We

calculate the estimated cost of a case by multiplying the Medicare

allowable covered charge by the overall hospital CCR.

Under the LTCH PPS, we determine a fixed-loss amount, that is, the

maximum loss that a LTCH can incur under the LTCH PPS for a case with

unusually high costs before the LTCH will receive any additional

payments. We calculate the fixed-loss amount by estimating aggregate

payments with and without an outlier policy. The fixed-loss amount will

result in estimated total outlier payments being projected to be equal

to 8 percent of projected total LTCH PPS payments. Currently, MedPAR

claims data and CCRs based on data from the most recent provider

specific file (PSF) (or from the applicable statewide average CCR if a

LTCH's CCR data are faulty or unavailable) are used to establish a

fixed-loss threshold amount under the LTCH PPS.

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

The following is a discussion of CCRs that are used in determining

payments for HCO and SSO cases under the LTCH PPS, at Sec. 412.525(a)

and Sec. 412.529, respectively. Although this section is specific to

HCO cases, because CCRs and the policies and methodologies pertaining

to them are used in determining payments for both HCO and SSO cases (to

determine the estimated cost of the case at Sec. 412.529(d)(2), we are

discussing the determination of CCRs under the LTCH PPS for both of

these type of cases simultaneously.

In determining both HCO payments (at Sec. 412.525(a)) and SSO

payments (at Sec. 412.529), we calculate the estimated cost of the

case by multiplying the LTCH's overall CCR by the Medicare allowable

charges for the case. In general, we use the LTCH's overall CCR, which

is computed based on either the most recently settled cost report or

the most recent tentatively settled cost report, whichever is from the

latest cost reporting period, in accordance with Sec.

412.525(a)(4)(iv)(B) and Sec. 412.529(c)(4)(iv)(B) for HCOs and SSOs,

respectively. (We note that, in some instances, we use an alternative

CCR, such as the statewide average CCR in accordance with the

regulations at Sec. 412.525(a)(4)(iv)(C) and Sec.

412.529(c)(4)(iv)(C), or a CCR that is specified by CMS or that is

requested by the hospital under the provisions of the regulations at

Sec. 412.525(a)(4)(iv)(A) and Sec. 412.529(c)(4)(iv)(A).) Under the

LTCH PPS, a single prospective payment per discharge is made for both

inpatient operating and capital-related costs. Therefore, we compute a

single ``overall'' or ``total'' LTCH-specific CCR based on the sum of

LTCH operating and capital costs (as described in

[[Page 24267]]

Chapter 3, section 150.24, of the Medicare Claims Processing Manual

(CMS Pub. 100-4)) as compared to total charges. Specifically, a LTCH's

CCR is calculated by dividing a LTCH's total Medicare costs (that is,

the sum of its operating and capital inpatient routine and ancillary

costs) by its total Medicare charges (that is, the sum of its operating

and capital inpatient routine and ancillary charges).

b. LTCH Total CCR Ceiling

Generally, a LTCH is assigned the applicable statewide average CCR

if, among other things, a LTCH's CCR is found to be in excess of the

applicable maximum CCR threshold (that is, the LTCH CCR ceiling). This

is because CCRs above this threshold are most likely due to faulty data

reporting or entry, and, therefore, CCRs based on erroneous data should

not be used to identify and make payments for outlier cases. Thus,

under our established policy, generally, if a LTCH's calculated CCR is

above the applicable ceiling, the applicable LTCH PPS statewide average

CCR is assigned to the LTCH instead of the CCR computed from its most

recent (settled or tentatively settled) cost report data.

In the FY 2009 IPPS final rule (73 FR 48682), in accordance with

Sec. 412.525(a)(4)(iv)(C)(2) for HCOs and Sec.

412.529(c)(4)(iv)(C)(2) for SSOs, using our established methodology for

determining the LTCH total CCR ceiling, based on IPPS total CCR data

from the December 2007 update of the Provider Specific File (PSF), we

established a total CCR ceiling of 1.262 under the LTCH PPS, effective

October 1, 2008, through September 30, 2009. (For further detail on our

current methodology for annually determining the LTCH total CCR

ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48119

through 48121).)

In this proposed rule, in accordance with Sec.

412.525(a)(4)(iv)(C)(2) for HCOs and Sec. 412.529(c)(4)(iv)(C)(2) for

SSOs, using our established methodology for determining the LTCH total

CCR ceiling (described above), based on IPPS total CCR data from the

December 2008 update of the PSF, we are proposing to establish a total

CCR ceiling of 1.227 under the LTCH PPS that would be effective for

discharges occurring on or after October 1, 2009, and on or before

September 30, 2010. We also are proposing that if more recent data

become available, we would use them to establish the LTCH PPS CCR

ceiling for RY 2010 in the final rule.

c. LTCH Statewide Average CCRs

Our general methodology established for determining the statewide

average CCRs used under the LTCH PPS is similar to our established

methodology for determining the LTCH total CCR ceiling (described

above) because it is based on ``total'' IPPS CCR data. Under the LTCH

PPS HCO policy at Sec. 412.525(a)(4)(iv)(C) and the SSO policy at

Sec. 412.529(c)(4)(iv)(C), the fiscal intermediary may use a statewide

average CCR, which is established annually by CMS, if it is unable to

determine an accurate CCR for a LTCH in one of the following

circumstances: (1) New LTCHs that have not yet submitted their first

Medicare cost report (for this purpose, consistent with current policy,

a new LTCH is defined as an entity that has not accepted assignment of

an existing hospital's provider agreement in accordance with Sec.

489.18); (2) LTCHs whose CCR is in excess of the LTCH CCR ceiling (as

discussed above); and (3) other LTCHs for whom data with which to

calculate a CCR are not available (for example, missing or faulty

data). (Other sources of data that the fiscal intermediary may consider

in determining a LTCH's CCR include data from a different cost

reporting period for the LTCH, data from the cost reporting period

preceding the period in which the hospital began to be paid as a LTCH

(that is, the period of at least 6 months that it was paid as a short-

term acute care hospital), or data from other comparable LTCHs, such as

LTCHs in the same chain or in the same region.)

In Table 8C of the Addendum to the FY 2009 IPPS final rule (73 FR

48998), in accordance with the regulations at Sec.

412.525(a)(4)(iv)(C) for HCOs and Sec. 412.529(c)(4)(iv)(C) for SSOs,

using our established methodology for determining the LTCH statewide

average CCRs, based on using the most recent complete IPPS total CCR

data from the March 2008 update of the PSF, we established the LTCH PPS

statewide average total CCRs for urban and rural hospitals effective

for discharges occurring on or after October 1, 2008, and on or before

September 30, 2009. (For further detail on our current methodology for

annually determining the LTCH statewide average CCRs, we refer readers

to the FY 2007 IPPS final rule (71 FR 48119 through 48121).)

In this proposed rule, using our established methodology for

determining the LTCH statewide average CCRs, based on the most recent

complete IPPS total CCR data from the December 2008 update of the PSF,

we are proposing LTCH PPS statewide average total CCRs for urban and

rural hospitals that would be effective for discharges occurring on or

after October 1, 2009, and through September 30, 2010, in Table 8C of

the Addendum to this proposed rule. We also are proposing that if more

recent data become available, we would use them to establish LTCH PPS

statewide average total CCRs for urban and rural hospitals for RY 2010

in the final rule.

We also note that all areas in the District of Columbia, New

Jersey, Puerto Rico, and Rhode Island are classified as urban;

therefore, there are no rural statewide average total CCRs listed for

those jurisdictions in Table 8C of the Addendum to this proposed rule.

This policy is consistent with the policy that we established when we

revised our methodology for determining the applicable LTCH statewide

average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121)

and as is the same as the policy applied under the IPPS. In addition,

although Massachusetts has areas that are designated as rural, there

are no short-term acute care IPPS hospitals or LTCHs located in those

areas as of March 2009. Therefore, for this proposed rule, there is no

rural statewide average total CCR listed for rural Massachusetts in

Table 8C of the Addendum of this proposed rule.

In addition, as we established when we revised our methodology for

determining the applicable LTCH statewide average CCRs in the FY 2007

IPPS final rule (71 FR 48120 through 48121), in determining the urban

and rural statewide average total CCRs for Maryland LTCHs paid under

the LTCH PPS, in this proposed rule, we use, as a proxy, the national

average total CCR for urban IPPS hospitals and the national average

total CCR for rural IPPS hospitals, respectively. We use this proxy

because we believe that the CCR data on the PSF for Maryland hospitals

may not be entirely accurate (as discussed in greater detail in that

same final rule (71 FR 48120)).

d. Reconciliation of LTCH HCO and SSO Payments

We note, under the LTCH PPS HCO policy at Sec.

412.525(a)(4)(iv)(D) and the LTCH PPS SSO policy at Sec.

412.529(c)(4)(iv)(D), the payments for HCO and SSO cases, respectively,

are subject to reconciliation. Specifically, any reconciliation of

outlier payments is based on the CCR that is calculated based on a

ratio of CCRs computed from the relevant cost report and charge data

determined at the time the cost report coinciding with the discharge is

settled. For additional information, we refer

[[Page 24268]]

readers to the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. Establishment of the Proposed LTCH PPS Fixed-Loss Amount for RY 2010

When we implemented the LTCH PPS, as discussed in the August 30,

2002 LTCH PPS final rule (67 FR 56022 through 56026), under the broad

authority of section 123 of the BBRA as amended by section 307(b) of

BIPA, we established a fixed-loss amount so that total estimated

outlier payments are projected to equal 8 percent of total estimated

payments under the LTCH PPS. To determine the fixed-loss amount, we

estimate outlier payments and total LTCH PPS payments for each case

using claims data from the MedPAR files. Specifically, to determine the

outlier payment for each case, we estimate the cost of the case by

multiplying the Medicare covered charges from the claim by the LTCH's

hospital specific CCR. Under Sec. 412.525(a)(3) (in conjunction with

the revised definition of ``LTC-DRG'' at Sec. 412.503), if the

estimated cost of the case exceeds the outlier threshold (the sum of

the adjusted Federal prospective payment for the MS-LTC-DRG and the

fixed-loss amount), we pay an outlier payment equal to 80 percent of

the difference between the estimated cost of the case and the outlier

threshold (the sum of the adjusted Federal prospective payment for the

MS-LTC-DRG and the fixed-loss amount).

In the RY 2009 LTCH PPS final rule (73 FR 26823), we used claims

data from the December 2007 update of the FY 2007 MedPAR claims data

and CCRs from the December 2007 update of the PSF to determine a fixed-

loss amount that would result in estimated outlier payments projected

to be equal to 8 percent of total estimated payments for the 2009 LTCH

PPS rate year. We determined the RY 2009 fixed-loss amount using the

MS-LTC-DRG classifications and relative weights from the version of the

GROUPER that was to be in effect as of the beginning of the 2009 LTCH

PPS rate year (July 1, 2008), that is, Version 25.0 of the GROUPER (as

established in the FY 2008 IPPS final rule (72 FR 47278). Furthermore,

in using CCRs from the December 2007 update of the PSF to determine the

RY 2009 fixed-loss amount, we used the FY 2008 applicable LTCH

``total'' CCR ceiling of 1.284 and LTCH statewide average ``total''

CCRs established in the FY 2008 IPPS final rule (72 FR 47404 and 48126

through 48127) such that the current applicable Statewide average CCR

was assigned if, among other things, a LTCH's CCR exceeded the current

ceiling (1.284).

Therefore, based on the data and policies described and under the

broad authority of section 123(a)(1) of the BBRA and section 307(b)(1)

of BIPA, in the RY 2009 LTCH PPS final rule, we established a fixed-

loss amount of $22,960 for RY 2009. Thus, for RY 2009, we currently pay

an outlier case 80 percent of the difference between the estimated cost

of the case and the outlier threshold (the sum of the adjusted Federal

LTCH payment for the MS-LTC-DRG and the fixed-loss amount of $22,960).

In this proposed rule, we are proposing to use the same methodology

that we used in the RY 2009 final rule to calculate the fixed-loss

amount for RY 2010 (using updated data and the proposed rates and

policies established in this proposed rule) in order to maintain

estimated HCO payments at the projected 8 percent of total estimated

LTCH PPS payments. Consistent with our historical practice of using the

best data available, in this proposed rule, in determining the proposed

fixed-loss amount for RY 2010, we used the most recent available LTCH

claims data and CCR data. Specifically, for this proposed rule, we used

LTCH claims data from the December 2008 update of the FY 2008 MedPAR

files and CCRs from the December 2008 update of the PSF to determine a

fixed-loss amount that would result in estimated outlier payments

projected to be equal to 8 percent of total estimated payments in RY

2010 because these data are the most recent complete LTCH data

currently available. Consistent with our historical practice of using

the best data available, we are proposing that if more recent LTCH

claims data become available, we will use them for determining the

fixed-loss amount for the 2010 LTCH PPS rate year in the final rule. We

are proposing to determine the proposed RY 2010 fixed-loss amount based

on the MS-LTC-DRG classifications and relative weights from the version

of the GROUPER that will be in effect as of the beginning of the 2010

LTCH PPS rate year (October 1, 2009), that is, proposed Version 27.0 of

the GROUPER (discussed in section VIII.B. of the preamble of this

proposed rule). Furthermore, in determining the proposed RY 2010 fixed-

loss amount using CCRs from the December 2008 update of the PSF, we

used the proposed RY 2010 LTCH ``total'' CCR ceiling of 1.227 and the

applicable proposed LTCH statewide average ``total'' CCRs presented in

Table 8C in the Addendum of this proposed rule such that the proposed

applicable statewide average CCR was assigned if, among other things, a

LTCH's CCR exceeded the proposed ceiling (1.227). We note that, in

determining the proposed RY 2010 fixed-loss amount in this proposed

rule using the CCRs from the December 2008 update of the PSF, there was

no need for us to independently assign the applicable proposed

statewide average CCR to any LTCHs, as none of the LTCHs' CCRs in the

PSF exceeds the proposed ceiling.

In this proposed rule, based on the data and policies described

earlier in this proposed rule under the broad authority of section

123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we are proposing

to establish a fixed-loss amount of $16,059 for the RY 2010. Thus, we

would pay an outlier case 80 percent of the difference between the

estimated cost of the case and the outlier threshold (the sum of the

adjusted Federal LTCH payment for the MS-LTC-DRG and the fixed-loss

amount of $16,059). The proposed fixed-loss amount for RY 2010 of

$16,059 is significantly lower than the RY 2009 fixed-loss amount of

$22,960. The proposed decrease in the fixed-loss amount for RY 2010 is

primarily due to the projected 2.8 percent increase in LTCH PPS

payments from RY 2009 to RY 2010 (discussed in greater detail in

section IX. of the Appendix A (the regulatory impact analysis) to this

proposed rule), which includes our current estimate that we are paying

less than the required 8 percent of total estimated LTCH PPS payments

as HCO payments in RY 2009 (as discussed below). Specifically, an

analysis of the most recent available LTCH PPS claims data (that is, FY

2008 claims from the December 2008 update of the MedPAR files)

indicates that the RY 2009 fixed-loss amount of $22,960 may result in

LTCH PPS HCO payments that fall below the estimated 8 percent

requirement. Specifically, we currently estimate that HCO payments are

approximately 6.1 percent of estimated total LTCH PPS payments in RY

2009.

In addition to the estimated increase in LTCH PPS payments in RY

2010 as compared to RY 2009 due to the projected increase in HCO

payments, as we discuss in section IX. of Appendix A to this proposed

rule, we estimate an increase LTCH PPS payments in RY 2010 due to the

proposed update to the standard Federal rate and a projected increase

in the payments for SSO cases that are paid based on the estimated cost

of the case. For these reasons, we believe that proposing to lower the

fixed-loss amount is appropriate and necessary to maintain that

estimated outlier payments would equal 8 percent

[[Page 24269]]

of estimated total LTCH PPS payments as required under Sec.

412.525(a). Maintaining the fixed-loss amount at the current level

would result in HCO payments that are significantly less than the

current regulatory requirement that estimated outlier payments be

projected to equal 8 percent of estimated total LTCH PPS payments. As

we explained in past LTCH PPS rules (such as the RY 2006 LTCH PPS final

rule (70 FR 24195 through 24196)), proposing to lower the fixed-loss

amount results in more cases qualifying as outlier cases as well as

increases the amount of the additional payment for a HCO case because

the maximum loss that a LTCH must incur before receiving an HCO payment

(that is, the fixed-loss amount) would be smaller. Thus, in order to

maintain that estimated HCO payments in RY 2010 will be equal to 8

percent of estimated total RY 2010 LTCH PPS payments, we believe it is

appropriate to lower the fixed-loss amount.

In the August 30, 2002 final rule (67 FR 56022 through 56024),

based on our regression analysis, we established the outlier ``target''

at 8 percent of estimated total LTCH PPS payments to allow us to

achieve a balance between the ``conflicting considerations of the need

to protect hospitals with costly cases, while maintaining incentives to

improve overall efficiency.'' We continue to believe that a HCO target

of 8 percent is appropriate, as discussed in greater detail below.

However, we are soliciting public comments on whether we should revisit

the regression analysis noted above in this section that was used to

establish the existing 8 percent outlier target, using the most recent

available data to evaluate whether the current outlier target of 8

percent should be adjusted, and which therefore may mitigate the

magnitude of the proposed change in the fixed-loss amount for RY 2010.

As an alternative to proposing to lower the fixed-loss amount for

RY 2010, we also examined adjusting the marginal cost factor (that is,

the percentage that Medicare will pay of the estimated cost of a case

that exceeds the sum of the adjusted Federal prospective payment for

the MS-LTC-DRG and the fixed-loss amount for LTCH PPS HCO cases as

specified in Sec. 412.525(a)(3)), as a means of ensuring that

estimated outlier payments would be projected to equal 8 percent of

estimated total LTCH PPS payments. As we established in the August 30,

2002 final rule (67 FR 56022 through 56026), under the LTCH PPS HCO

policy at Sec. 412.525(a)(3), the marginal cost factor is currently

equal to 80 percent. As discussed in the RY 2007 LTCH PPS final rule

(71 FR 4677 through 4678), a marginal cost factor equal to 80 percent

means that, for an outlier case, we pay the LTCH 80 percent of the

difference between the estimated cost of the case and the outlier

threshold (the sum of the adjusted Federal rate for the MS-LTC-DRG PPS

payment and the fixed-loss amount). In addition, as we discussed in the

August 30, 2002 final rule (67 FR 56023) that implemented the LTCH PPS,

the marginal cost factor is designed to ensure ``a balance between the

need to protect LTCHs financially, while encouraging them to treat

expensive patients and maintaining the incentives of a prospective

payment system to improve the efficient delivery of care.'' Increasing

the marginal cost factor from the established 80 percent, without

reducing the current fixed-loss amount, would increase total estimated

outlier payments because we would pay a larger percentage of the

estimated costs that exceed the outlier threshold (the sum of the

adjusted Federal rate for the MS-LTC-DRG and the fixed-loss amount).

For example, if we were to increase the marginal cost factor to 90

percent without lowering the fixed-loss amount, we would pay outlier

cases 10 percent more of the estimated costs that exceed the HCO

threshold. While this alternative could ensure that outlier payments

are projected to equal 8 percent of estimated total LTCH PPS payments

by increasing estimated aggregate HCO payments, it may not maintain the

existing balance between providing an incentive for LTCHs to treat

expensive patients and improving the efficient delivery of care because

a policy such as this would reduce the incentive to provide cost

efficient care that is in effect under the current HCO policy (with an

80 percent marginal cost factor). Such a result would be inconsistent

with the intent of the LTCH PPS HCO policy (noted above) as stated when

we implemented the LTCH PPS in the August 30, 2002 final rule (67

FR56025). As we discussed in that same final rule (67 FR 56023 through

56024), our analysis of payment-to-cost ratios for HCO cases showed

that a marginal cost factor of 80 percent appropriately addresses cases

that are significantly more expensive than nonoutlier cases, while

simultaneously maintaining the integrity of the LTCH PPS. Accordingly,

we are not proposing to adjust the marginal cost factor under the LTCH

PPS HCO policy at this time. However, we are soliciting public comments

on whether we should revisit the regression analysis that was used to

establish the existing 80 percent marginal cost factor, using the most

recent available data to evaluate whether the current marginal cost

factor of 8 percent in the current HCO policy should be adjusted, and

therefore may mitigate the proposed change in the fixed-loss amount for

RY 2010. We note that, as we discussed in the RY 2009 LTCH PPS final

rule (73 FR 26824 through 26825), for the past several rate years, in

proposing changes to the fixed-loss amount we solicited public comments

on whether we should revisit the regression analysis referenced above

that was used to establish the existing 8 percent outlier target and 80

percent marginal cost factor, using the most recent available data to

evaluate whether the current outlier target of 8 percent or the 80

percent marginal cost factor should be adjusted and, therefore, could

have mitigated the magnitude of the change in the fixed-loss amount for

RYs 2007, 2008, and 2009, respectively. In response to these

solicitations, we received no public comments in support of any option

that would allow us to revisit the regression analysis that was used to

establish the existing 80 percent marginal cost factor and existing

outlier target of 8 percent, and the commenters agreed that keeping the

marginal cost factor at 80 percent and the outlier pool at 8 percent

better identifies LTCH patients that are unusually costly cases, and

that this policy appropriately addresses HCO cases that are

significantly more expensive than nonoutlier cases.

In summary, we are proposing to establish a fixed-loss amount of

$16,059 for RY 2010 based on the best available LTCH data and the

policies presented in this proposed rule because we believe a proposed

decrease in the fixed-loss amount for RY 2010 is appropriate and

necessary to maintain estimated outlier payments equal to 8 percent of

estimated total LTCH PPS payments, as required under Sec. 412.525(a).

As explained above in this section, in section IX of Appendix A to this

proposed rule, we are projecting an increase in total LTCH PPS payments

systemwide. In accordance with Sec. 412.523(d)(1), we reduce the

standard Federal rate by 8 percent for the estimated proportion of LTCH

PPS HCO payments. Because we are estimating an increase in the average

payment per discharge, thereby increasing total estimated LTCH PPS

payments, and because we are currently estimating that HCO payments in

RY 2009 may fall below the 8 percent target, we believe the fixed-loss

amount must be lowered in order to maintain total outlier payments that

are projected to equal 8 percent of total payments under the

[[Page 24270]]

LTCH PPS, in accordance with Sec. 412.525(a).

4. Application of Outlier Policy to SSO Cases

As we discussed in the August 30, 2002 final rule (67 FR 56026),

under some rare circumstances, a LTCH discharge could qualify as a SSO

case (as defined in the regulations at Sec. 412.529 in conjunction

with the regulations at Sec. 412.503) and also as a HCO case. In this

scenario, a patient could be hospitalized for less than five-sixths of

the geometric ALOS for the specific MS-LTC-DRG, and yet incur

extraordinarily high treatment costs. If the costs exceeded the high

cost outlier threshold (that is, the SSO payment plus the fixed-loss

amount), the discharge is eligible for payment as a HCO. Thus, for a

SSO case in the 2010 LTCH PPS rate year, the HCO payment would be 80

percent of the difference between the estimated cost of the case and

the outlier threshold (the sum of the proposed fixed-loss amount of

$16,059 and the amount paid under the SSO policy as specified in Sec.

412.529).

D. Computing the Proposed Adjusted LTCH PPS Federal Prospective

Payments for RY 2010

In accordance with Sec. 412.525, the proposed standard Federal

rate is adjusted to account for differences in area wages by

multiplying the proposed labor-related share of the proposed standard

Federal rate by the appropriate proposed LTCH PPS wage index (as shown

in Tables 12A and 12B of the Addendum of this proposed rule). The

proposed standard Federal rate is also adjusted to account for the

higher costs of hospitals in Alaska and Hawaii by multiplying the

proposed nonlabor-related share of the proposed standard Federal rate

by the appropriate proposed cost-of-living factor (shown in the chart

in section V.C.5. of the Addendum of this proposed rule). In this

proposed rule, we are proposing to establish a standard Federal rate

for the 2010 LTCH PPS rate year of $39,349.05, as discussed in section

V.A.2. of the Addendum of this proposed rule. We illustrate the

methodology to adjust the proposed Federal rate for the 2010 LTCH PPS

rate year in the following example:

Example: During the 2010 LTCH PPS rate year, a Medicare patient

is in a LTCH located in Chicago, Illinois (CBSA 16974). The proposed

RY 2010 LTCH PPS wage index value for CBSA 16974 is 1.0478 (Table

12A of the Addendum of this proposed rule). The Medicare patient is

classified into MS-LTC-DRG 28 (Spinal Procedures with MCC), which

has a proposed relative weight for RY 2010 of 1.1175 (Table 11 of

the Addendum of this proposed rule).

To calculate the LTCH's total adjusted Federal prospective

payment for this Medicare patient, we compute the wage-adjusted

proposed Federal prospective payment amount by multiplying the

unadjusted proposed standard Federal rate ($39,349.05) by the

proposed labor-related share (75.904 percent) and the proposed wage

index value (1.0478). This wage-adjusted amount is then added to the

proposed nonlabor-related portion of the unadjusted proposed

standard Federal rate (24.096 percent; adjusted for cost of living,

if applicable) to determine the adjusted proposed Federal rate,

which is then multiplied by the proposed MS-LTC-DRG relative weight

(1.1175) to calculate the total adjusted proposed Federal

prospective payment for the 2010 LTCH PPS rate year ($45,567.98).

The table below illustrates the components of the calculations in

this example.

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Unadjusted Proposed Standard Federal Prospective $39,349.05

Payment Rate........................................

Proposed Labor-Related Share......................... x 0.75904

Labor-Related Portion of the Proposed Federal Rate... = 29,867.50

Proposed Wage Index (CBSA 16974)..................... x 1.0478

Proposed Wage-Adjusted Labor Share of Proposed = 31,295.17

Federal Rate........................................

Proposed Nonlabor-Related Portion of the Proposed + 9,481.55

Federal Rate ($39,349.05 x 0.24096).................

Adjusted Proposed Federal Rate Amount................ = 40,776.72

Proposed MS-LTC-DRG 9 Relative Weight................ x 1.1175

Total Adjusted Proposed Federal Prospective = 45,567.98

Payment.........................................

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VI. Tables

This section contains the tables referred to throughout the

preamble to this proposed rule and in this Addendum. Tables 1A, 1B, 1C,

1D, 1E, 2, 3A, 3B, 4A, 4B, 4C, 4D-1, 4D-2, 4F, 4J, 5, 7A, 7B, 8A, 8B,

8C, 9A, 9C, 10, 11, 12A, and 12B are presented below. Table 6G.--

Additions to the CC Exclusions List, Table 6H.--Deletions from the CC

Exclusions List, Table 6I.--Complete List of Complication and

Comorbidity (CC) Exclusions, Table 6J.--Major Complication and

Comorbidity (MCC) List, and Table 6K.--Complications and Comorbidity

(CC) List are available only through the Internet on the CMS Web site

at: http://www.cms.hhs.gov/AcuteInpatientPPS/. The tables presented

below are as follows:

Table 1A.--National Adjusted Operating Standardized Amounts, Labor/

Nonlabor (67.1 Percent Labor Share/32.9 Percent Nonlabor Share If

Wage Index Is Greater Than 1)

Table 1B.--National Adjusted Operating Standardized Amounts, Labor/

Nonlabor (62 Percent Labor Share/38 Percent Nonlabor Share If Wage

Index Is Less Than or Equal To 1)

Table 1C.--Adjusted Operating Standardized Amounts for Puerto Rico,

Labor/Nonlabor

Table 1D.--Capital Standard Federal Payment Rate

Table 1E.--LTCH Standard Federal Prospective Payment Rate

Table 2.--Acute Care Hospitals Case-Mix Indexes for Discharges

Occurring in Federal Fiscal Year 2008; Hospital Wage Indexes for

Federal Fiscal Year 2010; Hospital Average Hourly Wages for Federal

Fiscal Years 2008 (2004 Wage Data), 2009 (2005 Wage Data), and 2010

(2006 Wage Data); and 3-Year Average of Hospital Average Hourly

Wages

Table 3A.--FY 2010 and 3-Year Average Hourly Wage for Acute Care

Hospitals in Urban Areas by CBSA

Table 3B.--FY 2010 and 3-Year Average Hourly Wage for Acute Care

Hospitals in Rural Areas by CBSA

Table 4A.--Wage Index and Capital Geographic Adjustment Factor (GAF)

for Acute Care Hospitals in Urban Areas by CBSA and by State--FY

2010

Table 4B.--Wage Index and Capital Geographic Adjustment Factor (GAF)

for Acute Care Hospitals in Rural Areas by CBSA and by State--FY

2010

Table 4C.--Wage Index and Capital Geographic Adjustment Factor (GAF)

for Acute Care Hospitals That Are Reclassified by CBSA and by

State--FY 2010

Table 4D-1.--Rural Floor Budget Neutrality Factors for Acute Care

Hospitals--FY 2010

Table 4D-2.--Urban Areas with Acute Care Hospitals Receiving the

Statewide Rural Floor or Imputed Floor Wage Index--FY 2010

Table 4E.--Urban CBSAs and Constituent Counties for Acute Care

Hospitals--FY 2010

Table 4F.--Puerto Rico Wage Index and Capital Geographic Adjustment

Factor (GAF) for Acute Care Hospitals by CBSA--FY 2010

Table 4J.--Out-Migration Adjustment for Acute Care Hospitals--FY

2010

Table 5.--List of Medicare Severity Diagnosis-Related Groups (MS-

DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean

Length of Stay

Table 6A.--New Diagnosis Codes

Table 6B.--New Procedure Codes

Table 6C.--Invalid Diagnosis Codes

[[Page 24271]]

Table 6D.--Invalid Procedure Codes

Table 6E.--Revised Diagnosis Code Titles

Table 6F.--Revised Procedure Code Titles

Table 7A.--Medicare Prospective Payment System Selected Percentile

Lengths of Stay: FY 2008 MedPAR Update--December 2008 GROUPER V26.0

MS-DRGs

Table 7B.--Medicare Prospective Payment System Selected Percentile

Lengths of Stay: FY 2008 MedPAR Update--December 2008 GROUPER V27.0

MS-DRGs

Table 8A.--Proposed Statewide Average Operating Cost-to-Charge

Ratios (CCRs) for Acute Care Hospitals--March 2009

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Table 8B.--Proposed Statewide Average Capital Cost-to-Charge Ratios

(CCRs) for Acute Care Hospitals--March 2009

Table 8C.--Proposed Statewide Average Total Cost-to-Charge Ratios

(CCRs) for LTCHs--March 2009

Table 9A.--Hospital Reclassifications and Redesignations--FY 2010

Table 9C.--Hospitals Redesignated as Rural under Section

1886(d)(8)(E) of the Act--FY 2010

Table 10.--Geometric Mean Plus the Lesser of .75 of the National

Adjusted Operating Standardized Payment Amount (Increased to Reflect

the Difference Between Costs and Charges) or .75 of One Standard

Deviation of Mean Charges by Medicare Severity Diagnosis-Related

Group (MS-DRG)--March 2009

Table 11.--Proposed MS-LTC-DRGs, Relative Weights, Geometric Average

Length of Stay, and Short-Stay Outlier (SSO) Threshold for

Discharges Occurring from October 1, 2009 through September 30, 2010

under the LTCH PPS

Table 12A.--LTCH PPS Wage Index for Urban Areas for Discharges

Occurring from October 1, 2009 through September 30, 2010

Table 12B.--LTCH PPS Wage Index for Rural Areas for Discharges

Occurring from October 1, 2009 through September 20, 2010

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[[Page 24272]]

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[[Page 24273]]

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From the Federal Register Online via GPO Access [wais.access.gpo.gov]

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[[pp. 24279-24328]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24278]]

[[Page 24279]]

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[[Page 24328]]

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[[pp. 24329-24378]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24328]]

[[Page 24329]]

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[[Page 24364]]

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[[Page 24365]]

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[[Page 24366]]

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[[Page 24367]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.110

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[[Page 24378]]

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[[pp. 24379-24428]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24378]]

[[Page 24379]]

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[[Page 24382]]

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[[Page 24428]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.171

[[Continued on page 24429]]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

]

[[pp. 24429-24478]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24428]]

[[Page 24429]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.172

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[[Page 24478]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.221

[[Continued on page 24479]]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

]

[[pp. 24479-24528]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24478]]

[[Page 24479]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.222

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[GRAPHIC] [TIFF OMITTED] TP22MY09.271

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From the Federal Register Online via GPO Access [wais.access.gpo.gov]

]

[[pp. 24529-24578]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24528]]

[[Page 24529]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.272

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[[Page 24578]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.321

[[Continued on page 24579]]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

]

[[pp. 24579-24628]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24578]]

[[Page 24579]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.322

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[GRAPHIC] [TIFF OMITTED] TP22MY09.371

[[Continued on page 24629]]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

]

[[pp. 24629-24678]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24628]]

[[Page 24629]]

[GRAPHIC] [TIFF OMITTED] TP22MY09.372

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[GRAPHIC] [TIFF OMITTED] TP22MY09.393

[[Page 24651]]

Appendix A: Regulatory Impact Analysis

I. Overall Impact

We have examined the impacts of this proposed rule as required by

Executive Order 12866 (September 1993, Regulatory Planning and Review)

and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L.

96-354), section 1102(b) of the Social Security Act, the Unfunded

Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on

Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and

benefits of available regulatory alternatives and, if regulation is

necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety

effects, distributive impacts, and equity). A regulatory impact

analysis (RIA) must be prepared for major rules with economically

significant effects ($100 million or more in any 1 year).

We have determined that this proposed rule is a major rule as

defined in 5 U.S.C. 804(2). We estimate that the proposed changes for

FY 2010 acute care hospital operating and capital payments would

redistribute in excess of $100 million among different types of

inpatient cases. The proposed changes to rebase and revise the market

basket for purposes of the market basket update to the IPPS rates

required by the statute, in conjunction with other proposed payment

changes in this proposed rule, would result in an estimated $586

million decrease in FY 2010 operating payments (or 0.5 percent

decrease), and $393 million decrease in FY 2010 capital payments (or

4.8 percent decrease), or a total $979 million decrease in FY 2010

operating and capital payments to acute care hospitals. The impacts

analysis of the capital payments can be found in section VIII. of this

Appendix. In addition, as described in section IX. of this Appendix,

LTCHs are expected to experience an increase in payments by $135

million (or 2.8 percent).

Our operating impact estimate includes the proposed -2.5 percent

documentation and coding adjustment applied to the hospital-specific

rates, the -1.1 percent documentation and coding adjustment applied to

the Puerto Rico-specific rates and the -1.9 percent adjustment for

documentation and coding changes to the IPPS standardized amounts and

capital Federal rates for FY 2010. In addition, our operating impact

estimate includes the 2.1 percent market basket update to the

standardized amount. The estimates of IPPS operating payments to acute

care hospitals do not reflect any changes in hospital admissions or

real case-mix intensity, which would also affect overall payment

changes.

The RFA requires agencies to analyze options for regulatory relief

of small businesses. For purposes of the RFA, small entities include

small businesses, nonprofit organizations, and small government

jurisdictions. Most hospitals and most other providers and suppliers

are considered to be small entities, either by being nonprofit

organizations or by meeting the Small Business Administration

definition of a small business (having revenues of $34.5 million or

less in any 1 year). (For details on the latest standards for health

care providers, we refer readers to the Table of Small Business Size

Standards for NAIC 622 found on the Small Business Administration

Office of Size Standards Web site at: http://www.sba.gov/

contractingopportunities/officials/size/GC-SMALL-BUS-SIZE-

STANDARDS.html.) For purposes of the RFA, all hospitals and other

providers and suppliers are considered to be small entities.

Individuals and States are not included in the definition of a small

entity. We believe that the provisions of this proposed rule relating

to acute care hospitals would have a significant impact on small

entities as explained in this Appendix. Because we lack data on

individual hospital receipts, we cannot determine the number of small

proprietary LTCHs. Therefore, we are assuming that all LTCHs are

considered small entities for the purpose of the analysis in section

IX. of this Appendix. Medicare fiscal intermediaries and MACs are not

considered to be small entities. Because we acknowledge that many of

the affected entities are small entities, the analysis discussed

throughout the preamble of this proposed rule constitutes our proposed

regulatory flexibility analysis. Therefore, we are soliciting public

comments on our estimates and analysis of the impact of this proposed

rule on those small entities.

The Small Business Regulatory Enforcement Fairness Act of 1996

(SBREFA), Public Law 104-121, as amended by section 8302 of Public Law

110-28 (enacted on May 25, 2007), requires an agency to provide

compliance guides for each rule or group of related rules for which an

agency is required to prepare a final regulatory flexibility analysis.

The compliance guides associated with this proposed rule are available

on the CMS IPPS Web page at http://www.cms.hhs.gov/AcuteInpatientPPS/

01\_overview.asp. We also note that the Hospital Center Web page at

http://www.cms.hhs.gov/center/hospital.asp was developed to assist

hospitals in understanding and adapting to changes in Medicare

regulations and in billing and payment procedures. This Web page

provides hospitals with substantial downloadable explanatory materials.

In addition, section 1102(b) of the Act requires us to prepare a

regulatory impact analysis for any proposed or final rule that may have

a significant impact on the operations of a substantial number of small

rural hospitals. This analysis must conform to the provisions of

section 603 of the RFA. With the exception of hospitals located in

certain New England counties, for purposes of section 1102(b) of the

Act, we now define a small rural hospital as a hospital that is located

outside of an urban area and has fewer than 100 beds. Section 601(g) of

the Social Security Amendments of 1983 (Pub. L. 98-21) designated

hospitals in certain New England counties as belonging to the adjacent

urban area. Thus, for purposes of the IPPS and the LTCH PPS, we

continue to classify these hospitals as urban hospitals. (We refer

readers to Table 1 and section VI. of this Appendix for the

quantitative effects of the proposed policy changes under the IPPS for

operating costs.)

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L.

104-4) also requires that agencies assess anticipated costs and

benefits before issuing any rule whose mandates require spending in any

1 year of $100 million in 1995 dollars, updated annually for inflation.

That threshold level is currently approximately $133 million. This

proposed rule will not mandate any requirements for State, local, or

tribal governments, nor would it affect private sector costs.

Executive Order 13132 establishes certain requirements that an

agency must meet when it promulgates a proposed rule (and subsequent

final rule) that imposes substantial direct requirement costs on State

and local governments, preempts State law, or otherwise has Federalism

implications. As stated above, this proposed rule would not have a

substantial effect on State and local governments.

The following analysis, in conjunction with the remainder of this

document, demonstrates that this proposed rule is consistent with the

regulatory philosophy and principles identified in Executive Order

12866, the RFA, and section 1102(b) of the Act. The proposed rule would

affect payments to a substantial number of

[[Page 24652]]

small rural hospitals, as well as other classes of hospitals, and the

effects on some hospitals may be significant.

II. Objectives of the IPPS

The primary objective of the IPPS is to create incentives for

hospitals to operate efficiently and minimize unnecessary costs while

at the same time ensuring that payments are sufficient to adequately

compensate hospitals for their legitimate costs. In addition, we share

national goals of preserving the Medicare Hospital Insurance Trust

Fund.

We believe the proposed changes in this proposed rule would further

each of these goals while maintaining the financial viability of the

hospital industry and ensuring access to high quality health care for

Medicare beneficiaries. We expect that these proposed changes would

ensure that the outcomes of the prospective payment systems are

reasonable and equitable while avoiding or minimizing unintended

adverse consequences.

III. Limitations of Our Analysis

The following quantitative analysis presents the projected effects

of our proposed policy changes, as well as statutory changes effective

for FY 2010, on various hospital groups. We estimate the effects of

individual policy changes by estimating payments per case while holding

all other payment policies constant. We use the best data available,

but, generally, we do not attempt to make adjustments for future

changes in such variables as admissions, lengths of stay, or case-mix.

However, in the FY 2008 IPPS final rule with comment period, we

indicated that we believe that implementation of the MS-DRGs would lead

to increases in case-mix that do not reflect actual increases in

patients' severity of illness as a result of more comprehensive

documentation and coding. As explained in section II.D. of the preamble

of this proposed rule, the FY 2008 IPPS final rule with comment period

established a documentation and coding adjustment of -1.2 percent for

FY 2008, -1.8 percent for FY 2009, and -1.8 percent for FY 2010 to

maintain budget neutrality for the transition to the MS-DRGs.

Subsequently, Congress enacted Public Law 110-90. Section 7 of Public

Law 110-90 reduced the IPPS documentation and coding adjustment from -

1.2 percent to -0.6 percent for FY 2008 and from -1.8 percent to -0.9

percent for FY 2009. For FY 2010, we are proposing to reduce the

national standardized amount by an additional 1.9 percent. Based on our

analysis, described in II.D. of the preamble of this proposed rule, we

believe that, in FY 2008, hospitals experienced a documentation and

coding effect of 2.5 percent, which exceeds the FY 2008 documentation

and coding adjustment of 0.6 percent by 1.9 percent. Therefore, we are

proposing to reduce the national standardized amounts in FY 2010 by -

1.9 percent. We will address in the FY 2011 rulemaking cycle any change

in FY 2009 case-mix due to documentation and coding changes that do not

reflect real changes in case-mix for discharges occurring during FY

2009.

Furthermore, we believe that hospitals that are paid under the

hospital-specific payment rate, specifically SCHs and MDHs, experience

similar increases in case-mix due to documentation and coding changes

that do not reflect real changes in case-mix. Our actuarial office

estimates that hospitals paid under the hospital-specific rate

experienced a 4.8 percent increase in payments due to documentation and

coding changes in FY 2008 and FY 2009. We did not apply a documentation

and coding adjustment to the hospital-specific rates when we first

implemented the MS-DRG system. For FY 2010, we are proposing to reduce

the hospital-specific rate by 2.5 percent in FY 2010 to account for the

case-mix increase that occurred in FY 2008 due to changes in

documentation and coding under the adoption of MS-DRGs that do not

reflect real changes in case-mix. We will address any increase in case-

mix in FY 2009 due to changes in documentation and coding that do not

reflect real changes in case-mix in the FY 2011 rulemaking cycle.

Our analysis, as described in II.D. of the preamble, shows that

Puerto Rico hospitals experienced an increase in case-mix by 1.1

percent in FY 2008 due to changes in documentation and coding. We did

not apply a documentation and coding adjustment to the Puerto Rico-

specific rate when we first implemented the MS-DRG system. For FY 2010,

we are proposing to reduce the Puerto Rico-specific standardized amount

by 1.1 percent to account for the case-mix increase due to

documentation and coding that occurred in FY 2008. We will address any

increase in case-mix in FY 2009 for Puerto Rico hospitals in the FY

2011 rulemaking cycle.

The impacts shown below illustrate the impact of the proposed FY

2010 IPPS changes on acute care hospital operating payments, including

the proposed -1.9 percent FY 2010 documentation and coding adjustment

to the IPPS national standardized amounts, the -2.5 percent FY 2010

documentation and coding adjustment to the hospital-specific rates, and

the -1.1 percent FY 2010 documentation and coding adjustment to the

Puerto Rico-specific standardized amount. The proposed documentation

and coding adjustment that would be applicable to the Federal rate

under the LTCH PPS for RY 2010 is discussed in section IX. of this

Appendix. As we have done in the previous rules, we are soliciting

public comments and information about the anticipated effects of the

proposed changes on acute care hospitals and our methodology for

estimating them.

IV. Hospitals Included In and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating

and capital-related costs of acute care hospitals encompass most

general short-term, acute care hospitals that participate in the

Medicare program. There were 33 Indian Health Service hospitals in our

database, which we excluded from the analysis due to the special

characteristics of the prospective payment methodology for these

hospitals. Among other short-term, acute care hospitals, only the 46

such hospitals in Maryland remain excluded from the IPPS pursuant to

the waiver under section 1814(b)(3) of the Act.

As of March 2009, there are 3,513 IPPS acute care hospitals to be

included in our analysis. This represents about 58 percent of all

Medicare-participating hospitals. The majority of this impact analysis

focuses on this set of hospitals. There are also approximately 1,306

CAHs. These small, limited service hospitals are paid on the basis of

reasonable costs rather than under the IPPS. (We refer readers to

section VII. of this Appendix for a further description of the impact

of CAH-related proposed policy changes.) There are also 1,228 IPPS-

excluded hospitals and 2,209 IPPS-excluded hospital units. These IPPS-

excluded hospitals and units include IPFs, IRFs, LTCHs, RNHCIs,

children's hospitals, and cancer hospitals, which are paid under

separate payment systems. Changes in the prospective payment systems

for IPFs and IRFs are made through separate rulemaking. Payment impacts

for these IPPS-excluded hospitals and units are not included in this

proposed rule. The impact of the proposed update and policy changes to

the LTCH PPS for RY 2010 are discussed in section IX. of this Appendix.

V. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2009, there were 1,228 hospitals excluded from the

IPPS. Of these 1,228 hospitals, 78 children's

[[Page 24653]]

hospitals, 11 cancer hospitals, and 16 RNHCIs are being paid on a

reasonable cost basis subject to the rate-of-increase ceiling under

Sec. 413.40. The remaining providers, 223 IRFs and 406 LTCHs, are paid

the Federal prospective per discharge rate under the IRF PPS and the

LTCH PPS, respectively, and 1,312 IPFs are paid the Federal per diem

amount under the IPF PPS. As stated above, IRFs and IPFs are not

affected by rate updates in this proposed rule. The impacts of the

proposed changes to LTCHs are discussed in section IX. of this

Appendix. In addition, there are 1,312 IPF units located in hospitals

otherwise subject to the IPPS. There are 972 IRFs (paid under the IRF

PPS) located in hospitals otherwise subject to the IPPS.

In the past, certain hospitals and units excluded from the IPPS

have been paid based on their reasonable costs subject to limits as

established by the Tax Equity and Fiscal Responsibility Act of 1982

(TEFRA). Cancer and children's hospitals continue to be paid on a

reasonable cost basis subject to TEFRA limits for FY 2010. For these

hospitals (cancer and children's hospitals), consistent with the

authority provided in section 1886(b)(3)(B)(ii) of the Act, the

proposed update is the percentage increase in the FY 2010 IPPS

operating market basket. In compliance with section 404 of the MMA, in

this proposed rule, we are proposing to replace the FY 2002-based IPPS

operating and capital market baskets with the revised and rebased FY

2006-based IPPS operating and capital market baskets for FY 2010.

Therefore, consistent with current law, based on IHS Global Insight,

Inc.'s 2009 first quarter forecast, with historical data through the

2008 fourth quarter, we are estimating that the FY 2010 update to the

IPPS operating market basket will be 2.1 percent (that is, the current

estimate of the market basket rate-of-increase. In addition, in

accordance with Sec. 403.752(a) of the regulations, RNHCIs are paid

under Sec. 413.40, which also uses section 1886(b)(3)(B)(ii) of the

Act to update target amounts by the rate-of-increase percentage. For

RNHCIs, the proposed update is the percentage increase in the FY 2010

IPPS operating market basket increase, which is estimated to be 2.1

percent, based on IHS Global Insight, Inc.'s 2009 first quarter

forecast of the IPPS operating market basket increase.

The impact of the proposed update in the rate-of-increase limit on

those excluded hospitals depends on the cumulative cost increases

experienced by each excluded hospital since its applicable base period.

For excluded hospitals that have maintained their cost increases at a

level below the rate-of-increase limits since their base period, the

major effect is on the level of incentive payments these excluded

hospitals receive. Conversely, for excluded hospitals with per-case

cost increases above the cumulative update in their rate-of-increase

limits, the major effect is the amount of excess costs that will not be

reimbursed.

We note that, under Sec. 413.40(d)(3), an excluded hospital that

continues to be paid under the TEFRA system, whose costs exceed 110

percent of its rate-of-increase limit receives its rate-of-increase

limit plus 50 percent of the difference between its reasonable costs

and 110 percent of the limit, not to exceed 110 percent of its limit.

In addition, under the various provisions set forth in Sec. 413.40,

cancer and children's hospitals can obtain payment adjustments for

justifiable increases in operating costs that exceed the limit.

VI. Quantitative Effects of the Policy Changes Under the IPPS for

Operating Costs

A. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes

and payment rate updates for the IPPS for operating costs of acute care

hospitals. Updates to the capital payments to acute care hospitals are

discussed in section VIII. of this Appendix.

Based on the overall percentage change in payments per case

estimated using our payment simulation model, we estimate that total FY

2010 operating payments would decrease by 0.5 percent compared to FY

2009, largely due to the statutorily mandated update to the IPPS rates.

This amount also reflects the proposed FY 2010 documentation and coding

adjustments described above and in section II.D. of the preamble: -1.9

percent for the IPPS national standardized amounts, -2.5 percent for

the IPPS hospital specific rates, and -1.1 percent for the IPPS Puerto

Rico-specific standardized amount. The impacts do not illustrate

changes in hospital admissions or real case-mix intensity, which would

also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes

to each system. This section deals with changes to the operating

prospective payment system for acute care hospitals. Our payment

simulation model relies on the most recent available data to enable us

to estimate the impacts on payments per case of certain proposed

changes in this proposed rule. However, there are other proposed

changes for which we do not have data available that would allow us to

estimate the payment impacts using this model. For those proposed

changes, we have attempted to predict the payment impacts based upon

our experience and other more limited data.

The data used in developing the quantitative analyses of changes in

payments per case presented below are taken from the FY 2008 MedPAR

file and the most current Provider-Specific File that is used for

payment purposes. Although the analyses of the proposed changes to the

operating PPS do not incorporate cost data, data from the most recently

available hospital cost report were used to categorize hospitals. Our

analysis has several qualifications. First, in this analysis, we do not

make adjustments for future changes in such variables as admissions,

lengths of stay, or underlying growth in real case-mix. Second, due to

the interdependent nature of the IPPS payment components, it is very

difficult to precisely quantify the impact associated with each

proposed change. Third, we use various sources for the data used to

categorize hospitals in the tables. In some cases, particularly the

number of beds, there is a fair degree of variation in the data from

different sources. We have attempted to construct these variables with

the best available source overall. However, for individual hospitals,

some miscategorizations are possible.

Using cases from the FY 2008 MedPAR file, we simulated payments

under the operating IPPS given various combinations of payment

parameters. Any short-term, acute care hospitals not paid under the

IPPS (Indian Health Service hospitals and hospitals in Maryland) were

excluded from the simulations. The impact of payments under the capital

IPPS, or the impact of payments for costs other than inpatient

operating costs, are not analyzed in this section. Estimated payment

impacts of the capital IPPS for FY 2010 are discussed in section VIII.

of this Appendix.

The changes discussed separately below are the following:

The effects of the annual reclassification of diagnoses

and procedures, full implementation of the MS-DRG system and 100

percent cost-based MS-DRG relative weights.

The effects of the proposed changes in hospitals' wage

index values reflecting wage data from hospitals' cost reporting

periods beginning during FY 2006, compared to the FY 2005 wage data.

The effects of the proposed changes to the hospital labor-

related share,

[[Page 24654]]

where the proposed hospital labor-related share for hospitals with a

wage index greater than 1 has been rebased from 69.7 percent to 67.1

percent. Hospitals with a wage index less than or equal to 1 will

continue to have a hospital labor-related share of 62 percent.

The effects of the recalibration of the DRG relative

weights as required by section 1886(d)(4)(C) of the Act, including the

wage and recalibration budget neutrality factors.

The effects of geographic reclassifications by the MGCRB

that would be effective in FY 2010.

The effects of the second year of the 3-year transition to

apply rural floor budget neutrality adjustment at the State level. In

FY 2010, hospitals would receive a blended wage index that is 50

percent of a wage index with the State level rural and imputed floor

budget neutrality adjustment and 50 percent of a wage index with the

national budget neutrality adjustment.

The effects of section 505 of Public Law 108-173, which

provides for an increase in a hospital's wage index if the hospital

qualifies by meeting a threshold percentage of residents of the county

where the hospital is located who commute to work at hospitals in

counties with higher wage indexes.

The effect of the budget neutrality adjustment being made

for the adoption of the MS-DRGs under section 1886(d)(3)(A)(iv) of the

Act for the change in aggregate payments that is a result of changes in

the documentation and coding of discharges that do not reflect real

changes in case-mix. These documentation and coding adjustments include

a -1.9 percent documentation and coding adjustment for the national

standardized amount, a -2.5 percent documentation and coding adjustment

for the hospital-specific rate, and a -1.1 percent documentation and

coding adjustment for the Puerto Rico-specific rate.

The total estimated change in payments based on the

proposed FY 2010 policies relative to payments based on FY 2009

policies that include the proposed market basket update of 2.1 percent.

To illustrate the impacts of the proposed FY 2010 changes, our

analysis begins with a FY 2009 baseline simulation model using: the

proposed FY 2010 market basket update of 2.1 percent; the FY 2009 MS-

DRG GROUPER (Version 26.0); the most current CBSA designations for

hospitals based on OMB's MSA definitions; the FY 2009 wage index; and

no MGCRB reclassifications. Outlier payments are set at 5.1 percent of

total operating DRG and outlier payments.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a)

of Public Law 109-171, provides that, for FY 2007 and subsequent years,

the update factor will be reduced by 2.0 percentage points for any

hospital that does not submit quality data in a form and manner and at

a time specified by the Secretary. At the time this impact was

prepared, 94 hospitals did not receive the full market basket rate-of-

increase for FY 2009 because they failed the quality data submission

process. For purposes of the simulations shown below, we modeled the

proposed payment changes for FY 2010 using a reduced update for these

94 hospitals. However, we do not have enough information at this time

to determine which hospitals will not receive the full market basket

rate-of-increase for FY 2010.

Each policy change, statutorily or otherwise, is then added

incrementally to this baseline, finally arriving at an FY 2010 model

incorporating all of the proposed changes. This simulation allows us to

isolate the effects of each proposed change.

Our final comparison illustrates the proposed percent change in

payments per case from FY 2009 to FY 2010. Three factors not discussed

separately have significant impacts here. The first is the update to

the standardized amount. In accordance with section 1886(b)(3)(B)(i) of

the Act, we are proposing to update the standardized amounts for FY

2010 using the most recently forecasted hospital market basket increase

for FY 2010 of 2.1 percent. (Hospitals that fail to comply with the

quality data submission requirements to receive the full update will

receive an update reduced by 2.0 percentage points from 2.1 percent to

0.1 percent.) Under section 1886(b)(3)(B)(iv) of the Act, the updates

to the hospital-specific amounts for SCHs and for MDHs are also equal

to the market basket percentage increase, or 2.1 percent.

A second significant factor that affects the proposed changes in

hospitals' payments per case from FY 2010 to FY 2010 is the change in a

hospital's geographic reclassification status from one year to the

next. That is, payments may be reduced for hospitals reclassified in FY

2009 that are no longer reclassified in FY 2010. Conversely, payments

may increase for hospitals not reclassified in FY 2009 that are

reclassified in FY 2010. In addition, section 508 of Public Law 108-

173, the special reclassification provision, is set to expire in FY

2010. The section 508 reclassification is a nonbudget neutral

provision, so overall payments will be reduced as a result of the

expiration of this provision. In the impact analysis for this proposed

rule, the expiration of certain special exceptions as well as section

508 of Public Law 108-173 resulted in substantial impacts for a

relatively small number of hospitals in a particular category because

those providers would have lost their reclassification status resulting

in a percentage change in payments for the category to be below the

national mean.

A third significant factor is that we currently estimate that

actual outlier payments during FY 2009 will be 5.4 percent of total DRG

payments. When the FY 2008 final rule was published, we projected FY

2009 outlier payments would be 5.1 percent of total DRG plus outlier

payments; the average standardized amounts were offset correspondingly.

The effects of the higher than expected outlier payments during FY 2010

(as discussed in the Addendum to this proposed rule) are reflected in

the analyses below comparing our current estimates of FY 2009 payments

per case to estimated FY 2010 payments per case (with outlier payments

projected to equal 5.1 percent of total DRG payments).

B. Analysis of Table I

Table I displays the results of our analysis of the proposed

changes for FY 2010. The table categorizes hospitals by various

geographic and special payment consideration groups to illustrate the

varying impacts on different types of hospitals. The top row of the

table shows the overall impact on the 3,513 acute care hospitals

included in the analysis.

The next four rows of Table I contain hospitals categorized

according to their geographic location: all urban, which is further

divided into large urban and other urban; and rural. There are 2,535

hospitals located in urban areas included in our analysis. Among these,

there are 1,386 hospitals located in large urban areas (populations

over 1 million), and 1,149 hospitals in other urban areas (populations

of 1 million or fewer). In addition, there are 978 hospitals in rural

areas. The next two groupings are by bed-size categories, shown

separately for urban and rural hospitals. The final groupings by

geographic location are by census divisions, also shown separately for

urban and rural hospitals.

The second part of Table I shows hospital groups based on

hospitals' FY 2010 payment classifications, including any

reclassifications under section 1886(d)(10) of the Act. For example,

the

[[Page 24655]]

rows labeled urban, large urban, other urban, and rural show that the

numbers of hospitals paid based on these categorizations after

consideration of geographic reclassifications (including

reclassifications under section 1886(d)(8)(B) and section 1886(d)(8)(E)

of the Act that have implications for capital payments) are 2,585,

1,417, 1,168 and 928, respectively.

The next three groupings examine the impacts of the proposed

changes on hospitals grouped by whether or not they have GME residency

programs (teaching hospitals that receive an IME adjustment) or receive

DSH payments, or some combination of these two adjustments. There are

2,479 nonteaching hospitals in our analysis, 800 teaching hospitals

with fewer than 100 residents, and 234 teaching hospitals with 100 or

more residents.

In the DSH categories, hospitals are grouped according to their DSH

payment status, and whether they are considered urban or rural for DSH

purposes. The next category groups together hospitals considered urban

or rural, in terms of whether they receive the IME adjustment, the DSH

adjustment, both, or neither.

The next five rows examine the impacts of the proposed changes on

rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There

were 187 RRCs, 338 SCHs, 181 MDHs, 105 hospitals that are both SCHs and

RRCs, and 14 hospitals that are both an MDH and an RRC.

The next series of groupings are based on the type of ownership and

the hospital's Medicare utilization expressed as a percent of total

patient days. These data were taken from the FY 2006 Medicare cost

reports.

The next two groupings concern the geographic reclassification

status of hospitals. The first grouping displays all urban hospitals

that were reclassified by the MGCRB for FY 2010. The second grouping

shows the MGCRB rural reclassifications.

The final category shows the impact of the proposed policy changes

on the 20 cardiac hospitals in our analysis.

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[[Page 24656]]

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[[Page 24660]]

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[[Page 24661]]

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C. Effects of the Proposed Changes to the MS-DRG Reclassifications and

Relative Cost-Based Weights (Column 1)

In Column 1 of Table I, we present the effects of the proposed DRG

reclassifications, as discussed in section II. of the preamble to this

proposed rule. Section 1886(d)(4)(C)(i) of the Act requires us annually

to make appropriate classification changes in order to reflect changes

in treatment patterns, technology, and any other factors that may

change the relative use of hospital resources.

As discussed in the preamble of this proposed rule, the proposed FY

2010 DRG relative weights would be 100 percent cost-based and 100

percent MS-DRGs. For FY 2010, the MS-DRGs are calculated using the FY

2008 MedPAR data grouped to the Version 27.0 (FY 2010) DRGs. The

methods of calculating the proposed relative weights and the

reclassification changes to the GROUPER are described in more detail in

section II.H. of the preamble to this proposed rule. The proposed

changes to the relative weights and MS-DRGs shown in Column 2 are prior

to any offset for budget neutrality. Overall, hospitals would

experience a 0.2 percent increase in payments due to the changes in the

MS-DRGs and relative weights prior to budget neutrality. Urban

hospitals would experience a 0.3 percent increase in payments under the

updates to the relative weights and DRGs, while rural hospitals would

experience a 0.1 percent decrease in payments. Under the MS-DRG system,

rural hospitals would generally experience a decrease in payments from

recalibration due to the lower acuity of services provided.

D. Effects of the Application of Recalibration Budget Neutrality

(Column 2)

Column 2 shows the effects of the changes to the MS-DRGs and

relative weights with the application of the recalibration budget

neutrality factor to the standardized amounts. Consistent with section

1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration

budget neutrality factor to account for the changes in MS-DRGs and

relative weights to ensure that the overall payment impact is budget

neutral. Beginning in FY 2010, we are calculating a budget neutrality

factor to account for changes in MS-DRGs and relative weights

separately from the budget neutrality factor to account for changes in

wage data.

The ``All Hospitals'' line in Column 1 indicates that proposed

changes due to MS-DRGs and relative weights would increase payments by

0.2 percent before application of the budget neutrality factor. The

proposed recalibration budget neutrality factor is 0.997663, which is

applied to the standardized amount. Thus, the impact after accounting

only for budget neutrality for proposed changes to the MS-DRG relative

weights and classification is somewhat lower than the figures shown in

this column (approximately 0.2 percent). Consequentially, urban

hospitals would not experience a change in payments when recalibration

budget neutrality is applied, while rural hospitals would experience a

0.3 percent decrease in payments due to the lower acuity of services

provided.

E. Effects of Proposed Wage Index Changes (Column 3)

Section 1886(d)(3)(E) of the Act requires that, beginning October

1, 1993, we annually update the wage data used to calculate the wage

index. In accordance with this requirement, the proposed wage index for

acute care hospitals for FY 2010 is based on data submitted for

hospital cost reporting periods beginning on or after October 1, 2005

and before October 1, 2006. The estimated impact of the updated wage

data and labor share on hospital payments is isolated in Column 3 by

holding the other payment parameters constant in this simulation. That

is, Column 3 shows the percentage change in payments when going from a

model using the FY 2009 wage index, based on FY 2005 wage data, the

current labor-related share and having a 100-percent occupational mix

adjustment applied, to a model using the proposed FY 2010 pre-

reclassification wage index with the proposed labor-related share, also

having a 100-percent occupational mix adjustment applied, based on FY

2006 wage data (while holding other payment parameters such as use of

the Version 26.0 DRG GROUPER constant). The occupational mix adjustment

is based on the FY 2007/2008 occupational mix survey. The wage data

collected on the FY 2006 cost report include overhead costs for

contract labor that were not collected on FY 2005 and earlier cost

reports. The impacts below incorporate the effects of the FY 2006 wage

data collected on hospital cost reports, including additional overhead

costs for contract labor compared to the wage data from FY 2005 cost

reports that were used to calculate the FY 2009 wage index.

As discussed in section III. of this proposed rule, under section

1886(d)(3)(E) of the Act, the Secretary estimates from time to time the

proportion of payments that are labor-related. ``The Secretary shall

adjust the proportion (as estimated by the Secretary from time to time)

of hospitals' costs which are attributable to wages and wage-related

costs of the DRG prospective payment rates \* \* \* '' We refer to the

proportion of hospitals' costs that are attributable to wages and wage-

related costs as the ``labor-related share.''

The labor-related share is used to determine the proportion of the

national IPPS base payment rate to which the area wage index is

applied. In this proposed rule, we describe our updated methodology and

data sources to calculate the national labor-related share. Using the

proposed cost category weights from the FY 2006-based IPPS market

basket, we calculated a labor-related share of 67.1 percent,

approximately 3 percentage points lower than the current labor-related

share of 69.7 percent. Accordingly, in this proposed rule, we are

implementing a national labor-related share of 67.1 percent for

discharges occurring on or after October 1, 2009. This proposal only

affects hospitals with a wage index greater than 1. According to

section

[[Page 24662]]

1886(d)(3)(E)(ii) of the Act, hospitals with a wage index less than or

equal to 1 have their wage index adjusted to 62 percent of the national

standardized amount; therefore, these hospitals remain unaffected by

the labor-related share proposal. In addition, we are proposing to

update the labor-related share for Puerto Rico. Using FY 2006-based

Puerto Rico cost category weights, we calculated a labor-related share

of 60.347 percent, approximately 2 percentage points higher than the

current Puerto-Rico specific labor-related share of 58.721.

Accordingly, we are adopting an updated Puerto Rico labor-related share

of 60.3 percent.

Column 3 shows the impacts of updating the wage data using FY 2006

cost reports and the updated labor-related share. The payment changes

simulated in this column are used to calculate the wage budget

neutrality. Beginning in FY 2010, we are calculating separate wage

budget neutrality and recalibration budget neutrality factors, in

accordance with section 1886(d)(3)(E) of the Act, which specifies that

budget neutrality to account for wage changes or updates made under

that subparagraph must be made without regard to the 62 percent labor-

related share guaranteed under section 1886(d)(3)(E)(ii) of the Act.

Therefore, for FY 2010, we are calculating the wage budget neutrality

factor to ensure that payments under updated wage data and the proposed

labor-related share are budget neutral without regard to the lower

labor-related share of 62 percent applied to hospitals with a wage

index less than or equal to 1. In other words, the wage budget

neutrality is calculated under the assumption that all hospitals

receive the higher labor-related share of the standardized amount.

Column 3 shows the effects of the new wage data and new labor share

before budget neutrality under the assumption that all providers have

their wage index adjusted by the same labor-related share. Overall, the

new wage data would lead to a 0.0 percent change for all hospitals

before being combined with the proposed wage budget neutrality

adjustment shown in Column 5. Thus, the figures in this column are

estimated to be the same as what they otherwise would be if they also

illustrated a budget neutrality adjustment solely for changes to the

wage index. Among the regions, the largest increase is in the urban

Puerto Rico region, which experiences a 1.8 percent increase before

applying an adjustment for budget neutrality. The largest decline from

updating the wage data is seen in rural New England (0.5 percent

decrease).

In looking at the wage data itself, the national average hourly

wage increased 3.9 percent compared to FY 2009. Therefore, the only

manner in which to maintain or exceed the previous year's wage index

was to match or exceed the national 3.9 percent increase in average

hourly wage. Of the 3,469 hospitals with wage data for both FYs 2009

and 2010, 1,682, or 48.5 percent, experienced an average hourly wage

increase of 3.9 percent or more.

The following chart compares the shifts in proposed wage index

values for hospitals for FY 2010 relative to FY 2009. Among urban

hospitals, 29 will experience an increase of more than 5 percent and

less than 10 percent and 8 will experience an increase of more than 10

percent. Among rural hospitals, 8 will experience an increase of more

than 5 percent and less than 10 percent, and none will experience an

increase of more than 10 percent. However, 955 rural hospitals will

experience increases or decreases of less than 5 percent, while 2,427

urban hospitals will experience increases or decreases of less than 5

percent. Thirty-four urban hospitals will experience decreases in their

wage index values of more than 5 percent and less than 10 percent.

Eight urban hospitals will experience decreases in their wage index

values of greater than 10 percent. No rural hospitals will experience

decreases of more than 5 percent. These figures reflect proposed

changes in the wage index which is an adjustment to either 67.1 percent

or 62 percent of a hospital's proposed standardized amount, depending

upon whether its wage index is greater than 1.0 or less than or equal

to 1.0. Therefore, these figures are illustrating a somewhat larger

change in the wage index than would occur to the hospital's total

payment.

The following chart shows the projected impact for urban and rural

hospitals.

------------------------------------------------------------------------

Number of

hospitals

Percentage change in area wage index values -----------------

Urban Rural

------------------------------------------------------------------------

Increase more than 10 percent......................... 8 0

Increase more than 5 percent and less than 10 percent. 29 8

Increase or decrease less than 5 percent.............. 2,427 955

Decrease more than 5 percent and less than 10 percent. 34 0

Decrease more than 10 percent......................... 8 0

------------------------------------------------------------------------

F. Application of the Wage Budget Neutrality Factor (Column 4)

Column 4 shows the impact of the new wage data, new labor share

with the application of the wage budget neutrality factor. For FY 2010,

we will calculate the wage budget neutrality factor without regard to

the lower labor share of 62 percent for hospitals with a wage index

less than or equal to 1, in accordance with section 1886(d)(3)(E)(i) of

the Act. In other words, the wage budget neutrality is calculated under

the assumption that all hospitals receive the proposed labor-related

share of 67.1 percent of the standardized amount compared to the

current labor-related share of 69.7 percent of the standardized amount.

Because the wage data changes did not change overall payments

(displayed in Column 3), the wage budget neutrality factor is minimal

at 1.000404, and the overall payment change is 0.0 percent.

G. Combined Effects of Proposed MS-DRG and Wage Index Changes (Column

5)

Section 1886(d)(4)(C)(iii) of the Act requires that changes to MS-

DRG reclassifications and the relative weights cannot increase or

decrease aggregate payments. In addition, section 1886(d)(3)(E) of the

Act specifies that any updates or adjustments to the wage index are to

be budget neutral. We computed a proposed wage budget neutrality factor

of 1.000404, and a proposed recalibration budget neutrality factor of

0.997663 (which is applied to the Puerto Rico specific standardized

amount and the hospital-specific rates). The product of the two budget

neutrality factors is the cumulative wage and recalibration budget

neutrality factor. The proposed cumulative wage and recalibration

budget neutrality adjustment is 0.998066 or approximately -0.2 percent

which is applied to the national standardized amounts. Because the wage

budget neutrality and the recalibration budget neutrality are

calculated under different methodologies according to the statute, when

the two budget neutralities are combined and applied to the

standardized amount, the cumulative wage and recalibration budget

neutrality results in a 0.1 percent decrease in payments relative to no

budget neutrality adjustment at all. In Table I, the combined overall

impacts of the effects of both the proposed MS-DRG reclassifications

and the updated wage index are shown in Column 5. The estimated changes

shown in this column reflect the combined effects of the proposed

changes in Columns 2, 3,

[[Page 24663]]

and 4 and the proposed budget neutrality factors discussed previously.

We estimate that the combined impact of the proposed changes to the

relative weights and DRGs, the proposed updated wage data and proposed

changes to the labor share with budget neutrality applied will decrease

payments to hospitals located in all urban areas by approximately 0.1

percent. Rural hospitals would generally experience a decrease in

payments (-0.5 percent) primarily due to payment decreases under the

MS-DRGs. Among the rural hospital categories, rural hospitals with less

than 50 beds and rural New England hospitals will experience the

greatest decline in payment (-0.8 percent) primarily due to the

proposed changes to MS-DRGs and the relative cost weights.

H. Effects of MGCRB Reclassifications (Column 6)

Our impact analysis to this point has assumed acute care hospitals

are paid on the basis of their actual geographic location (with the

exception of ongoing policies that provide that certain hospitals

receive payments on other bases than where they are geographically

located). The proposed changes in Column 7 reflect the per case payment

impact of moving from this baseline to a simulation incorporating the

MGCRB decisions for FY 2010 which affect hospitals' wage index area

assignments.

By Spring of each year, the MGCRB makes reclassification

determinations that will be effective for the next fiscal year, which

begins on October 1. The MGCRB may approve a hospital's

reclassification request for the purpose of using another area's wage

index value. Hospitals may appeal denials of MGCRB decisions to the CMS

Administrator. Further, hospitals have 45 days from publication of the

IPPS rule in the Federal Register to decide whether to withdraw or

terminate an approved geographic reclassification for the following

year. This column reflects all MGCRB decisions, Administrator appeals

and decisions of hospitals for FY 2010 geographic reclassifications.

The overall effect of geographic reclassification is required by

section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for

the purposes of this impact analysis, we are proposing to apply an

adjustment of 0.991690 to ensure that the effects of the section

1886(d)(10) reclassifications are budget neutral. (See section II.A. of

the Addendum to this proposed rule.) Geographic reclassification

generally benefits hospitals in rural areas. We estimate that

geographic reclassification will increase payments to rural hospitals

by an average of 1.7 percent.

Table 9A of the Addendum to this proposed rule reflects the

approved reclassifications for FY 2010.

I. Effects of the Rural Floor and Imputed Floor, Including the

Transition To Apply Budget Neutrality at the State Level (Column 7)

As discussed in section III.B. of the preamble of the FY 2009 IPPS

final rule and this proposed rule, section 4410 of Public Law 105-33

established the rural floor by requiring that the wage index for a

hospital in any urban area cannot be less than the wage index received

by rural hospitals in the same State. In FY 2008, we changed how we

applied budget neutrality to the rural floor. Rather than applying a

budget neutrality adjustment to the standardized amount, a uniform

budget neutrality adjustment is applied to the wage index. In the FY

2009 final rule, we finalized the policy to apply the rural floor

budget neutrality at the State level with a 3-year transition. In FY

2009, hospitals received a blended wage index that is 20 percent of a

wage index with the State level rural and imputed floor budget

neutrality adjustment and 80 percent of a wage index with the national

budget neutrality adjustment. As described in FY 2009 IPPS final rule

(73 FR 48570), in FY 2010, hospitals will receive a blended wage index

that is 50 percent of a wage index with the State level rural and

imputed floor budget neutrality and 50 percent of a wage index with the

national budget neutrality adjustment. The national rural floor budget

neutrality applied to the wage index is 0.997466. The within-State

rural floor budget neutrality factors applied to the proposed wage

index are shown in Table 4D in the Addendum to this proposed rule.

After the wage index is blended, an additional adjustment of 1.000017

is applied to the wage index to ensure that payments before the

application of the rural floor are equivalent to the payments under the

blended budget neutral rural floor wage index.

Furthermore, the FY 2005 IPPS final rule (69 FR 49109) established

a temporary imputed floor for all urban States from FY 2005 to FY 2007.

The rural floor requires that an urban wage index cannot be lower than

the wage index for any rural hospital in that State. Therefore, an

imputed floor was established for States that do not have rural areas

or rural IPPS hospitals. In the FY 2008 IPPS final rule with comment

period (72 FR 47321), we finalized our proposal to extend the imputed

floor for 1 additional year. In the FY 2009 IPPS final rule (73 FR

48573), we extended the imputed floor for an additional 3 years through

FY 2011. Furthermore, in that final rule, we provided for a 3-year

transition to the rural floor budget neutrality adjustment at the State

level. Therefore, we also apply the imputed floor budget neutrality

adjustment at the State level through a 3-year transition, so that wage

indices adjusted for the imputed floor will be blended where 50 percent

of the wage index will have the national rural and imputed floor budget

neutrality factor applied and 50 percent of the wage index will have

the within-State rural and imputed budget neutrality factor applied.

The national rural floor budget neutrality factor listed also

incorporates the imputed floor in its adjustment to the wage index.

Column 7 shows the projected impact of the rural floor and the

imputed floor, including the application of the transition to within-

State rural and imputed floor budget neutrality. The column compares

the proposed post-reclassification FY 2010 wage index of providers

before the rural floor adjustment and the post-reclassification FY 2010

wage index of providers with the rural floor and imputed floor

adjustment. Only urban hospitals can benefit from the rural floor

provision. Because the provision is budget neutral, in prior years, all

other hospitals (that is, all rural hospitals and those urban hospitals

to which the adjustment is not made) had experienced a decrease in

payments due to the budget neutrality adjustment applied nationally.

However, because, for FY 2010, the rural floor adjusted wage index is

based on a blend where 50 percent of the wage index would have a

within-State budget neutrality factor applied and 50 percent of the

wage index would have a national rural floor budget neutrality factor

applied, rural hospitals and urban hospitals that do not benefit from

the rural floor will continue to see decreases in payments, to a lesser

extent. Conversely, all hospitals in States with hospitals receiving a

rural floor will have their wage indices only partly downwardly

adjusted to achieve budget neutrality within the State.

We project that, in aggregate, rural hospitals will experience a

0.1 percent decrease in payments as a result of the transition to

within-State rural floor budget neutrality because these hospitals do

not benefit from the rural floor, but have their wage indexes

downwardly adjusted to ensure that the application of the rural floor

is budget neutral overall. We project hospitals located in other urban

areas (populations of 1 million or fewer) will experience a 0.1 percent

increase in

[[Page 24664]]

payments because those providers benefit from the rural floor. Rural

hospitals located in the South Atlantic, East South Central and West

South Central and Pacific regions can expect the decreases in payments

by 0.1 percent. Urban Middle Atlantic hospitals can expect a payment

increase of 0.1 percent primarily due to payment increases among urban

hospitals in New Jersey, which is the only State that benefits from the

imputed floor.

J. Effects of the Proposed Wage Index Adjustment for Out-Migration

(Column 8)

Section 1886(d)(13) of the Act, as added by section 505 of Public

Law 108-173, provides for an increase in the wage index for hospitals

located in certain counties that have a relatively high percentage of

hospital employees who reside in the county, but work in a different

area with a higher wage index. Hospitals located in counties that

qualify for the payment adjustment are to receive an increase in the

wage index that is equal to a weighted average of the difference

between the wage index of the resident county, post-reclassification

and the higher wage index work area(s), weighted by the overall

percentage of workers who are employed in an area with a higher wage

index. With the out-migration adjustment, small rural providers with

less than 49 beds and MDHs will experience a 0.2 percent increase in

payments in FY 2010 relative to no adjustment at all. We included these

additional payments to providers in the impact table shown above, and

we estimate the impact of these providers receiving the out-migration

increase to be approximately $17 million.

K. Effects of All Proposed Changes Prior to Documentation and Coding

(or CMI) Adjustment (Column 9)

Column 9 shows our estimate of the change in operating payments

from FY 2009 and FY 2010 resulting from all proposed changes in this

rule other than the proposed documentation and coding adjustment. This

column includes a 2.1 percent market basket update to the standardized

amount. In addition, it reflects the -0.3 percentage point difference

between the projected outlier payments in FY 2009 (5.1 percent of total

MS-DRG payments) and the current estimate of the percentage of actual

outlier payments in FY 2009 (5.4 percent), as described in the

introduction to this Appendix and the Addendum to this proposed rule.

As a result, payments are projected to be 0.3 percentage points higher

in FY 2009 than originally estimated, resulting in a 0.3 percentage

point decrease for FY 2010 than would otherwise occur. This analysis

also accounts for the impact of expiration of certain special

exceptions and section 508 reclassification, a nonbudget neutral

provision, which results in a decrease in estimated payments by 0.2

percent. In addition, the separate calculation of wage budget

neutrality (which does not account for the 62 percent labor-related

share) from the recalibration budget neutrality (which does account for

the 62 percent labor-related share) results in a 0.2 percent decrease

in payments relative to last year. We estimate that overall payments to

hospitals paid under the IPPS would increase 1.4 percent prior to the

application of the proposed documentation and coding adjustment. For

the proposed rule, we are proposing to apply a -1.9 percent

documentation and coding adjustment to the IPPS national standardized

amount, a -2.5 documentation and coding adjustment applied to the

hospitals-specific rate, and a -1.1 documentation and coding adjustment

applied to the Puerto Rico-specific rate. Because SCHs and MDHs are

paid in whole or in part based on the hospital-specific rate if higher

than the rate based on the national standardized amount, these

hospitals may switch between these payment rates in Column 9 and Column

10.

Without the documentation and coding adjustments, hospitals located

in urban areas would experience higher payment increases (1.4 percent)

than hospitals in rural areas (0.8 percent) because urban hospitals

generally treat patients with higher acuity of illness and have a

higher case-mix under the MS-DRGs.

L. Effects of All Proposed Changes With CMI Adjustment (Column 10)

Column 10 shows our estimate of the changes in payments per

discharge from FY 2009 and FY 2010, resulting from all proposed changes

reflected in this proposed rule for FY 2010 (including statutory

changes). This column includes the proposed FY 2010 documentation and

coding adjustment of -1.9 percent on the national standardized amount,

-2.5 percent on the hospital-specific amount and -1.1 percent on the

Puerto Rico-specific rate, which overall accounts for a 1.9 percent

decrease in payments. Because the hospital payment projections are

based on FY 2008 Medicare claims data and we believe that case-mix was

expected to increase an additional 1.6 percent in FY 2009, the payment

models reflect a case-mix growth of 1.6 percent in FY 2009.

Column 10 reflects the impact of all proposed FY 2010 changes

relative to FY 2009, including those shown in Columns 1 through 9. The

average decrease in payments under the IPPS for all hospitals is

approximately 0.5 percent. As described in Column 9, this average

decrease includes the effects of the 2.1 percent market basket update,

the -0.3 percentage point difference between the projected outlier

payments in FY 2009 (5.1 percent of total DRG payments), the current

estimate of the percentage of actual outlier payments in FY 2009 (5.4

percent), the 0.2 percent decrease in payments due to the expiration of

section 508 reclassification, and the 0.2 percent decrease in payments

due to the calculation of wage and recalibration budget neutrality.

There might also be interactive effects among the various factors

comprising the payment system that we are not able to isolate. For

these reasons, the values in Column 10 may not equal the sum of the

percentage changes described above.

The overall proposed change in payments per discharge for hospitals

paid under the IPPS in FY 2010 is estimated to decrease by 0.5 percent.

The payment decreases among the hospital categories are largely

attributed to the proposed documentation and coding adjustments.

Hospitals in urban areas would experience an estimated 0.4 percent

decrease in payments per discharge in FY 2010 compared to FY 2009.

Hospitals in large urban areas would experience an estimated 0.4

percent decrease and hospitals in other urban areas would experience an

estimated 0.5 percent decrease in payments per discharge in FY 2010 as

compared to FY 2009. Hospital payments per discharge in rural areas are

estimated to decrease by 1.3 percent in FY 2010 as compared to FY 2009.

The decreases that are smaller than the national average for larger

urban areas and larger than the national average for rural areas are

largely attributed to the differential impact of adopting MS-DRGs and

due to the -1.9 percent documentation and coding adjustment applied to

the national standardized amount and the -2.5 percent documentation and

coding adjustment to the hospital-specific rate, applied to SCHs and

MDHs which are generally classified as rural hospitals.

Among urban census divisions, the largest estimated payment

decreases would be -0.9 percent in the Pacific region and -0.7 percent

in the Middle Atlantic region. Among the rural regions, the providers

in the New England region would experience the largest decrease in

payments (-2.5

[[Page 24665]]

percent) primarily due to a combination of the MS-DRG changes, the

transition to the State rural floor budget neutrality and the

documentation and coding adjustment. The rural providers in the East

South Central regions would have the smallest decreases among rural

regions at -0.3 percent because the benefits from the MGCRB

reclassification partially offset the documentation and coding

adjustments.

Among special categories of rural hospitals, MDHs would receive an

estimated payment decrease of -0.1 percent. MDHs are paid the higher of

the IPPS rate based on the national standardized amount, that is, the

Federal rate, or, if the hospital-specific rate exceeds the Federal

rate, the Federal rate plus 75 percent of the difference between the

Federal rate and the hospital-specific rate. MDHs experience a decrease

in payments due to the 1.9 percent documentation and coding adjustment

applied to the federal rate and the 2.5 percent documentation and

coding adjustment applied to the hospital-specific rate. In addition,

this payment impact accounts for the corrected wage and recalibration

budget neutrality factor, described in section V.B.2. of the preamble

of this proposed rule, applied to the hospital-specific rates for MDHs

that are paid based on their FY 2002 hospital-specific rate. Overall,

SCHs would experience an estimated decrease in payments by -2.3 percent

largely due to the proposed -2.5 percent documentation and coding

adjustment applied to the hospital-specific rate. In addition, section

112 of Public Law 110-275 (MIPPA) allowed for SCHs to be paid based on

a FY 2006 hospital-specific rate (that is, based on their updated costs

per discharge from their 12-month cost reporting period beginning

during Federal FY 2006), if this results in the greatest payment to the

SCH, effective for cost reporting periods beginning on or after January

1, 2009. We estimated the FY 2006 hospital-specific rate for SCHs that

we believed would benefit from the rebased rate and included those

rates in our analysis. SCHs are estimated to experience a greater

decrease in payments compared to the MDHs because the documentation and

coding adjustment applied to the hospital-specific rates impacts SCHs

and MDHs differently. SCHs that are paid under the hospital-specific

rate have not had their payment rates adjusted for documentation and

coding previously and would experience a -2.5 percent documentation and

coding adjustment to their rates. However, MDHs, which are paid the

Federal rate plus 75 percent of the amount by which the hospital-

specific rate exceeds the Federal rate, have had the portion of their

payment rate based on the Federal rate adjusted in the past (-0.6

percent adjustment in FY 2008 and -0.9 percent adjustment in FY 2009),

whereas the -2.5 percent documentation and coding adjustment applied to

the hospital-specific rate affects a relatively smaller portion of

their rate based on the hospital-specific rate (compared to SCHs),

thereby resulting in a smaller payment impact. Thus, the change in

payment for SCHs relative to last year is more significant than the

payment change for MDHs.

Urban hospitals reclassified for FY 2010 are anticipated to receive

a decrease in payments under the IPPS of 0.6 percent, while urban

hospitals that are not reclassified for FY 2010 are expected to receive

a decrease of 0.4 percent. Rural hospitals reclassified for FY 2010 are

anticipated to receive a -1.1 percent payment decrease, and rural

hospitals that are not reclassifying are estimated to receive a payment

decrease of -1.6 percent.

Cardiac hospitals are the only category of hospitals under the IPPS

expected to experience payment increases in FY 2010 as compared to FY

2009 (an increase of 0.3 percent).

M. Effects of Policy on Payment Adjustments for Low-Volume Hospitals

For FY 2010, we are proposing to continue to apply the volume

adjustment criteria we specified in the FY 2005 IPPS final rule (69 FR

49099). We expect that three providers will receive the low-volume

adjustment for FY 2010. We estimate that low-volume hospitals will

experience a 3.1 percent decrease in payments in FY 2010 relative to FY

2009.

N. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for

FY 2010 for urban and rural hospitals and for the different categories

of hospitals shown in Table I. It compares the estimated average

payments per discharge for FY 2009 with the payments per discharge for

FY 2010, as calculated under our models. Thus, this table presents, in

terms of the average dollar amounts paid per discharge, the combined

effects of the proposed changes presented in Table I. The estimated

percentage changes shown in the last column of Table II equal the

estimated percentage changes in average payments per discharge from

Column 9 of Table I.

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[[Page 24669]]

VII. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed above that

we are able to model using our IPPS payment simulation model, we are

proposing to make various other changes in this proposed rule.

Generally, we have limited or no specific data available with which to

estimate the impacts of these proposed changes. Our estimates of the

likely impacts associated with these other proposed changes are

discussed below.

A. Effects of Proposed Policy on HACs, Including Infections

In section II.F. of the preamble of this proposed rule, we discuss

our implementation of section 1886(d)(4)(D) of the Act, which requires

the Secretary to identify conditions that are: (1) High cost, high

volume, or both; (2) result in the assignment of a case to an MS-DRG

that has a higher payment when present as a secondary diagnosis; and

(3) could reasonably have been prevented through application of

evidence-based guidelines. For discharges occurring on or after October

1, 2008, hospitals will not receive additional payment for cases in

which one of the selected conditions was not present on admission,

unless based on data and clinical judgment, it cannot be determined at

the time of admission whether a condition is present. That is, the case

will be paid as though the secondary diagnosis were not present.

However, the statute also requires the Secretary to continue counting

the condition as a secondary diagnosis that results in a higher IPPS

payment when doing the budget neutrality calculations for MS-DRG

reclassifications and recalibration. Therefore, we will perform our

budget neutrality calculations as though the payment provision did not

apply, but Medicare will make a lower payment to the hospital for the

specific case that includes the secondary diagnosis. Thus, the

provision results in cost savings to the Medicare program.

We note that the provision will only apply when one or more of the

selected conditions are the only secondary diagnosis or diagnoses

present on the claim that will lead to higher payment. Medicare

beneficiaries will generally have multiple secondary diagnoses during a

hospital stay, such that beneficiaries having one MCC or CC will

frequently have additional conditions that also will generate higher

payment. Only a small percentage of the cases will have only one

secondary diagnosis that would lead to a higher payment. Therefore, if

at least one nonselected secondary diagnosis that leads to higher

payment is on the claim, the case will continue to be assigned to the

higher paying MS-DRG and there will be no Medicare savings from that

case.

The HAC payment provision went into effect on October 1, 2008. Our

savings estimates for the next 5 fiscal years are shown below:

------------------------------------------------------------------------

Savings (in

Year millions)

------------------------------------------------------------------------

FY 2010................................................. $21

FY 2011................................................. 21

FY 2012................................................. 22

FY 2013................................................. 22

FY 2014................................................. 22

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B. Effects of Proposed Policy Change Relating to New Medical Service

and Technology Add-On Payments

In section II.I. of the preamble to this proposed rule, we discuss

the five applications for add-on payments for new medical services and

technologies for FY 2010, as well as the status of the new technology

that was approved to receive new technology add-on payments in FY 2009.

As explained in that section, add-on payments for new technology under

section 1886(d)(5)(K) of the Act are not required to be budget neutral.

As discussed in section II.I.4. of the preamble of this proposed rule,

we have yet to determine whether any of the five applications we

received for consideration for new technology add-on payments for FY

2010 will meet the specified criteria. Consequently, it is premature to

estimate the potential payment impact of any potential new technology

add-on payments for FY 2010. We note that if any of the five

applications are found to be eligible for new technology add-on

payments for FY 2010 in the final rule, we would discuss the estimated

payment impact for FY 2010 in that final rule.

However, we are providing an estimate of additional payments for

new technology add-on payments because such payments would have an

impact on total operating IPPS payments in FY 2010. Because we are

proposing to continue to make new technology add-on payments in FY 2010

for the Cardiowest TM Temporary Total Artificial Heart

System (TAH-t), we are providing an estimate of total payments for the

TAH-t in FY 2010. We note that new technology add-on payments per case

are limited to the lesser of (1) 50 percent of the costs of the new

technology or (2) 50 percent of the amount by which the costs of the

case exceed the standard MS-DRG payment for the case. Because it is

difficult to predict the actual new technology add-on payment for each

case, our estimate below is based on the increase in add-on payments

for FY 2010 as if every claim that would qualify for a new technology

add-on payments would receive the maximum add-on payment. Therefore, we

currently estimate that payments for the TAH-t will increase overall FY

2010 payments by $9.54 million.

C. Effects of Proposed Requirements for Hospital Reporting of Quality

Data for Annual Hospital Payment Update

In section V.A. of the preamble of this proposed rule, we discuss

our proposed requirements for hospitals to report quality data under

the RHQDAPU program in order to receive the full payment update for FY

2010 and FY 2011. We estimate that 96 hospitals may not receive the

full payment update for FY 2010 and that 96 hospitals may not receive

the full payment update for FY 2011. Most of these hospitals are either

small rural or small urban hospitals. However, at this time,

information is not available to determine the hospitals that do not

meet the requirements for the full hospital market basket increase for

FY 2010 and FY 2011.

For the FY 2010 payment update, hospitals must pass our validation

requirement of a minimum of 80 percent reliability based upon our

chart-audit validation process. For all but two measures (SCIP-

Infection-4 and SCIP-Infection-6), this process uses four quarters of

data from FY 2008. These data were due to the QIO Clinical Warehouse by

May 15, 2008 (fourth quarter CY 2007 discharges), August 15, 2008

(first quarter CY 2008 discharges), November 15, 2008 (second quarter

CY 2008 discharges), and February 15, 2009 (third quarter CY 2008

discharges). For the SCIP-Infection-4 and SCIP-Infection-6 measures,

the validation process is based on two quarters of data from FY 2008.

These data were due to the QIO Clinical Warehouse by November 15, 2008

(second quarter CY 2008 discharges) and February 15, 2009 (third

quarter CY 2008 discharges).

In section V.A.9. of the preamble of this proposed rule, we are

proposing that if we determine that a hospital is not entitled to

receive the full FY 2010 payment update because it failed to satisfy

the validation requirement, and the hospital asks for a reconsideration

of that decision, the hospital must submit complete copies of the

medical records that it submitted to the CDAC contractor for purposes

of the validation. We estimate that no more than 20 hospitals would

fail the validation requirement for the FY 2010 payment update. We

estimate that this proposal would cost

[[Page 24670]]

hospitals approximately 12 cents per page for copying and approximately

$4.00 per chart for postage. We have found, based on experience, that

an average sized medical chart is approximately 150 pages. Hospitals

would be required to return all 20 sampled medical records for the four

quarters of data from FY 2008. We estimate that the total cost to the

20 impacted hospitals would be approximately $8,800, or $440 per

hospital. We believe that this cost is minimal, compared with the 2.0

percentage point RHQDAPU program component of the annual payment update

at risk. This proposed requirement is necessary so that CMS has all the

information it needs to fairly and timely make a decision on the

hospital's reconsideration request. We also anticipate that this

requirement will benefit hospitals seeking reconsiderations because it

will enable us to resolve potential issues earlier in the appeals

process, obviating the need for a hearing before the Provider

Reimbursement Review Board (PRRB). We believe that this benefit will

greatly outweigh the burden of copying and mailing the requested

records.

For the FY 2011 payment update, hospitals must pass our validation

requirement of a minimum of 80 percent reliability based upon our

chart-audit validation process. For all but one measure (SCIP-

Cardiovascular-2), this process will use four quarters of data from FY

2009. These data are due to the QIO Clinical Warehouse by May 15, 2009

(fourth quarter CY 2008 discharges), August 15, 2009 (first quarter CY

2009 discharges), November 15, 2009 (second quarter CY 2009

discharges), and February 15, 2010 (third quarter CY 2009 discharges).

For the SCIP-Cardiovascular-2 measure, the validation process is based

on two quarters of data from FY 2009. SCIP-Cardiovascular-2 data are

due to the QIO Clinical Warehouse by November 15, 2009 (second quarter

CY 2009 discharges) and February 15, 2010 (third quarter CY 2009

discharges).

We have continued our efforts to ensure that QIOs provide

assistance to all hospitals that wish to participate in the RHQDAPU

program. The requirement of 5 charts per hospital would result in

approximately 21,500 charts per quarter being submitted to CMS for the

FY 2010 payment update and for the FY 2011 payment update. We reimburse

hospitals for the cost of sending charts to the Clinical Data

Abstraction Center (CDAC) contractor at the rate of 12 cents per page

for copying and approximately $4.00 per chart for postage. Our

experience shows that the average chart received by the CDAC contractor

is approximately 150 pages. Thus, CMS would have expenditures of

approximately $597,600 per quarter to collect the charts. Because we

reimburse hospitals for the data collection effort, we believe that a

requirement for five charts per hospital per quarter represents a

minimal burden to the participating hospital.

We are proposing to modify our validation process for the FY 2012

payment update. We believe that our proposal to validate data submitted

by 800 hospitals for the FY 2012 RHQDAPU payment determination would

not change the number of hospitals that fail the validation requirement

for the FY 2012 payment update from previous years. We have proposed to

change the way we calculate the validation matches (that is, all

relevant data elements submitted by the hospital must match the

independently re-abstracted data elements to count as a match), which

will make it more difficult for hospitals to satisfy the validation

requirement. However, we have also proposed to validate data for a much

smaller number of hospitals each year and proposed to reduce the

validation score needed to satisfy the validation requirement. In

combination, we believe that these proposed revisions will

counterbalance each other and result in no additional impact on the

number of hospitals failing our validation requirement for the FY 2012

payment update.

D. Effects of Correcting the FY 2002-Based Hospital-Specific Rates for

MDHs

In section V.B. of the preamble of this proposed rule, we discuss

the need to correct the calculation of the FY 2002 hospital-specific

rates for MDHs and apply a cumulative budget neutrality adjustment

factor for DRG changes for FYs 1993 through 2002, in addition to the

cumulative budget neutrality adjustment factors for FYs 2003 forward

(which have already been applied). The cumulative budget neutrality

adjustment factor of 0.982557 is calculated as the product of the

following budget neutrality adjustment factors for FYs 1993 through

2002: 0.999851 for FY 1993; 0.999003 for FY 1994; 0.998050 for FY 1995;

0.999306 for FY 1996; 0.998703 for FY 1997; 0.997731 for FY 1998;

0.998978 for FY 1999; 0.997808 for FY 2000; 0.997174 for FY 2001; and

0.995821 for FY 2002. We estimate that there are currently about 195

MDHs. We estimate that approximately 60 percent of MDHs qualified for

the rebasing to a FY 2002 hospital-specific rate (that is, their FY

2002 hospital-specific rate was higher than the other hospital-specific

rates (FY 1982 or FY 1987)), of which about 46 percent of those MDHs

were paid based on their FY 2002 hospital-specific rate because it was

higher than the Federal rate. The remaining 54 percent of those MDHs

are estimated to have been paid based solely on the Federal rate

because the Federal rate was higher than their FY 2002 hospital-

specific rate. We estimate that correcting the FY 2002 hospital-

specific rate to ensure cumulative budget neutrality for FY 1993 though

FY 2002 would result in an estimated decrease in operating IPPS

payments in FY 2010 of approximately $6 million. However, this figure

may be lower because application of the cumulative budget neutrality

adjustment factor will, in some cases, lower the FY 2002 hospital-

specific rate to below the Federal rate, thus creating a floor to the

potential reduction.

E. Effect of Proposed Policy Changes Relating to the Payment

Adjustments to Disproportionate Share Hospitals

1. Proposed Change Relating to Inclusion of Labor and Delivery Days in

DSH Calculation

In section V.E.2. of the preamble of this proposed rule, we discuss

our proposal to amend the regulations so that patient days associated

with labor and delivery services are included in both the Medicaid and

Medicare fractions of the DPP used for calculating the DSH payment

adjustment, regardless of whether the patient occupied a routine bed

prior to occupying an ancillary labor and delivery bed. We believe that

the impact of the proposed inclusion of these days in the Medicare

fraction of the DPP would be negligible because, generally, there are

not many labor and delivery patient days among the Medicare population.

In addition, with regard to the Medicaid fraction, we are not able to

provide a detailed analysis of the potential of this proposed policy

change because the impact would depend on the proportion of days

associated with Medicaid-eligible patients who occupied an ancillary

labor and delivery bed at some point after being admitted as an

inpatient, but prior to occupying a routine bed, to days associated

with similarly situated non-Medicaid-eligible patients relative to a

hospital's current Medicaid-to-total-days ratio (which would not have

included the types of days we are proposing to include in this policy).

We expect that the Medicaid fraction for some hospitals would increase

while it would decrease for other hospitals. Therefore, we estimate

[[Page 24671]]

that the impact of this proposed policy change would be negligible.

2. Proposed Change Relating to Calculation of Inpatient Days in

Medicaid Fraction

In section V.E.3. of the preamble of this proposed rule, we discuss

our proposal to allow a hospital to change its methodology of reporting

days in the numerator of the Medicaid fraction of the DPP used in the

DSH payment adjustment calculation. Under the proposed change, we would

allow a hospital to report the Medicaid days in the numerator of the

Medicaid fraction of the DPP based on one of the following: date of

discharge; date of admission; or dates of service. Hospitals would be

permitted to use only one basis for all of the Medicaid days for the

entire cost reporting period. In addition, under the proposal, CMS, or

its fiscal intermediaries or MACs, has the authority to make

adjustments to the number of Medicaid days reported to avoid counting

Medicaid days in one cost reporting period of a hospital that may have

been reported in a hospital's previous cost reporting period. We do not

believe that the proposed change in the methodology of counting days in

the numerator of the Medicaid fraction of the DPP would result in any

increase in aggregate DSH payments.

3. Proposed Change Relating to Exclusion of Observation Beds and

Patient Days from DSH Calculation

In section V.E.4. of the preamble of this proposed rule, we discuss

our proposal to amend the regulations so that patient days associated

with beds used for observation services for patients who are

subsequently admitted as an inpatient are no longer included in the DPP

for calculating the DSH payment adjustment or in the available bed day

count for calculating the DSH payment adjustment and IME payments. Some

hospitals may receive increased DSH payment adjustments and others may

expect to receive lower DSH payment adjustments, depending on how the

exclusion of observation patient days affects the hospital's overall

DPP. For IME payment purposes, a decrease in a hospital's number of

available beds results in an increase in the resident-to-bed ratio. The

exclusion of observation bed days from the available bed count for IME

would reduce the available beds, increase the resident-to-bed ratio,

and, consequently, increase IME payments to teaching hospitals. Based

on an analysis from our Office of the Actuary, we believe that any

savings associated with proposed changes in DSH payment adjustments

would be offset by proposed additional spending for IME payments.

Therefore, we anticipate the impact of these proposed policy changes to

be negligible.

F. Effects of Proposed Policy Revisions Related to Payment to Hospitals

for Direct GME

In section V.G. of the preamble of this proposed rule, we discuss

our proposal to clarify the definition of a new medical residency

training program in the regulations by specifying that a new medical

residency program is one that receives initial accreditation for the

first time, as opposed to a reaccreditation of a program that existed

previously at the same or another hospital. In addition, we discuss our

proposed change to add a provision to the regulations relating to

Medicare GME affiliation agreements to specify that a hospital that is

new after July 1 and that begins training residents for the first time

after the July 1 start date of that academic year would be permitted to

submit a Medicare GME affiliation agreement prior to the end of its

cost reporting period in order to participate in an existing Medicare

GME affiliated group for the remainder of the academic year.

With respect to the first proposed provision regarding a new

medical residency training program, there is no financial impact on the

Medicare program because this is a proposed clarification of existing

policy and is not a proposed policy revision or addition of a new

policy. Further, there is no financial impact related to the second

proposal concerning Medicare GME affiliated groups because it does not

provide for an increase in the aggregate number of resident FTEs.

Rather, it merely provides increased flexibility for a hospital that is

new after July 1 and that begins training residents for the first time

after the start date of that academic year to enter into an existing

Medicare GME affiliation agreement after July 1, so that, in that

academic year, it may train and receive IME and direct GME payments

relating to FTE for residents that would otherwise be counted for IME

and direct GME at another hospital.

G. Effects of Proposed Policy Changes Relating to Hospital Emergency

Services under EMTALA

In section V.H. of the preamble of this proposed rule, we discuss

our proposal to amend the regulations pertaining to the waiver of

EMTALA sanctions in an emergency area during an emergency period to

make the regulations consistent with the statutory language of section

1135 of the Act. Specifically, we are proposing to revise the existing

regulations to reflect the Secretary's authority under section 1135 of

the Act to waive or modify requirements for a single health care

provider, a class of health care providers, or a geographic subset of

health care providers located within an emergency area during an

emergency period or portion of an emergency period. We are proposing to

amend the regulations to clarify that, in cases where the Secretary has

delegated implementation of a waiver of EMTALA sanctions to CMS, CMS is

also authorized to apply a section 1135 waiver to a subset of the

emergency area and some or all of the emergency period, as necessary.

We also are proposing to make the regulations consistent with the

language at section 1135 of the Act to state that a waiver of EMTALA

sanctions pursuant to an inappropriate transfer only applies if the

transfer arises out of the circumstances of the emergency. We are

further proposing to make the regulation text consistent with the

language at section 1135 of the Act to provide that the sanctions

waived for an inappropriate transfer or for the relocation or

redirection of an individual to receive a medical screening examination

at an alternate location are only in effect if the hospital to which

the waiver applies does not discriminate on the source of an

individual's payment or ability to pay. We estimate that these proposed

changes would have no impact on Medicare expenditures and no

significant impact on hospitals with emergency departments.

H. Effects of Implementation of Rural Community Hospital Demonstration

Program

In section V.I. of the preamble to this proposed rule, we discuss

our implementation of section 410A of Public Law 108-173 that required

the Secretary to establish a demonstration that will modify

reimbursement for inpatient services for up to 15 small rural

hospitals. Section 410A(c)(2) requires that ``[i]n conducting the

demonstration program under this section, the Secretary shall ensure

that the aggregate payments made by the Secretary do not exceed the

amount which the Secretary would have paid if the demonstration program

under this section was not implemented.'' There are currently 13

hospitals participating in the demonstration; 4 of these hospitals were

selected to participate in the demonstration as of July 1, 2008, as a

result of our February 6, 2008 solicitation (73 FR 6971).

As discussed in section V.I. of the preamble to this proposed rule,

we are

[[Page 24672]]

proposing to satisfy this budget neutrality requirement by proposing to

adjust the national IPPS rates by a factor that is sufficient to

account for the added costs of this demonstration. First, we are

estimating the cost of the demonstration program for FY 2010 for the 13

currently participating hospitals. The estimated cost of the

demonstration for FY 2010 for 9 of the 13 currently participating

hospitals (specifically the 9 hospitals that have participated in the

demonstration since its inception and that still are participating in

the demonstration) is based on data from their first and second year

cost reports--that is, cost reporting periods beginning in CY 2005 and

CY 2006. In addition, the estimated cost of the demonstration for FY

2010 for the 4 hospitals selected in 2008 to participate in the

demonstration is based on data from their cost reports for cost

reporting periods beginning October 1, 2005, through July 1, 2006 (that

is, cost reporting periods that include CY 2006). When we add together

the estimated costs of the demonstration for FY 2010 for the 9

hospitals that have participated in the demonstration since its

inception and the 4 new hospitals selected in 2008, the total estimated

cost is $14,613,632. This estimated amount reflects the difference

between the participating hospitals' estimated costs under the

methodology set forth in Public Law 108-173 and the amount the

hospitals would have been paid if they were paid under the IPPS.

Second, because the cost reports of all hospitals participating in

the demonstration in its first year (that is, FY 2005) have been

finalized, we are able to determine how much the cost of the

demonstration program exceeded the amount that was offset by the budget

neutrality adjustment for FY 2005. For all 13 hospitals that

participated in the demonstration in FY 2005, the amount is $7,179,461.

The proposed budget neutrality adjustment factor applied to the

IPPS Federal rate to account for the added $21,793,093 in costs for the

demonstration is 0.999790.

J. Effects of Proposed Policy Changes Relating to Payments to Satellite

Facilities

In section VII.B. of the preamble of this proposed rule, we discuss

our proposed policy change that, effective for cost reporting periods

beginning on or after October 1, 2009, in addition to meeting the other

criteria in the regulations, to be excluded from the IPPS, the

governing body of the hospital of which the satellite facility is a

part cannot be under the control of any third entity that controls both

the hospital of which the satellite facility is a part and the hospital

with which the satellite facility is co-located. We also are proposing

that if a hospital and its satellite facility were excluded from the

IPPS under Sec. 412.22(h) for the most recent cost reporting period

beginning prior to October 1, 2009, the hospital does not have to meet

the requirements of proposed Sec. 412.22(h)(2)(iii)(A)(1) with respect

to that satellite facility in order to retain its IPPS-excluded status.

The creation of any satellite facility that would trigger the hospital

of which it is a part to comply with the proposed additional criteria

would occur at some point in the future. Therefore, we are unable to

quantify the impact of the proposed changes.

K. Effects of Proposed Policy Changes Relating to Payments to CAHs

In section VII.C.2. of the preamble of this proposed rule, we

discuss our proposal to implement section 148 of Public Law 110-275

(MIPPA). We are proposing that a CAH may receive reasonable cost-based

payment for outpatient clinical diagnostic laboratory tests furnished

to an individual who is an outpatient of the CAH (that is, receiving

outpatient services directly from the CAH) even if the individual with

respect to whom the laboratory services are furnished is not physically

present in the CAH at the time the specimen is collected. In order for

an individual who is not physically present in the CAH at the time the

specimen is collected to be determined to be receiving services

directly from the CAH, we are proposing that the individual must either

receive outpatient services in the CAH on the same day the specimen is

collected or that the specimen must be collected by an employee of the

CAH. We anticipate that, for FY 2009 through FY 2016, the cost of

implementing the provisions of section 148 of Public Law 110-275, would

be less than $50 million per year.

In section VII.C.3. of this preamble of this proposed rule, we

discuss our proposal to amend the regulations to make them consistent

with the plain reading of section 1834(g)(2)(A) of the Act. Section

1834(g)(2)(A) of the Act requires that CAHs that select the optional

method of reimbursement receive reasonable cost payment for outpatient

facility services. We are proposing to revise the regulations to state

that CAHs that select the optional method would receive reasonable

cost-based payment for outpatient facility services instead of 101

percent of reasonable cost for outpatient facility services. Therefore,

those CAHs that elect the optional method of payment would receive

reasonable cost payment for the facility portion of outpatient

services.

L. Effects of Proposed Policy Changes Relating to Provider-Based Status

of Entities and Organizations

In section VII.D. of the preamble of this proposed rule, we discuss

our proposal to amend the regulations to require facilities that

furnish only clinical diagnostic laboratory tests and operate as part

of a CAH to meet the provider-based status rules currently in the

regulations at Sec. 413.65. If a facility that is part of a CAH and

furnishes only clinical diagnostic laboratory tests meets the provider-

based status rules, the CAH would be paid for services furnished by the

laboratory facility under the CAH payment methodology of reasonable

cost. If a facility that furnishes only clinical diagnostic laboratory

tests does not meet the provider-based status rules, the services

furnished in the facility would be paid under the CLFS, unless the

laboratory specimen is collected from an outpatient of the CAH as

described in VII.C.2. of the preamble of this proposed rule. We believe

it would be difficult to quantify the payment impact of these proposed

changes because we cannot estimate the number of CAHs that would be

affected by this proposal. We are soliciting public comments on these

issues.

VIII. Effects of Proposed Changes in the Capital IPPS

A. General Considerations

Fiscal year (FY) 2001 was the last year of the 10-year transition

period established to phase in the PPS for hospital capital-related

costs. During the transition period, hospitals were paid under one of

two payment methodologies: fully prospective or hold harmless. Under

the fully prospective methodology, hospitals were paid a blend of the

capital Federal rate and their hospital-specific rate (see Sec.

412.340). Under the hold-harmless methodology, unless a hospital

elected payment based on 100 percent of the capital Federal rate,

hospitals were paid 85 percent of reasonable costs for old capital

costs (100 percent for SCHs) plus an amount for new capital costs based

on a proportion of the capital Federal rate (see Sec. 412.344). As we

state in section VI. of the preamble of this proposed rule, with the

10-year transition period ending with hospital cost reporting periods

beginning on or after October 1, 2001 (FY 2002), payments for most

hospitals under the capital IPPS are based solely on the

[[Page 24673]]

capital Federal rate. Therefore, we no longer include information on

obligated capital costs or projections of old capital costs and new

capital costs, which were factors needed to calculate payments during

the transition period, for our impact analysis.

The basic methodology for determining a capital IPPS payment is set

forth at Sec. 412.312. The basic methodology for calculating capital

IPPS payments in FY 2010 is as follows:

(Standard Federal Rate) x (DRG weight) x (GAF) x (COLA for

hospitals located in Alaska and Hawaii) x (1 + DSH Adjustment Factor,

if applicable).

In accordance with Sec. 412.322(d), there is no longer an

additional payment for indirect teaching medical education (IME

adjustment factor) under the capital IPPS costs for FY 2010 and

subsequent years, as discussed in section VI.B.2. of the preamble of

this proposed rule. However, we note that the 50-percent reduction to

capital IME adjustments for FY 2009 in the current regulations at Sec.

412.322(c) was repealed in section 4301(b)(1) of Public Law 111-5

(ARRA). We discuss below the ramifications of restoring the full IME

adjustment in FY 2009 when comparing proposed changes in capital IPPS

payments to FY 2010. In addition, hospitals may also receive outlier

payments for those cases that qualify under the threshold established

for each fiscal year.

The data used in developing the impact analysis presented below are

taken from the December 2008 update of the FY 2008 MedPAR file and the

December 2008 update of the Provider-Specific File (PSF) that is used

for payment purposes. Although the analyses of the changes to the

capital prospective payment system do not incorporate cost data, we

used the December 2008 update of the most recently available hospital

cost report data (FYs 2005 and 2006) to categorize hospitals. Our

analysis has several qualifications. We use the best data available and

make assumptions about case-mix and beneficiary enrollment as described

below. In addition, as discussed in section VI.B.1. of the preamble to

this proposed rule, as we established in FYs 2008 and 2009, we are

proposing to adjust the national capital rate to account for changes in

documentation and coding under the MS-DRGs in FY 2010. As discussed in

section VI.B.1.c. of the preamble to this proposed rule, we also are

proposing to adjust the Puerto Rico-specific capital rate in FY 2010 to

account for changes in documentation and coding resulting from the

adoption of the MS-DRGs. Due to the interdependent nature of the IPPS,

it is very difficult to precisely quantify the impact associated with

each change. We draw upon various sources for the data used to

categorize hospitals in the tables. In some cases (for instance, the

number of beds), there is a fair degree of variation in the data from

different sources. We have attempted to construct these variables with

the best available sources overall. However, for individual hospitals,

some miscategorizations are possible.

Using cases from the December 2008 update of the FY 2008 MedPAR

file, we simulated payments under the capital PPS for FY 2009 and FY

2010 for a comparison of total payments per case. Any short-term, acute

care hospitals not paid under the general IPPS (Indian Health Service

hospitals and hospitals in Maryland) are excluded from the simulations.

The final capital rates and factors for FY 2009 were published in a

subsequent notice in the Federal Register (73 FR 57891).

As we discuss in section III.A.4. of the Addendum to this proposed

rule, payments are no longer made under the regular exceptions

provision under Sec. Sec. 412.348(b) through (e). Therefore, we no

longer use the actuarial capital cost model (described in Appendix B of

the August 1, 2001 proposed rule (66 FR 40099)). We modeled payments

for each hospital by multiplying the capital Federal rate by the GAF

and the hospital's case-mix. We only included estimated payments for

the IME adjustment in our modeling of FY 2009 capital IPPS payments

because, under current law, capital IME payments are eliminated

beginning in FY 2010 in accordance with Sec. 412.322(d) (as discussed

in section VI.B.2. of the preamble of this proposed rule). We then

added estimated payments for disproportionate share, and outliers, if

applicable. For purposes of this impact analysis, the model includes

the following assumptions:

We estimate that the Medicare case-mix index will increase

by 1.0 percent in both FYs 2009 and 2010. (We note that this does not

reflect the expected growth in case-mix due to improvement in

documentation and coding under the MS-DRGs, as discussed below.)

We estimate that the Medicare discharges will be

approximately 13 million in both FY 2009 and FY 2010.

The capital Federal rate was updated beginning in FY 1996

by an analytical framework that considers changes in the prices

associated with capital-related costs and adjustments to account for

forecast error, changes in the case-mix index, allowable changes in

intensity, and other factors. As discussed in section III.A.2.a. of the

Addendum to this proposed rule, the proposed FY 2010 update is 1.2

percent.

In addition to the FY 2010 update factor, the proposed FY

2010 capital Federal rate was calculated based on a proposed GAF/DRG

budget neutrality factor of 0.9994, a proposed outlier adjustment

factor of 0.9454, and a proposed exceptions adjustment factor of

0.9999.

For FY 2010, as discussed in section VI.B.1. of the

preamble of this proposed rule, the proposed FY 2010 national capital

rate was further adjusted by a factor to account for estimated changes

in documentation and coding that result in an increase in case-mix

under the MS-DRGs. Specifically, as discussed in greater detail in

section VI.B.1. of the preamble of this proposed rule, we are proposing

a 1.9 percent reduction in the proposed FY 2010 national capital

Federal rate for changes in documentation and coding resulting from the

adoption of the MS-DRGs. As also discussed in section VI.A.6. of the

preamble to this proposed rule, we also are proposing to adjust the

Puerto Rico-specific capital rate to account for changes in

documentation and coding under the MS-DRGs in FY 2010. Specifically, we

are proposing a 1.1 percent reduction in the proposed FY 2010 Puerto

Rico-specific capital rate for changes in documentation and coding

resulting from the adoption of the MS-DRGs.

B. Results

We used the actuarial model described above to estimate the

potential impact of our proposed changes for FY 2010 on total capital

payments per case, using a universe of 3,513 hospitals. As described

above, the individual hospital payment parameters are taken from the

best available data, including the December 2008 update of the FY 2008

MedPAR file, the December 2008 update to the PSF, and the most recent

cost report data from the December 2008 update of HCRIS. In Table III,

we present a comparison of estimated total payments per case for FY

2009 compared to proposed estimated total payments per case for FY 2010

based on the proposed FY 2010 payment rates and policies. Column 2

shows estimates of payments per case under our model for FY 2009.

Column 3 shows estimates of payments per case under our model for FY

2010. Column 4 shows the total percentage change in payments from FY

2009 to FY 2010. The change represented in Column 4 includes the

proposed 1.2 percent update to the capital Federal rate, other changes

in the adjustments to the capital Federal rate (for example, the

[[Page 24674]]

phase out of the IME adjustment for FY 2010), and the proposed

additional 1.9 percent reduction in the national capital rate (and the

proposed 1.1 percent reduction in the Puerto Rico-specific capital

rate) to account for changes in documentation and coding (or other

changes in documentation and coding that do not reflect real changes in

case-mix) for implementation of the MS-DRGs. For purposes of this

impact analysis, we also account for estimated case-mix growth for FYs

2009 and 2010, as determined by the Office of the Actuary, because, as

discussed previously, we believe the adoption of the MS-DRGs will

result in case-mix growth due to documentation and coding changes that

do not reflect real changes in patients' severity of illness. The

comparisons are provided by: (1) Geographic location; (2) region; and

(3) payment classification.

The simulation results show that capital payments per case in FY

2010 are expected to decrease as compared to capital payments per case

in FY 2009. The proposed capital rate for FY 2010 would decrease

approximately 0.8 percent as compared to the FY 2009 capital rate,

which contributes to the estimated decrease in capital payments.

However, the phase-out of the IME adjustment for FY 2010 is the major

factor affecting capital payments in FY 2010 as compared to FY 2009;

that is, full capital IME payments in FY 2009 as specified by section

4302(b)(1) of Public Law 111-5 as compared to no capital IME payments

in FY 2010, as specified under current law (Sec. 412.322(d) of the

regulations). Countering these factors is the projected case-mix growth

as a result of changes in documentation and coding (discussed above).

The net result of these changes is an estimated 4.8 percent decrease in

capital payments per discharge from FY 2009 to FY 2010 for all

hospitals (as shown below in Table III).

The results of our comparisons by geographic location and by region

are consistent with the results we expected with the phase-out of the

IME adjustment for FY 2010 (Sec. 412.322(d)). The majority of the

estimated decreases in capital payments from FY 2009 to FY 2010 are not

a result of any of the proposed changes to policies presented in this

proposed rule. Our policy to phase-out capital IME adjustments, such

that there would be no adjustment for capital IME beginning in FY 2010,

was established in FY 2008, and was based on analyses of capital

margins from the past 10 years for which data were available; that is,

FY 1996 through FY 2006. These margins clearly demonstrated that

capital IME payment adjustments were contributing to the significantly

large positive margins experienced by teaching hospitals. We initially

implemented a phase-out of the IME adjustment over a 3-year period

which included a 50-percent reduction to the capital IME adjustment in

FY 2009 and the elimination of the remaining 50 percent in FY 2010.

Under that 3-year phase-out, including the elimination of the capital

IME adjustment in FY 2010, we expected that capital margins would

decrease and be more in line with other hospitals in the system. As

discussed in section VI.B.2 of the preamble of this proposed rule,

however, section 4301(b)(1) of Public Law 111-5 restored the capital

IME adjustment for FY 2009 (that is, it eliminated the 50-percent

reduction to the capital IME adjustment), while section 4301(b)(2) of

Public Law 111-5 specified that the law has no effect on the

established elimination of the capital IME adjustment in FY 2010. The

combination of restoring the full capital IME adjustment in FY 2009 and

eliminating it in FY 2010 has resulted in larger estimated decreases in

capital payments from FY 2009 to FY 2010 in this impact analysis. While

the end results in FY 2010 would have been the same had the 50-percent

reduction to capital IME adjustments in FY 2009 not have been restored,

and had the remaining 50 percent of the capital IME adjustment been

eliminated in FY 2010 as planned, the estimated decrease in capital

payments from FY 2009 to FY 2010 would have been moderated, such that

the somewhat dramatic decreases reflected in Table III in this impact

analysis would not have resulted.

To a lesser degree, but nevertheless, a mitigating factor to the

estimated decrease in capital payments from FY 2009 to FY 2010 are

changes in documentation and coding under the MS-DRGs and the

associated adjustments to the capital rates. When we implemented the

MS-DRGs in FY 2008, in order to maintain budget neutrality, it was

necessary to adjust the capital Federal rate to account for potential

increases in aggregate capital payments when there was not a

corresponding increase in patients' severity of illness. As discussed

in greater detail in section VI.B.1. of the preamble of this proposed

rule, the FY 2009 capital Federal rate includes a cumulative -1.5

percent documentation and coding adjustment as determined by our Office

of the Actuary. As also discussed in that same section, in this

proposed rule, we are proposing to apply an additional documentation

and coding adjustment of -1.9 percent to the FY 2010 capital Federal

rate, yielding a proposed cumulative adjustment of 3.4 perecent. The

proposed additional -1.9 percent adjustment contributes to the larger

decrease in capital payments in FY 2010 when compared to FY 2009.

The geographic comparison shows that, on average, all urban

hospitals are expected to experience a 5.1 percent decrease in capital

IPPS payments per case in FY 2010 as compared to FY 2009, while

hospitals in large urban areas are expected to experience a 6.0 percent

decrease in capital IPPS payments per case in FY 2010 as compared to FY

2009. Capital IPPS payments per case for rural hospitals are also

expected to decrease, but to a lesser degree, that is, 1.9 percent.

This variation in the estimated decreases in payments per case by

geographic location is mostly due to the elimination of the IME

adjustment. Because teaching hospitals generally tend to be located in

urban or large urban areas, we expect that the phase-out of the IME

adjustment for FY 2010 would have a more significant impact on

hospitals in those areas than hospitals located in rural areas. As

discussed above, the magnitude of the estimated decreases, however, is

attributable to the phase-out of the IME adjustment occurring in 2

years rather than over 3 years.

All regions are estimated to experience a decrease in total capital

payments per case from FY 2009 to FY 2010. These decreases vary by

region and range from a 0.3 percent decrease in the Mountain rural

region to a 9.4 percent decrease in the New England rural region. Three

urban regions are projected to experience a relatively larger decrease

in capital payments, with the difference, again, primarily due to the

phase-out of the IME adjustment for FY 2010: -8.8 percent in the New

England urban region, -8.2 percent in the Middle Atlantic urban region,

and -7.0 percent in the East North Central urban region.

By type of ownership, voluntary and government hospitals are

estimated to experience a decrease of 5.0 percent and 6.9 percent,

respectively. The projected smaller decrease in capital payments per

case for proprietary hospitals, 2.0 percent, is mostly because these

hospitals are expected to experience a smaller than average decrease in

their payments due to the phase-out of the IME adjustment for FY 2010.

Section 1886(d)(10) of the Act established the MGCRB. Before FY

2005, hospitals could apply to the MGCRB for reclassification for

purposes of the standardized amount, wage index, or both. Section

401(c) of Public Law

[[Page 24675]]

108-173 equalized the standardized amounts under the operating IPPS.

Therefore, beginning in FY 2005, there is no longer reclassification

for the purposes of the standardized amounts; however, hospitals still

may apply for reclassification for purposes of the wage index for FY

2010. Reclassification for wage index purposes also affects the GAFs

because that factor is constructed from the hospital wage index.

To present the effects of the hospitals being reclassified for FY

2010, we show estimated average capital payments per case for

reclassified hospitals for FY 2009. All classifications of reclassified

hospitals are expected to experience a decrease in payments in FY 2010

as compared to FY 2009. Urban reclassified and urban nonreclassified

hospitals are expected to have the largest decreases in capital

payments: -5.3 percent and -5.0 percent, respectively. Rural

reclassified and rural nonreclassified are expected to have decreases

in capital payments of 1.7 percent and 2.2 percent, respectively. Other

reclassified hospitals (that is, hospitals reclassified under section

1886(d)(8)(B) of the Act) are expected to experience the smallest

decrease in capital payment from FY 2009 to FY 2010 (-1.3 percent). As

discussed above, the variation in the estimated decreases in payments

per case is mostly due to the phase-out of the IME adjustment. Because

teaching hospitals generally tend to be located in urban areas, we

expect that the phase-out of the IME adjustment for FY 2010 would have

a more significant impact on both reclassified and nonreclassified

hospitals in those areas than reclassified and nonreclassified

hospitals located in rural areas.

It is important to note that had our original policy of phasing out

the capital IME adjustment over 3 years not been changed by section

4301(b)(1) of Public Law 111-5 subsequent to the implementation of the

transition period, the decrease in capital payments from FY 2009 to FY

2010 would not have been as large. Although the end result of the

changes to the IME adjustment implemented in FY 2008 would have been

the same, the decreases would have occurred over 2 years instead of

essentially just 1 year--FY 2010.

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[[Page 24676]]

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[[Page 24678]]

IX. Effects of Proposed Payment Rate Changes and Policy Changes under

the LTCH PPS

A. Introduction and General Considerations

In section VIII. of the preamble of this proposed rule, we are

setting forth the proposed annual update to the payment rates for the

LTCH PPS for RY 2010. In the preamble, we specify the statutory

authority for the proposed provisions that are presented, identify

those proposed policies where discretion has been exercised, and

present rationale for our decisions as well as alternatives that were

considered. In this section of Appendix A to this proposed rule, we

discuss the impact of the proposed changes to the payment rates,

factors, and other payment rate policies related to the LTCH PPS that

are presented in the preamble of this proposed rule in terms of their

estimated fiscal impact on the Medicare budget and on LTCHs.

Currently, our database of 399 LTCHs includes the data for 81

nonprofit (voluntary ownership control) LTCHs and 267 proprietary

LTCHs. Of the remaining 51 LTCHs, 12 LTCHs are government-owned and

operated and the ownership type of the other 39 LTCHs is unknown. In

the impact analysis, we are using the proposed rates, factors and

policies presented in this proposed rule, including proposed updated

wage index values and the labor-related share, and the best available

claims and CCR data to estimate the change in payments for the 2010

LTCH PPS rate year. The standard Federal rate for RY 2009 is

$39,114.36. As discussed in section V.A.2. of the Addendum to this

proposed rule, consistent with our historical practice, we are

proposing to update the standard Federal rate for RY 2009 by 0.6

percent in order to establish the proposed RY 2010 standard Federal

rate at $39,349.05. Based on the best available data for the 399 LTCHs

in our database, we estimate that the proposed update to the standard

Federal rate for RY 2010 (discussed in section VIII. of the preamble of

this proposed rule) and the proposed changes to the area wage

adjustment (discussed in section V.A. of the Addendum to this proposed

rule) for the 2010 LTCH PPS rate year, in addition to an estimated

increase in HCO payments and an estimated increase in SSO payments,

would result in an increase in estimated payments from the 2009 LTCH

PPS rate year of approximately $135 million (or about 2.8 percent).

Based on the 399 LTCHs in our database, we estimate RY 2009 LTCH PPS

payments to be approximately $4.76 billion and RY 2010 LTCH PPS

payments to be approximately $4.90 billion. Because the combined

distributional effects and estimated changes to the Medicare program

payments would be greater than $100 million, this proposed rule is

considered a major economic rule, as defined in this section. We note

the approximately $135 million for the projected increase in estimated

aggregate LTCH PPS payments from RY 2009 to RY 2010 do not reflect

changes in LTCH admissions or case-mix intensity in estimated LTCH PPS

payments, which would also affect overall payment changes.

The projected 2.8 percent increase in estimated payments per

discharge from the 2009 LTCH PPS rate year to the 2010 LTCH PPS rate

year is attributable to several factors, including the proposed 0.6

percent increase to the standard Federal rate and projected increases

in estimated HCO and SSO payments. As Table IV shows, the proposed

change attributable solely to the standard Federal rate is projected to

result in an increase of 0.5 percent in estimated payments per

discharge from RY 2009 to RY 2010, on average, for all LTCHs, while the

proposed changes to the area wage adjustment are projected to result in

neither an increase nor decrease in estimated payments, on average, for

all LTCHs (Columns 6 and 7 of Table IV, respectively). We note that

because payments for cost-based SSO cases and a portion of payments for

SSO cases that are paid based on the ``blend'' option (that is, SSO

cases paid under Sec. 412.529(c)(2)(iv)) are not affected by the

proposed update to the standard Federal rate, we estimate that the

effect of the proposed 0.6 percent update to the standard Federal rate

would result in a 0.5 percent increase (as shown in Column 6 of Table

IV) on estimated aggregate LTCH PPS payments for all LTCH PPS cases,

including SSO cases.

While the effects of the estimated increase in SSO and HCO payments

and the proposed change to the standard Federal rate are projected to

increase estimated payments from RY 2009 to RY 2010, the proposed

changes to the area wage adjustment from RY 2009 to RY 2010 are

expected to result in neither an increase nor a decrease in estimated

aggregate LTCH PPS payments from the 2009 LTCH PPS rate year to the

2010 LTCH PPS rate year (Column 7 of Table IV). As discussed in section

V.B. of the Addendum to this proposed rule, we are proposing to update

the wage index values for FY 2010 based on the most recent available

data. In addition, we are proposing to increase the labor-related share

from 75.662 percent to 75.904 percent under the LTCH PPS for RY 2010

based on the most recent available data on the relative importance of

the labor-related share of operating and capital costs of the RPL

market basket (also discussed in section VIII.C.2. of this proposed

rule).

We note that the overall percent change in estimated LTCH payments

from RY 2009 to RY 2010 for all proposed changes (shown in Column 8)

cannot be determined by adding the incremental effect of the proposed

standard Federal rate (Column 6) and the proposed area wage adjustment

changes (Column 7) on estimated aggregate LTCH PPS payments because

each of those two columns are intended to show the isolated impact of

the respective change (that is, the proposed change to the standard

Federal rate or the proposed change to the area wage adjustment) on

estimated payments for RY 2010 as compared to RY 2009, but the

interactive effects resulting from both the proposed change to the

standard Federal rate and the proposed change to the area wage

adjustment, as well as estimated changes to HCO and SSO payments, are

not reflected in each of these columns. However, the interactive

effects of all proposed changes, including the change in estimated HCO

and SSO payments, are reflected in the estimated change in payments for

all proposed changes for RY 2010 as compared to RY 2009 (shown in

Column 8 of Table IV).

Notwithstanding this limitation in comparing the various columns in

Table IV, the projected increase in payments per discharge from RY 2009

to RY 2010 is 2.8 percent (shown in Column 8). This projected increase

in payments is attributable to the proposed impacts of the proposed

change to the standard Federal rate (0.5 percent in Column 6) and the

proposed change due to the area wage adjustment (0 percent in Column

7), and is also due to the effect of the estimated increase in payments

for HCO cases and SSO cases in RY 2010 as compared to RY 2009. That is,

estimated total HCO payments are projected to increase from RY 2009 to

RY 2010 in order to ensure that estimated HCO payments will be 8

percent of total estimated LTCH PPS payments in RY 2010. As discussed

in detail in section V. of the Addendum to of this proposed rule, an

analysis of the most recent available LTCH PPS claims data (that is, FY

2008 claims from the December 2008 update of the MedPAR files)

indicates that the RY 2009 HCO threshold of $22,960 may result in HCO

payments in RY 2009 that fall below the estimated 8 percent.

Specifically, we currently estimate that HCO payments will be

approximately 6.1 percent of estimated

[[Continued on page 24679]]

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[[pp. 24679-24686]] Medicare Program; Proposed Changes to the Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and Fiscal Year

2010 Rates and to the Long-Term Care Hospital Prospective Payment

System and Rate Year 2010 Rates

[[Continued from page 24678]]

[[Page 24679]]

total LTCH PPS payments in RY 2009. Consequently, it is necessary to

propose to decrease the HCO threshold for RY 2010 in order to ensure

that estimated HCO payments will be 8 percent of total estimated LTCH

PPS payments in RY 2010. We estimate that the impact of the increase

HCO payments would result in approximately a 2 percent increase in

estimated payments from RY 2009 to RY 2010. Furthermore, in calculating

the estimated increase in payments from RY 2009 to RY 2010 for HCO and

SSO cases, we increased estimated costs by the applicable market basket

percentage increase as projected by our actuaries. We note that

estimated payments for SSO cases comprise approximately 15 percent of

estimated total LTCH PPS payments, and estimated payments for HCO cases

comprise approximately 8 percent of estimated total LTCH PPS payments.

Payments for HCO cases are based on 80 percent of the estimated cost

above the HCO threshold, while the majority of the payments for SSO

cases (over 70 percent) are based on the estimated cost of the SSO

case. A thorough discussion of the regulatory impact analysis for the

proposed changes presented in this proposed rule can be found below in

section V. of the Addendum to this proposed rule.

As we discuss in detail throughout this proposed rule, based on the

most recent available data, we believe that the proposed provisions of

this proposed rule relating to the LTCH PPS would result in an increase

in estimated aggregate LTCH PPS payments and that the resulting LTCH

PPS payment amounts result in appropriate Medicare payments.

B. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural

hospital as a hospital that is located outside of a Metropolitan

Statistical Area and has fewer than 100 beds. As shown in Table IV, we

are projecting a 4.2 percent increase in estimated payments per

discharge for the 2010 LTCH PPS rate year as compared to the 2009 LTCH

PPS rate year for rural LTCHs that would result from the proposed

changes presented in this proposed rule (that is, the update to the

standard Federal rate discussed in section V.A. of the Addendum to this

proposed rule and the proposed changes to the area wage adjustment as

discussed in section V.B. of the Addendum to this proposed rule) as

well as the effect of estimated changes to HCO and SSO payments. This

estimated impact is based on the data of the 26 rural LTCHs in our

database of 399 LTCHs for which complete data were available.

The estimated increase in LTCH PPS payments from the 2009 LTCH PPS

rate year to the 2010 LTCH PPS rate year for rural LTCHs is primarily

due to the estimated change in HCO payments; that is, our current

estimate that HCO payments in RY 2009 will be less than 8 percent of

total estimated LTCH PPS payments (as discussed in greater detail in

section V.C. of the Addendum to this proposed rule), the proposed

change to the standard Federal rate (as discussed in greater detail in

section V.A. of the Addendum to this proposed rule), and the proposed

change in the area wage adjustment (as discussed in greater detail in

section V.B. of the Addendum to this proposed rule). We believe that

the proposed changes to the area wage adjustment presented in this

proposed rule (that is, the proposed use of updated wage data and the

proposed change in the labor-related share) would result in accurate

and appropriate LTCH PPS payments in RY 2010 because they are based on

the most recent available data. Such updated data appropriately reflect

national differences in area wage levels and appropriately identifies

the portion of the standard Federal rate that should be adjusted to

account for such differences in area wages, thereby resulting in

accurate and appropriate LTCH PPS payments.

C. Anticipated Effects of Proposed LTCH PPS Payment Rate Change and

Policy Changes

We discuss the impact of the proposed changes to the payment rates,

factors, and other payment rate policies under the LTCH PPS for RY 2010

(in terms of their estimated fiscal impact on the Medicare budget and

on LTCHs) in section VIII. of the preamble of this proposed rule.

1. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for

LTCHs ``maintain budget neutrality.'' We believe that the statute's

mandate for budget neutrality applies only to the first year of the

implementation of the LTCH PPS (that is, FY 2003). Therefore, in

calculating the FY 2003 standard Federal rate under Sec.

412.523(d)(2), we set total estimated payments for FY 2003 under the

LTCH PPS so that estimated aggregate payments under the LTCH PPS were

estimated to equal the amount that would have been paid if the LTCH PPS

had not been implemented.

As discussed in section IX.A. of this Appendix A, we project an

increase in aggregate LTCH PPS payments in RY 2010 of approximately

$135 million (or 2.8 percent) based on the 399 LTCHs in our database.

2. Impact on Providers

The basic methodology for determining a per discharge LTCH PPS

payment is set forth in Sec. 412.515 through Sec. 412.536. In

addition to the basic MS-LTC-DRG payment (standard Federal rate

multiplied by the MS-LTC-DRG relative weight), we make adjustments for

differences in area wage levels, COLA for Alaska and Hawaii, and SSOs.

Furthermore, LTCHs may also receive HCO payments for those cases that

qualify based on the threshold established each rate year.

To understand the impact of the proposed changes to the LTCH PPS

payments presented in this proposed rule on different categories of

LTCHs for the 2010 LTCH PPS rate year, it is necessary to estimate

payments per discharge for the 2009 LTCH PPS rate year using the rates,

factors and policies established in the RY 2009 LTCH PPS final rule (73

FR 26788 through 26874) and the FY 2009 GROUPER (Version 26.0) and

relative weights established in the FY 2009 IPPS final rule (73 FR

23537 through 23617). It is also necessary to estimate the payments per

discharge that would be made under the proposed LTCH PPS rates,

factors, policies, and GROUPER for the 2010 LTCH PPS rate year (as

discussed in VIII. of the preamble and section V. of the Addendum to

this proposed rule). These estimates of RY 2009 and RY 2010 LTCH PPS

payments are based on the best available LTCH claims data and other

factors such as the application of inflation factors to estimate costs

for SSO and HCO cases in each year. We also evaluated the change in

estimated 2009 LTCH PPS rate year payments to estimated 2010 LTCH PPS

rate year payments (on a per discharge basis) for each category of

LTCHs.

Hospital groups were based on characteristics provided in the OSCAR

data, FY 2004 through FY 2006 cost report data in HCRIS, and PSF data.

Hospitals with incomplete characteristics were grouped into the

``unknown'' category. Hospital groups include the following:

Location: large urban/other urban/rural.

Participation date.

Ownership control.

Census region.

Bed size.

To estimate the impacts of the proposed payment rates and policy

changes among the various categories of existing providers, we used

LTCH cases from the FY 2008 MedPAR file to estimate payments for RY

2009 and to estimate payments for RY 2010 for 399 LTCHs. While

currently there are just

[[Page 24680]]

over 400 LTCHs, the most recent growth is predominantly in for-profit

LTCHs that provide respiratory and ventilator-dependent patient care.

We believe that the discharges based on the FY 2008 MedPAR data for the

399 LTCHs in our database, which includes 267 proprietary LTCHs,

provide sufficient representation in the MS-LTC-DRGs containing

discharges for patients who received LTCH care for the most commonly

treated LTCH patients' diagnoses.

3. Calculation of Prospective Payments

For purposes of this impact analysis, to estimate per discharge

payments under the LTCH PPS, we simulated payments on a case-by-case

basis using LTCH claims from the FY 2008 MedPAR files. For modeling

estimated LTCH PPS payments for RY 2009, we applied the RY 2009

standard Federal rate (that is, $39,114.36, which is effective for LTCH

discharges occurring on or after July 1, 2008, and through September

30, 2009). For modeling estimated LTCH PPS payments for RY 2010, we

applied the proposed RY 2010 standard Federal rate of $39,349.05, which

would be effective for LTCH discharges occurring on or after October 1,

2009, and through September 30, 2010).

Furthermore, in modeling estimated LTCH PPS payments for both RY

2009 and RY 2010 in this impact analysis, we applied the RY 2009 and

proposed RY 2010 adjustments for area wage differences and the COLA for

Alaska and Hawaii. Specifically, we adjusted for area wage differences

for estimated 2009 LTCH PPS rate year payments using the current LTCH

PPS labor-related share of 75.662 percent (73 FR 26815), the wage index

values established in the Tables 1 and 2 of the Addendum of the RY 2009

final rule (73 FR 26840 through 26863) and the COLA factors established

in Table III of the preamble of the RY 2009 final rule (73 FR 26819).

Similarly, we adjusted for area wage differences for estimated proposed

2010 LTCH PPS rate year payments using the LTCH PPS proposed RY 2010

labor-related share of 75.904 percent (section VIII.C.2. of the

preamble of this proposed rule), the proposed RY 2010 wage index values

presented in the Tables 12A and 12B of the Addendum to this proposed

rule, and the proposed RY 2010 COLA factors shown in the table in

section V. of the Addendum to this proposed rule.

As discussed above, our impact analysis reflects an estimated

change in payments for SSO cases as well as an estimated increase in

payments for HCO cases (as described in section V.C. of the Addendum to

this proposed rule). In modeling payments for SSO and HCO cases in RY

2009, we applied an inflation factor of 1.024 percent (determined by

OACT) to the estimated costs of each case determined from the charges

reported on the claims in the FY 2008 MedPAR files and the best

available CCRs from the December 2008 update of the PSF. In modeling

proposed payments for SSO and HCO cases in RY 2010, we applied an

inflation factor of 1.049 (determined by OACT) to the estimated costs

of each case determined from the charges reported on the claims in the

FY 2008 MedPAR files and the best available CCRs from the December 2008

update of the PSF.

These impacts reflect the estimated ``losses'' or ``gains'' among

the various classifications of LTCHs from the 2009 LTCH PPS rate year

to the 2010 LTCH PPS rate year based on the proposed payment rates and

policy changes presented in this proposed rule. Table IV illustrates

the estimated aggregate impact of the LTCH PPS among various

classifications of LTCHs.

The first column, LTCH Classification, identifies the type

of LTCH.

The second column lists the number of LTCHs of each

classification type.

The third column identifies the number of LTCH cases.

The fourth column shows the estimated payment per

discharge for the 2009 LTCH PPS rate year (as described above).

The fifth column shows the estimated payment per discharge

for the 2010 LTCH PPS rate year (as described above).

The sixth column shows the percentage change in estimated

payments per discharge from the 2009 LTCH PPS rate year to the 2010

LTCH PPS rate year for proposed changes to the standard Federal rate

(as discussed in section V. of the Addendum to this proposed rule).

The seventh column shows the percentage change in

estimated payments per discharge from the 2009 LTCH PPS rate year to

the 2010 LTCH PPS rate year for proposed changes to the area wage

adjustment at Sec. 412.525(c) (as discussed in section V.B.4. of the

Addendum to this proposed rule).

The eighth column shows the percentage change in estimated

payments per discharge from the 2009 LTCH PPS rate year (Column 4) to

the 2010 LTCH PPS rate year (Column 5) for all proposed changes (and

includes the effect of estimated changes to HCO and SSO payments).

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4. Results

Based on the most recent available data (as described previously

for 399 LTCHs), we have prepared the following summary of the impact

(as shown in Table IV) of the proposed LTCH PPS payment rate and policy

changes presented in this proposed rule. The impact analysis in Table

IV shows that estimated payments per discharge are expected to increase

approximately 2.8 percent, on average, for all LTCHs from the 2009 LTCH

PPS rate year to the 2010 LTCH PPS rate year as a result of the

proposed payment rate and policy changes presented in this proposed

rule as well as estimated increases in HCO and SSO payments. We note

that we are proposing a 0.6 percent increase to the standard Federal

rate for RY 2010, based on the latest market basket estimate (2.4

percent) and the proposed documentation and coding adjustment (-1.8

percent). We noted earlier in this section that or most categories of

LTCHs, as shown in Table IV (Column 6), the impact of the proposed

increase of 0.6 percent to the standard Federal rate is projected to

result in a 0.5 percent increase in estimated payments per discharge

for all LTCHs from the 2009 LTCH PPS rate year to the 2010 LTCH PPS

rate year. In addition to the proposed 0.6 percent increase to the

standard Federal rate for RY 2010, the projected percent increase in

estimated payments per discharge from the 2009 LTCH PPS rate year to

the 2010 LTCH PPS rate year of 2.8 percent shown in Table IV (Column 8)

reflects the effect of estimated increases in HCO and SSO payments, as

discussed previously. Furthermore, as discussed previously in this

regulatory impact analysis, the average increase in estimated payments

per discharge from the 2009 LTCH PPS rate year to the 2010 LTCH PPS

rate year for all LTCHs of approximately 2.8 (as shown in Table IV) was

determined by comparing estimated RY 2010 LTCH PPS payments (using the

proposed rates and policies discussed in this proposed rule) to

estimated RY 2009 LTCH PPS payments (as described above in section

IX.C. of this regulatory impact analysis).

a. Location

Based on the most recent available data, the majority of LTCHs are

in urban areas. Approximately 7 percent of the LTCHs are identified as

being located in a rural area, and approximately 5 percent of all LTCH

cases are treated in these rural hospitals. The impact analysis

presented in Table IV shows that the average percent increase in

estimated payments per discharge from the 2009 LTCH PPS rate year to

the 2010 LTCH PPS rate year for all hospitals is 2.8 percent for all

proposed changes. For rural LTCHs, the percent change for all proposed

changes is estimated to be 4.2 percent, while for urban LTCHs, we

estimate this increase to be the average of 2.8 percent. Large urban

LTCHs are projected to experience a slightly higher than average

increase (2.9 percent) in estimated payments per discharge from the

2009 LTCH PPS rate year to the 2010 LTCH PPS rate year, while other

urban LTCHs are projected to experience a slightly lower than average

increase (2.6 percent) in estimated payments per discharge from the

2009 LTCH PPS rate year to the 2010 LTCH PPS rate year, as shown in

Table IV.

b. Participation Date

LTCHs are grouped by participation date into four categories: (1)

Before October 1983; (2) between October 1983 and September 1993; (3)

between October 1993 and September 2002; and (4) after October 2002.

Based on the most recent available data, the majority (approximately 51

percent) of the LTCH cases are in hospitals that began participating

between October 1993 and September 2002, and are projected to

experience about the average increase (3.8 percent) in estimated

payments per discharge from the 2009 LTCH PPS rate year to the 2010

LTCH PPS rate year, as shown in Table IV.

In the two participation categories where LTCHs began participating

in Medicare before October 1983 (that is, the ``Before October 1983''

category and the ``October 1983 through September 1993'' category),

LTCHs are projected to experience higher than average percent increases

(3.7 and 3.4 percent, respectively) in estimated payments per discharge

from the 2009 LTCH PPS rate year to the 2010 LTCH PPS rate year, as

shown in Table IV, due to proposed changes in the wage index and an

estimated increase in HCO payments. Approximately 4 percent of LTCHs

began participating in Medicare before October 1983. The LTCHs in this

category are projected to experience a higher than average increase in

estimated payments because 65 percent of these LTCHs are located in

areas where the proposed RY 2010 wage index value is greater than the

RY 2009 wage index value, and also because the majority of these LTCHs

have a proposed wage index value of greater than 1.0. Approximately 11

percent of LTCHs began participating in Medicare between October 1983

and September 1993. These LTCHs are projected to experience a higher

than average increase in estimated payments because the majority (57

percent) are located in areas where the proposed RY 2010 wage index

value would be greater than the RY 2009 wage index value. The majority

of LTCHs, that is, those that began participating in Medicare since

October 1993, are projected to experience near average increases in

estimated payments per discharge from the 2009 LTCH PPS rate year to

the 2010 LTCH PPS rate year, as shown in Table IV.

c. Ownership Control

Other than LTCHs whose ownership control type is unknown, LTCHs are

grouped into three categories based on ownership control type:

voluntary, proprietary, and government. Based on the most recent

available data, approximately 20 percent of LTCHs are identified as

voluntary (Table IV). We expect that, for these LTCHs in the voluntary

category, estimated 2010 LTCH PPS rate year payments per discharge

would increase higher than the average (3.3 percent) in comparison to

estimated payments in the 2009 LTCH PPS rate year, as shown in Table

IV, primarily because the change in estimated HCO payments is projected

to be higher than the average for these LTCHs. The majority (67

percent) of LTCHs are identified as proprietary and these LTCHs are

projected to experience a near average (2.6 percent) increase in

estimated payments per discharge from the 2009 LTCH PPS rate year to

the 2010 LTCH PPS rate year. Finally, government-owned and operated

LTCHs (3 percent) are expected to experience a higher than the average

increase (3.8 percent) in estimated payments primarily due to larger

than the average increase in estimated HCO payments.

d. Census Region

Estimated payments per discharge for the 2010 LTCH PPS rate year

are projected to increase for LTCHs located in all regions in

comparison to the 2009 LTCH PPS rate year. Of the 9 census regions, we

project that the increase in estimated payments per discharge would

have the largest impact on LTCHs in the New England, East South

Central, Mountain, and Pacific regions (4.0 percent, 3.2 percent, 4.1

percent, and 3.8 percent, respectively, as shown in Table IV). As

explained in greater detail above in section XV.B.4. of this Appendix,

the estimated percent increase in payments per discharge from the 2009

LTCH PPS rate year to the 2010 LTCH PPS rate year for most regions is

largely attributable to the projected increase in estimated HCO and SSO

payments in addition to the proposed increase in the standard Federal

rate and the proposed changes to the area wage adjustment.

Specifically, for the

[[Page 24684]]

New England region, all the LTCHs located in this region have a

proposed wage index value of greater than 1.0; and the majority (87

percent) of these LTCHs are located in areas where the proposed RY 2010

wage index value is greater than the RY 2009 wage index value. The

projected increase in estimated payments per discharge from the 2009

LTCH PPS rate year to the 2010 LTCH PPS rate year for LTCHs in the East

South Central region, as shown in Table IV, is due to the estimated

increase in HCO payments, while for LTCHs in the Mountain and Pacific

regions, the projected increase in payments is due to both the

estimated increase in HCO payments and the significantly higher than

average estimated impact from the proposed changes to the area wage

adjustment. That is, the majority (60 percent) of the LTCHs located in

the Mountain region have a proposed wage index value of greater than

1.0, and in addition, most of these LTCHs are located in areas where

the proposed RY 2010 wage index value is greater than the RY 2009 wage

index value. Furthermore, all the LTCHs located in the Pacific region

have a proposed wage index value of greater than 1.0 and are located in

areas where the proposed RY 2010 wage index value would be greater than

the RY 2009 wage index value.

In contrast, LTCHs located in the Middle Atlantic and East North

Central regions are projected to experience a lower than average

increase in estimated payments per discharge from the 2009 LTCH PPS

rate year to the 2010 LTCH PPS rate year. The projected increase in

payments of 1.7 percent for LTCHs in the Middle Atlantic region is

primarily due to the 59 percent of LTCHs located in areas where the

proposed RY 2010 wage index value would be less than the RY 2009 wage

index value. In addition, 62 percent of the LTCHs in this category are

projected to have a proposed RY 2010 wage index value of greater than

1.0. Similarly, the lower than average increase in payments per

discharge for LTCHs in the East North Central region is largely due to

the majority of LTCHs in this region that are expected to experience a

decrease in estimated payments per discharge due to the proposed

changes in the area wage adjustment. For LTCHs in the Middle Atlantic

and East North Central regions, the increase in estimated payments is

less than the estimated average increase in payments for all providers

due to the proposed changes in the area wage adjustment as discussed

above. However, we note that the projected increase in estimated HCO

payments for LTCHs in this region in addition to the increase in the

standard Federal rate results in an overall estimated increase, albeit

less than the average increase, in estimated payments per discharge

from the 2009 LTCH PPS rate year to the 2010 LTCH PPS rate year. The

remaining regions, South Atlantic, West North Central, and West South

Central, are expected to experience near the average increases in

estimated payments per discharge from the 2009 LTCH PPS rate year to

the 2010 LTCH PPS rate year.

e. Bed Size

LTCHs were grouped into six categories based on bed size: 0-24

beds; 25-49 beds; 50-74 beds; 75-124 beds; 125-199 beds; and greater

than 200 beds.

We are projecting an increase in estimated 2010 LTCH PPS rate year

payments per discharge in comparison to the 2009 LTCH PPS rate year for

all bed size categories. Approximately 38 percent of LTCHs are in bed

size categories where estimated 2010 LTCH PPS rate year payments per

discharge are projected to increase at or near the average increase for

all LTCHS in comparison to estimated 2009 LTCH PPS rate year payments

per discharge. That is, LTCHs in bed size categories of 50-74 beds, 75-

124 beds, and 125-199 beds are projected to experience an overall

increase of 2.9 percent. LTCHs in the bed size category of 0-24 beds

are projected to experience a higher than the average increase (3.8

percent) in estimated payments per discharge from the 2009 LTCH PPS

rate year to the 2010 LTCH PPS rate year due primarily to the estimated

increase in HCO payments, while for LTCHs with 200+ beds, the projected

increase in estimated payments is largely due to the significantly

higher than average impact from the proposed changes to the area wage

adjustment. Specifically, 69 percent of LTCHs in this category are

expected to have a proposed RY 2010 wage index value of greater than

1.0, and 62 percent of the LTCHs in this category are located in areas

where the proposed RY 2010 wage index value is greater than the RY 2009

wage index value. We are projecting a slightly lower than the average

increase in estimated 2010 LTCH PPS rate year payments per discharge in

comparison to the 2009 LTCH PPS rate year for LTCHs in bed size

category 25-49 beds, which is largely due to the 87 percent of LTCHs in

this category expected to have a proposed RY 2010 wage index value of

less than 1.0. In addition, 54 percent of the LTCHs in this category

are located in areas where the proposed RY 2010 wage index value is

less than the RY 2009 wage index value.

D. Effect on the Medicare Program

As noted previously, we project that the provisions of this

proposed rule would result in an increase in estimated aggregate LTCH

PPS payments in RY 2010 of approximately $135 million (or about 2.8

percent) for the 399 LTCHs in our database.

E. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average

resources consumed by patients for each diagnosis. We do not expect any

changes in the quality of care or access to services for Medicare

beneficiaries under the LTCH PPS, but we expect that paying

prospectively for LTCH services would enhance the efficiency of the

Medicare program.

X. Alternatives Considered

This proposed rule contains a range of policies. The preamble of

this proposed rule provides descriptions of the statutory provisions

that are addressed, identifies implementing policies where discretion

has been exercised, and presents rationales for our decisions and,

where relevant, alternatives that were considered.

XI. Overall Conclusion

A. Acute Care Hospitals

Table I of section VI. of this Appendix demonstrates the estimated

distributional impact of the IPPS budget neutrality requirements for

the proposed MS-DRG and wage index changes, and for the wage index

reclassifications under the MGCRB. Table I also shows an overall

decrease of 0.5 percent in operating payments. We estimate that

operating payments will decrease by $586 million in FY 2010. This

accounts for the projected savings associated with the HACs policy,

which have an estimated savings of $21 million. In addition, this

estimate includes the hospital reporting of quality data program costs

of $2.39 million, and all proposed operating payment policies as

described in section VII. of this Appendix. We estimate that capital

payments will decrease by 4.8 percent per case, as shown in Table III

of section VIII. of this Appendix. Therefore, we project that the

decrease in capital payments in FY 2010 compared to FY 2009 will be

approximately $393 million. The proposed cumulative operating and

capital payments should result in a net decrease of $979 million to

IPPS providers. The discussions presented in the previous pages, in

combination with the rest of this

[[Page 24685]]

proposed rule, constitute a regulatory impact analysis.

B. LTCHs

Overall, LTCHs are projected to experience an increase in estimated

payments per discharge in RY 2010. In the impact analysis, we are using

the proposed rates, factors, and policies presented in this proposed

rule, including proposed updated wage index values, and the best

available claims and CCR data to estimate the change in payments for

the 2010 LTCH PPS rate year. Accordingly, based on the best available

data for the 399 LTCHs in our database, we estimate that RY 2010 LTCH

PPS payments will increase approximately $135 million (or about 2.8

percent).

XII. Accounting Statements

A. Acute Care Hospitals

As required by OMB Circular A-4 (available at http://

www.whitehousegov/omb/circulars/a004/a-4.pdf), in Table V below, we

have prepared an accounting statement showing the classification of the

expenditures associated with the provisions of this proposed rule as

they relate to acute care hospitals. This table provides our best

estimate of the increase in Medicare payments to providers as a result

of the proposed changes to the IPPS presented in this proposed rule.

All expenditures are classified as transfers to Medicare providers.

Table V--Accounting Statement: Classification of Estimated Expenditures

Under the IPPS From FY 2009 to FY 2010

------------------------------------------------------------------------

Category Transfers

------------------------------------------------------------------------

Annualized Monetized Transfers............ $-979 million.

From Whom to Whom......................... Federal Government to IPPS

Medicare Providers.

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Total................................. $-979 million.

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B. LTCHs

As discussed in section IX. of this Appendix , the impact analysis

for the proposed changes under the LTCH PPS for this proposed rule

projects an increase in estimated aggregate payments of approximately

$135 million (or about 2.8 percent) for the 399 LTCHs in our database

that are subject to payment under the LTCH PPS. Therefore, as required

by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/

circulars/a004/a-4.pdf), in Table VI we have prepared an accounting

statement showing the classification of the expenditures associated

with the provisions of this proposed rule as they relate to proposed

changes to the LTCH PPS. Table VI provides our best estimate of the

proposed increase in Medicare payments under the LTCH PPS as a result

of the proposed provisions presented in this proposed rule based on the

data for the 399 LTCHs in our database. All expenditures are classified

as transfers to Medicare providers (that is, LTCHs).

Table VI--Accounting Statement: Classification of Estimated

Expenditures, From the 2009 LTCH PPS Rate Year to the 2010 LTCH PPS Rate

Year

------------------------------------------------------------------------

Category Transfers

------------------------------------------------------------------------

Annualized Monetized Transfers............ Positive transfer--Estimated

increase in expenditures:

$135 million.

From Whom To Whom......................... Federal Government to LTCH

Medicare Providers.

------------------------------------------------------------------------

XIII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the

Executive Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates

of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary,

taking into consideration the recommendations of the MedPAC,

recommend update factors for inpatient hospital services for each

fiscal year that take into account the amounts necessary for the

efficient and effective delivery of medically appropriate and

necessary care of high quality. Under section 1886(e)(5) of the Act,

we are required to publish update factors recommended by the

Secretary in the proposed and final IPPS rules, respectively.

Accordingly, this Appendix provides the recommendations for the

update factors for the IPPS national standardized amount, the Puerto

Rico-specific standardized amount, the hospital-specific rates for

SCHs and MDHs, and the rate-of-increase limits for certain hospitals

excluded from the IPPS, as well as LTCHs, IPFs, and IRFs. We also

discuss our response to MedPAC's recommended update factors for

inpatient hospital services.

II. Inpatient Hospital Update for FY 2010

Section 1886(b)(3)(B)(i)(XX) of the Act, as amended by section

5001(a) of Public Law 109-171, sets the FY 2010 percentage increase

in the operating cost standardized amount equal to the rate-of-

increase in the hospital market basket for IPPS hospitals in all

areas, subject to the hospital submitting quality information under

rules established by the Secretary in accordance with section

1886(b)(3)(B)(viii) of the Act. For hospitals that do not provide

these data, the update is equal to the market basket percentage

increase less 2.0 percentage points.

In compliance with section 404 of the MMA, in this proposed

rule, we are proposing to replace the FY 2002-based IPPS operating

and capital market baskets with the revised and rebased FY 2006-

based IPPS operating and capital market baskets for FY 2010. In

addition to updating the base year to reflect more recent data, we

also are proposing to make several changes to the structure of the

market basket, including three new expense categories and revising

several price proxies.

We also are proposing to rebase the labor-related share to

reflect the more recent base year. The current labor-related share,

which is based on the FY 2002-based IPPS market basket, is 69.7. We

are proposing a labor-related share of 67.1, which is based on the

proposed rebased and revised FY 2006-based IPPS market basket. For a

complete discussion on the rebasing of the market basket and labor

share, we refer readers to section IV. of the preamble to this

proposed rule.

Consistent with current law, based on IHS Global Insight, Inc.

2009 first quarter forecast, with historical data through the 2008

fourth quarter, of the proposed rebased and revised FY 2006-based

IPPS market basket, we are estimating that the FY 2010 update to the

standardized amount will be 2.1 percent (that is, the current

estimate of the market basket rate-of-increase) for hospitals in all

areas, provided the hospital submits quality data in accordance with

our rules. For hospitals that do not submit quality data, we are

estimating that the update to the standardized amount will be 0.1

percent (that is, the current estimate of the market basket rate-of-

increase minus 2.0 percentage points).

Section 1886(d)(9)(C)(i) of the Act is the basis for determining

the percentage increase to the Puerto Rico-specific standardized

amount. For FY 2010, we are proposing to apply the full rate-of-

increase in the hospital market basket for IPPS hospitals to the

Puerto Rico-specific standardized amount. Therefore, the update to

the Puerto Rico-specific standardized amount is estimated to be 2.1

percent.

Section 1886(b)(3)(B)(iv) of the Act sets the FY 2010 percentage

increase in the hospital-specific rates applicable to SCHs and MDHs

equal to the rate set forth in section 1886(b)(3)(B)(i) of the Act

(that is, the same update factor as for all other hospitals subject

to the IPPS, or the rate-of-increase in the market basket).

Therefore, the update to the hospital-specific rates applicable to

SCHs and MDHs is estimated to be 2.1 or 0.1 percent, depending upon

whether the hospital submits quality data.

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of

determining the percentage increase in the rate-of-increase limits

for children's and cancer hospitals. Section 1886(b)(3)(B)(ii) of

the Act sets the percentage increase in the rate-of-increase

[[Page 24686]]

limits equal to the market basket percentage increase. In accordance

with Sec. 403.752(a) of the regulations, RNHCIs are paid under

Sec. 413.40, which also uses section 1886(b)(3)(B)(ii) of the Act

to update the percentage increase in the rate-of-increase limits.

Section 1886(j)(3)(C) of the Act addresses the increase factor for

the Federal prospective payment rate of IRFs. Section 123 of Public

Law 106-113, as amended by section 307(b) of Pub. L. 106-554,

provides the statutory authority for updating payment rates under

the LTCH PPS. In addition, section 124 of Public Law 106-113

provides the statutory authority for updating all aspects of the

payment rates for IPFs.

Currently, children's hospitals, cancer hospitals, and RNHCIs

are the remaining three types of hospitals still reimbursed under

the reasonable cost methodology. We are proposing to provide our

current estimate of the FY 2010 IPPS operating market basket

percentage increase (2.1 percent) to update the target limits for

children's hospitals, cancer hospitals, and RNHCIs.

For RY 2010, as discussed in section VIII. of the preamble to

this proposed rule, we are proposing an update of 0.6 percent to the

LTCH PPS Federal rate, which is based on a proposed market basket

increase of 2.4 percent (based on IHS Global Insight, Inc.'s first

quarter 2009 forecast of the FY 2002-based RPL market basket

increase for RY 2010) and a proposed adjustment of -1.8 percent to

account for the increase in case-mix in a prior year that resulted

from changes in coding practices rather than an increase in patient

severity.

Effective for cost reporting periods beginning on or after

January 1, 2005, IPFs are paid under the IPF PPS. IPF PPS payments

are based on a Federal per diem rate that is derived from the sum of

the average routine operating, ancillary, and capital costs for each

patient day of psychiatric care in an IPF, adjusted for budget

neutrality.

IRFs are paid under the IRF PPS for cost reporting periods

beginning on or after January 1, 2002. For cost reporting periods

beginning on or after October 1, 2002 (FY 2003), and thereafter, the

Federal prospective payments to IRFs are based on 100 percent of the

adjusted Federal IRF prospective payment amount, updated annually

(69 FR 45721).

III. Secretary's Recommendation

MedPAC is recommending an inpatient hospital update equal to the

market basket rate of increase for FY 2010. MedPAC's rationale for

this update recommendation is described in more detail below. Based

on IHS Global Insight, Inc.'s 2009 first quarter forecast, with

historical data through the 2008 fourth quarter, of the proposed

rebased and revised FY 2006-based IPPS market basket, we are

recommending an update to the standardized amount of 2.1 percent. We

are recommending that this same update factor apply to SCHs and

MDHs.

Section 1886(d)(9)(C)(i) of the Act is the basis for determining

the percentage increase to the Puerto Rico-specific standardized

amount. For FY 2010, we are proposing to apply the full rate-of-

increase in the hospital market basket for IPPS hospitals to the

Puerto Rico-specific standardized amount. Therefore, the update to

the Puerto Rico-specific standardized amount is estimated to be 2.1

percent.

In addition to making a recommendation for IPPS hospitals, in

accordance with section 1886(e)(4)(A) of the Act, we are

recommending update factors for all other types of hospitals. Using

IHS Global Insight, Inc.'s 2009 first quarter forecast, with

historical data through the 2008 fourth quarter, of the proposed

rebased and revised FY 2006-based IPPS market basket, we are

recommending an update based on the IPPS market basket increase for

children's hospitals, cancer hospitals, and RNHCIs of 2.1 percent.

Based on IHS Global Insight, Inc.'s first quarter 2009 forecast

of the RPL market basket increase, we are recommending an update to

the IPF PPS Federal rate for RY 2010 of 2.1 percent for the Federal

per diem payment amount.

For RY 2010, similar to our proposal in section VIII. of the

preamble of this proposed rule, we are recommending an update of 2.4

percent to the LTCH PPS Federal rate, which is based on a proposed

market basket increase of 2.4 percent (based on IHS Global Insight,

Inc.'s first quarter 2009 forecast of the FY 2002-based RPL market

basket increase for RY 2010) and a proposed adjustment of -1.8

percent to account for the increase in case-mix in a prior year that

resulted from changes in coding practices rather than an increase in

patient severity.

Finally, based on IHS Global Insight, Inc.'s first quarter 2009

forecast of the RPL market basket increase, we are recommending a

2.4 percent update to the IRF PPS Federal rate for FY 2010.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating

Payments in Traditional Medicare

In its March 2009 Report to Congress, MedPAC assessed the

adequacy of current payments and costs, and the relationship between

payments and an appropriate cost base, utilizing an established

methodology used by MedPAC in the past several years.

MedPAC recommended an update to the hospital inpatient rates

equal to the increase in the hospital market basket in FY 2010,

concurrent with implementation of a quality incentive program.

Similar to last year, MedPAC also recommended that CMS put pressure

on hospitals to control their costs rather than accommodate the

current rate of cost growth, which is, in part, caused by a lack of

pressure from private payers.

MedPAC noted that indicators of payment adequacy are almost

uniformly positive. MedPAC expects Medicare margins to remain low in

2010. At the same time though, MedPAC's analysis finds that

hospitals with low non-Medicare profit margins have below average

standardized costs and most of these facilities have positive

overall Medicare margins.

Response: Similar to our response last year, we agree with

MedPAC that hospitals should control costs rather than accommodate

the current rate of growth. An update equal to less than the market

basket will motivate hospitals to control their costs, consistent

with MedPAC's recommendation. As MedPAC noted, the lack of financial

pressure at certain hospitals can lead to higher costs and in turn

bring down the overall Medicare margin for the industry.

As discussed in section II. of the preamble of this proposed

rule, CMS implemented the MS-DRGs in FY 2008 to better account for

severity of illness under the IPPS and is basing the DRG weights on

costs rather than charges. We continue to believe that these

refinements will better match Medicare payment of the cost of care

and provide incentives for hospitals to be more efficient in

controlling costs.

We note that, because the operating and capital prospective

payment systems remain separate, we are proposing to continue to use

separate updates for operating and capital payments. The proposed

update to the capital rate is discussed in section III. of the

Addendum to this proposed rule.

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