Regulatory Procedures and the Federal Health Care Financing Programs

America's Essential Hospitals

Government Relations Academy

March 16, 2015

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Role of Federal Regulations

- Regulations (aka "rules") are the key policymaking tool for executive branch agencies
- Regulations have the force of law, and non-compliance may result in penalties (these vary)
- Several federal departments and agencies involved in issuing health care finance regulations

Department of Health and Human Services HHS)/ Centers for Medicare & Medicaid Services (CMS)	Medicare, Medicaid, CHIP, Health Insurance Portability and Accountability Act (HIPAA). much of the ACA
Department of Treasury/Internal Revenue Service	HIPAA , ACA (i.e., premium tax credits, individual responsibility penalty)
Department of Labor	ERISA, HIPAA, ACA (as applies to employer sponsored plans)

- Not all agency actions require rulemaking, and rulemaking process can be waived due to exigent circumstances (e.g., natural disasters, states of emergency)

REGULATORY PLANNING PROCESS

- Government-wide Regulatory Plan (fall) and Unified Agenda of Federal Regulatory and Deregulatory Actions (spring, fall)
  - Signals regulatory priorities, but not binding

- Annual Medicare provider payment regulations issued on a schedule necessary to achieve fiscal/calendar year implementation
  - Inpatient hospital: proposed by April 1st, final by August 1
  - Outpatient hospital: proposed by July 1st, final by November 1

Rulemaking Process Basics

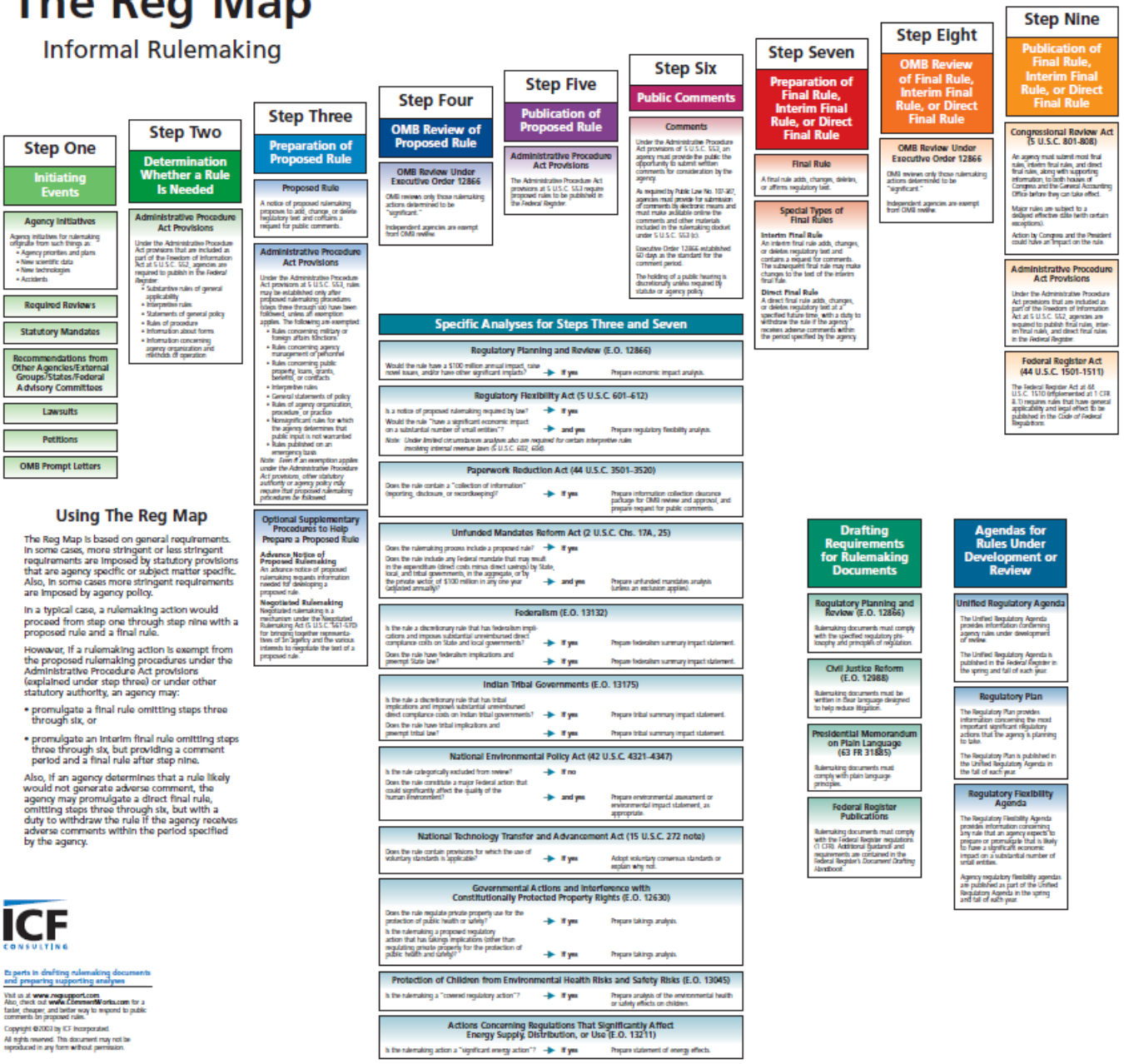
Basis for Rulemaking

- Rulemaking requires an underlying statutory authority
  - Some laws specifically require issuance of a rule
  - Some laws authorize issuance of rules

- Rulemaking procedures are governed chiefly by the Administrative Procedure Act (APA) and various Executive Orders and directives (e.g., Executive Orders 12866 (Clinton) and 13563 (Obama))
  - Agencies prescribe rulemaking processes within these requirements

The Reg Map

Informal Rulemaking



Using The Reg Map

The Reg Map is based on general requirements. In some cases, more stringent or less stringent requirements are imposed by statutory provisions that are agency specific or subject matter specific. Also, in some cases more stringent requirements are imposed by agency policy.

In a typical case, a rulemaking action would proceed from step one through step nine with a proposed rule and a final rule.

However, if a rulemaking action is exempt from the proposed rulemaking procedures under the Administrative Procedure Act provisions (explained under step three) or under other statutory authority, an agency may:

- promulgate a final rule omitting steps three through six, or
- promulgate an interim final rule omitting steps three through six, but providing a comment period and a final rule after step nine.

Also, if an agency determines that a rule likely would not generate adverse comment, the agency may promulgate a direct final rule, omitting steps three through six, but with a duty to withdraw the rule if the agency receives adverse comments within the period specified by the agency.

Federal Rulemaking Process: Key Steps

Statute Directs or Authorizes Agency Rulemaking

Agency drafts proposed rule

Review and clearance: Agency, Department and the Office of Management and Budget (OMB)

Federal Register publication; public comment period opens

Public submits comments

Agency drafts final rule

Review and clearance: Agency, Department and OMB

Federal Register publication of final rule

Codification in the *Code of Federal Regulations*

RULEMAKING BEGINS WITHIN AN AGENCY

- Agency drafts proposed rule (*aka* Notice of Proposed Rulemaking)
  - Consideration of advisory committee reports, work of staff and contractors
  - Consultations with external stakeholders
  - May issue formal Request for Information (RFI) or Request for Comments (RFC) or Advance Notice of Proposed Rulemaking
- Agency/Department internal review and clearance process for proposed rule
- Reviewed by the President's Office of Management and Budget (OMB)
  - Regulations under review at OMB posted on *reginfo.gov*

http://www.reginfo.gov

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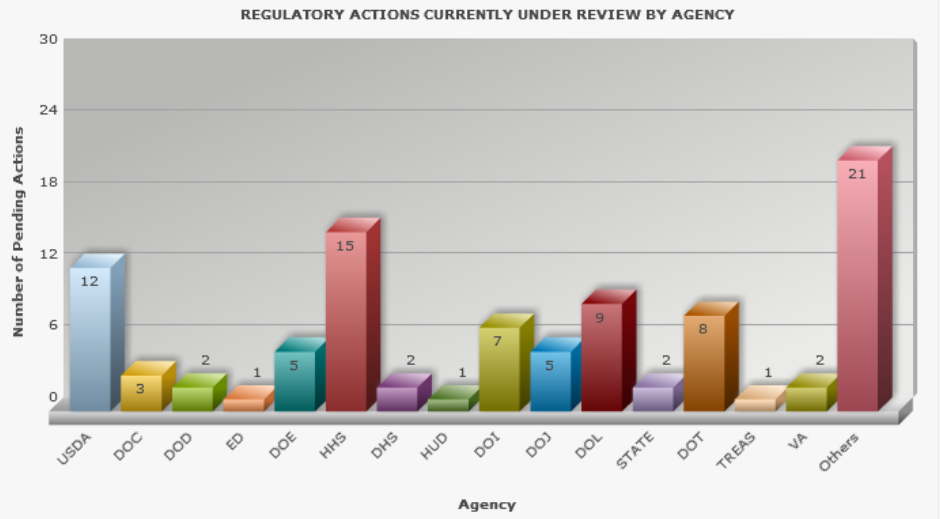

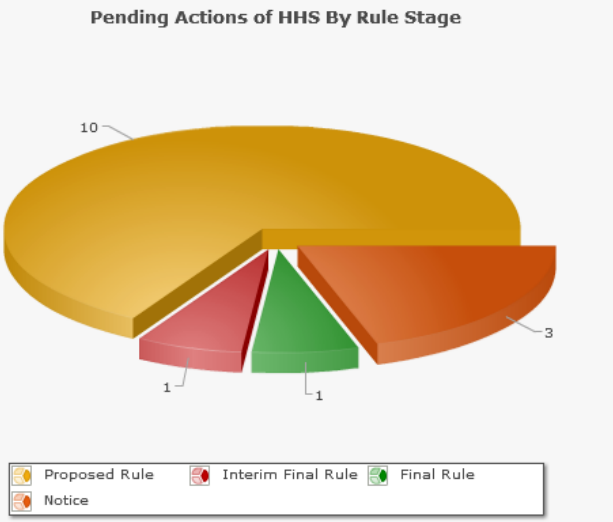

View By Agency

Total Pending Actions: 96

View By Rule Stage

List of Regulatory Actions Currently Under Review

(Agency: HHS; Rule Stage: ALL; Length of Review: ALL; Economically Significant: ALL; International Impact: ALL)

Department of Health and Human Services

AGENCY: HHS-ACF
RIN: 0970-AC63
TITLE: Head Start Performance Standards
STAGE: Proposed Rule
ECONOMICALLY SIGNIFICANT: No
RECEIVED DATE: 01/09/2015
LEGAL DEADLINE: None

AGENCY: HHS-CMS
RIN: 0938-AS24
TITLE: Mental Health Parity and Addiction Equity Act of 2008; the Application to Medicaid Managed Care, CHIP, and Alternative Benefit Plans (CMS-2333-P)
STAGE: Proposed Rule
ECONOMICALLY SIGNIFICANT: Yes
RECEIVED DATE: 01/07/2015
LEGAL DEADLINE: None

AGENCY: HHS-CMS
RIN: 0938-AS56
TITLE: Pre-Existing Condition Insurance Plan Program Updates (CMS-9995-IFC4)
STAGE: Interim Final Rule
ECONOMICALLY SIGNIFICANT: No

PUBLIC RULEMAKING PROCESS

- Once cleared by the agency, the department and OMB, a proposed rule is made public

- Available for public inspection online and subsequently published in the *Federal Register*
  - Public inspection may precede printed publication by days or weeks (e.g., lengthy Medicare rules)

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FEDERAL REGISTER

The Daily Journal of the United States Government

03/04/2015 Public Inspection

Public Inspection **Special Filing:** 9 documents / 10 agencies **Regular Filing:** 91 documents / 44 agencies

The following documents are on file at the Office of the Federal Register (OFR) and will be published in the Federal Register on the dates listed. Regular Filing documents are routinely placed on file at 8:45 a.m. Eastern Time, for publication in the next day's Federal Register. Special Filing documents are filed at other times and/or dates prior to publication. See About Public Inspection for more information.

March

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S	M	T	W	T	F	S
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15	16	17	18	19	20	21
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Special Filing

updated at 11:15 AM, on Wednesday, March 4th, 2015

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Commerce Department

See National Oceanic and Atmospheric Administration 2

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Farm Credit Administration

NOTICES

Meetings; Sunshine Act

PDF - 65.7 KB; 3 pages Filed on: 03/03/2015 at 04:15 PM FR Document: 2015-05221

ncies/farm-credit-administration link Publication Date: 03/05/2015

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Federal Motor Carrier Safety Administration

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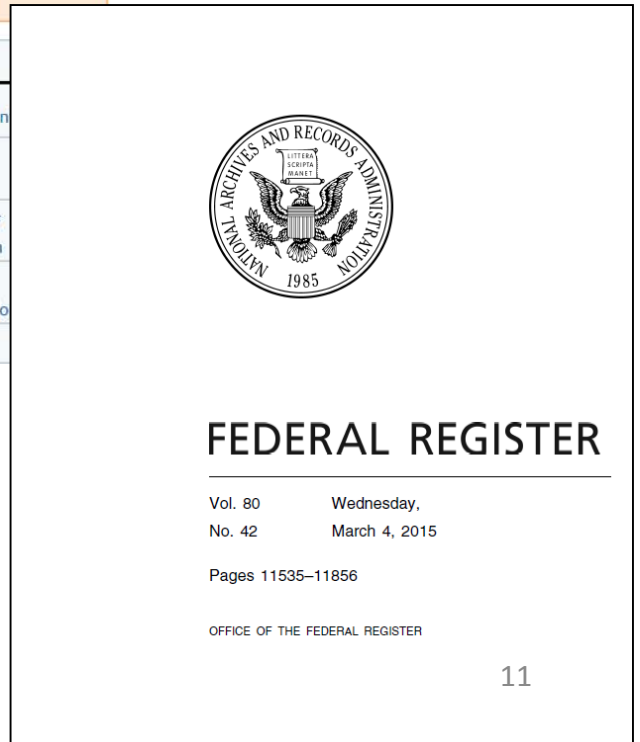

https://www.federalregister.gov/public-inspection

Public Comment

- Each proposed rule describes procedures for submitting public comment and specifies the deadline for accepting comments
- Public comment periods are generally 60 days; may not be less than 30 days
  - May be triggered by public inspection or *Federal Register* publication
- Comments may be submitted online and are publicly available on the *regulations.gov* website.
- Commenters may address some or all issues raised in the proposed rule
  - Agencies will sometimes specifically solicit comments on certain issues
  - Comments on issues not addressed in the proposed rule may not receive immediate agency attention

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medicaid uninsured

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PR Medicaid Program: Disproportionate Share Hospital Payments; Uninsured Definition

This Proposed Rule document was issued by the **Centers for Medicare Medicaid Services** (CMS)

For related information, Open Docket Folder

Action

Proposed rule.

Summary

This proposed rule addresses the hospital-specific limitation on Medicaid disproportionate share hospital (DSH) payments under the Social Security Act. Under this limitation, DSH payments to a hospital cannot exceed the uncompensated costs of furnishing hospital services by the hospital to individuals who are Medicaid-eligible or "have no health insurance (or other source of third party coverage) for the services furnished during the year." This rule would provide that the quoted phrase would refer in context to a lack of coverage on a service-specific basis, so that the calculation of uncompensated care for purposes of the hospital-specific DSH limit would include the cost of each service furnished to an individual who had no health insurance or other source of third party coverage for that service.

Dates

To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2012.

Addresses

In commenting, please refer to file code CMS-2315-P. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2315-P, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

Comment Period Closed
Feb 17 2012, at 11:59 PM ET

ID: CMS-2012-0006-0001

View original printed format:

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Document Information

Date Posted:
Jan 18, 2012

RIN:
Not Assigned

CFR:
42 CFR Part 447

Federal Register Number:
2012-00734

Show More Details

Comments

71
Comments Received*

Components of a proposed rule

- Preamble
- Proposed changes to regulatory text in the Code of Federal Regulations
- Other sections required by law or Executive Order

Components of a proposed rule: Preamble

- A narrative explaining
  - the statutory authority;
  - regulatory history;
  - proposed regulatory provisions and rationale;
  - effective dates of changes;
  - instructions for public comment; and
  - agency staff contacts for further information.

- May include links to further information on agency website or elsewhere
  - Data tables
  - Detailed reports and analysis

PROPOSED RULE: CHANGES TO REGULATORY TEXT

- Proposed changes to the Code of Federal Regulations (CFR)
  - Medicare and Medicaid appear in volume 42 of the CFR
  - ACA insurance coverage regulations from HHS appear in volume 45
- Not all proposed rules involve CFR changes
- Medicare Inpatient Prospective Payment System annual rules, for example

§412.8 Publication of schedules for determining prospective payment rates.

….

(b) Annual publication of schedule for determining prospective payment rates. (1) CMS proposes changes in the methods, amounts, and factors used to determine inpatient prospective payment rates in a Federal Register document published for public comment not later than the April 1 before the beginning of the Federal fiscal year in which the proposed changes would apply.

(2) Except as provided in paragraph (c) of this section, CMS publishes a Federal Register document setting forth final methods, amounts, and factors for determining inpatient prospective payment rates not later than the August 1 before the Federal fiscal year in which the rates would apply.

PROPOSED RULE: OTHER REQUIRED COMPONENTS

- Regulatory impact analysis of costs and benefits is included if economic impact of $100 million or more in any year
- Discussion of alternatives considered by the agency
- Paperwork Reduction Act requirements
- Regulatory Flexibility Act (effect on small entities)
- Unfunded Mandates Reform Act (aggregate effect on state, local, and tribal governments and on private sector)
- Federalism Impact Statement (state and local compliance costs, preemptions of state law)

Information Collection Requirements

- Paperwork Reduction Act of 1995 requires that agency information collections have practical utility, minimize duplication and burden, and support the agency mission.
- Requires OMB approval of surveys, other data collection forms
- Agencies must provide 30-day notice in the *Federal Register* and solicit public comment before a collection of information requirement is submitted to OMB.
- The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Proposed rule may describe proposed information collection requirements for comment (and provide link to forms), or may direct reader to a separate notice on collection of information requirements.

Federal Rulemaking Process in Brief

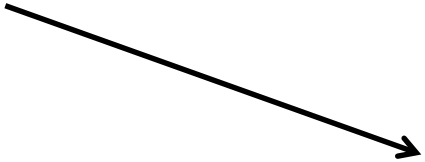
Statute Directs or Authorizes Agency Rulemaking

Agency drafts proposed rule

Review and clearance: Agency, Department and the Office of Management and Budget (OMB)

Federal Register publication; public comment period opens

Public submits comments



Agency drafts final rule

Review and clearance: Agency, Department and OMB

Federal Register publication of final rule

Codification in the *Code of Federal Regulations*

Development of final rule

- Agency reviews public comments on proposed rule
- Care taken in meetings with stakeholders on topics addressed in proposed rule
  - Agency practices vary regarding “ex parte” communication
- Final decisions made and response to public comments prepared
- Agency/Department internal review and clearance process
- Review by OMB
- Final rule publication in the *Federal Register*
- New or revised regulatory text updated on ecfr.gov and the Code of Federal Regulations publications

TIMING OF FINAL RULE

- For rules with a statutory deadline, time between proposed and final rule may be compressed
- Issuance of a final rule may be delayed, particularly if there is no statutory deadline
  - For example,
    - Medicaid Program: Disproportionate Share Hospital Payments, Uninsured Definition

      Proposed: January 18, 2012 Final: December 3, 2014
    - "Medicaid Program: Methods for Assuring Access to Covered Medicaid Services"

      Proposed : May 6, 2011 Final: ???

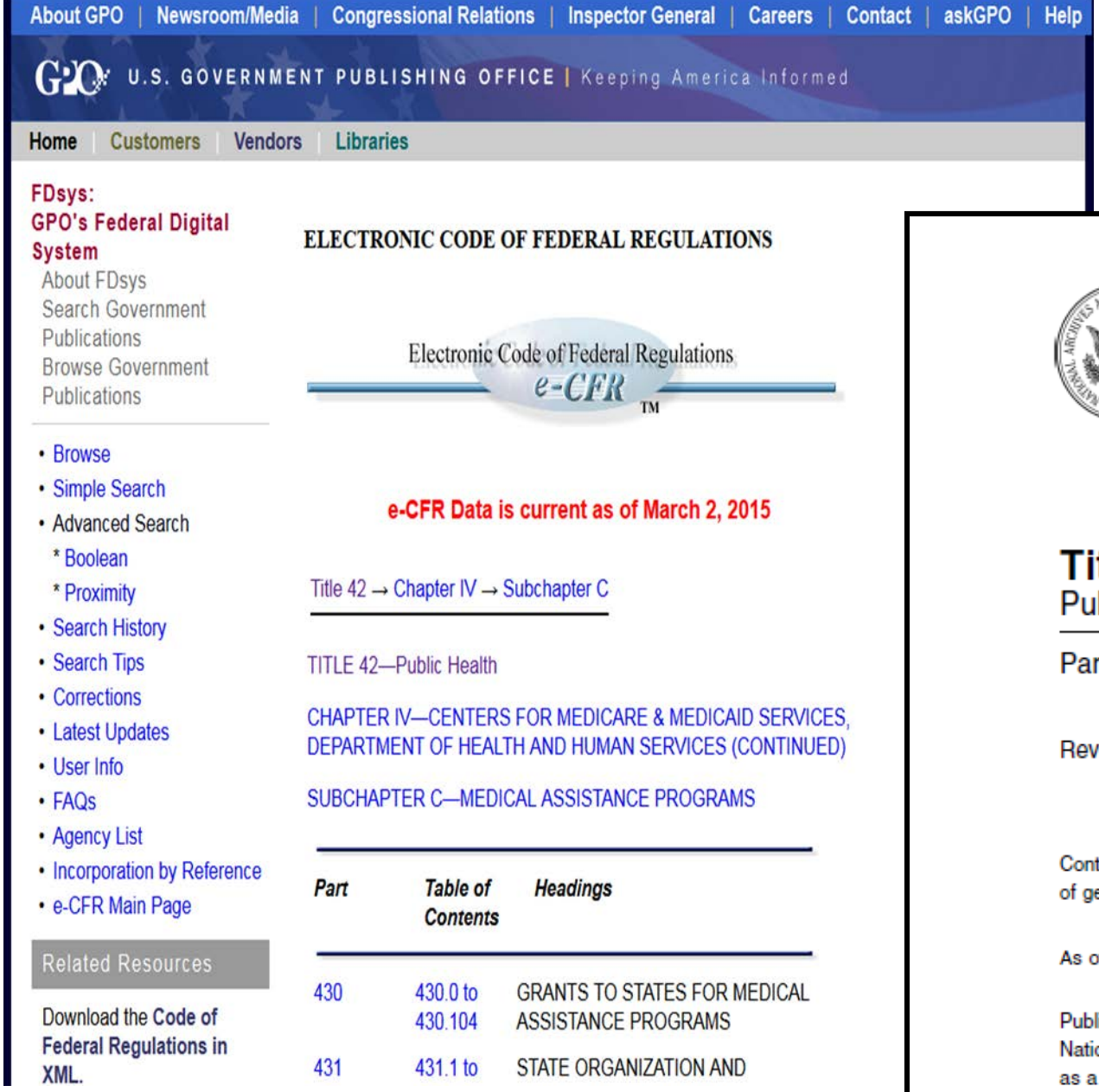
Components of Final Rule

- Follows structure of proposed rule
- In the preamble to the final rule, comments received on the proposed rule are summarized and the agency response presented
- Provisions of the proposed rule may be finalized without change, adopted with modification, or may not be finalized
- A policy may not be finalized if the proposed rule did not clearly provide notice to the public that it may be adopted
- Effective dates of changes adopted in the final rule are specified
  - Major rules may not take effect for at least 60 days
- Final regulatory impact analysis, collection of information requirements, and other required material

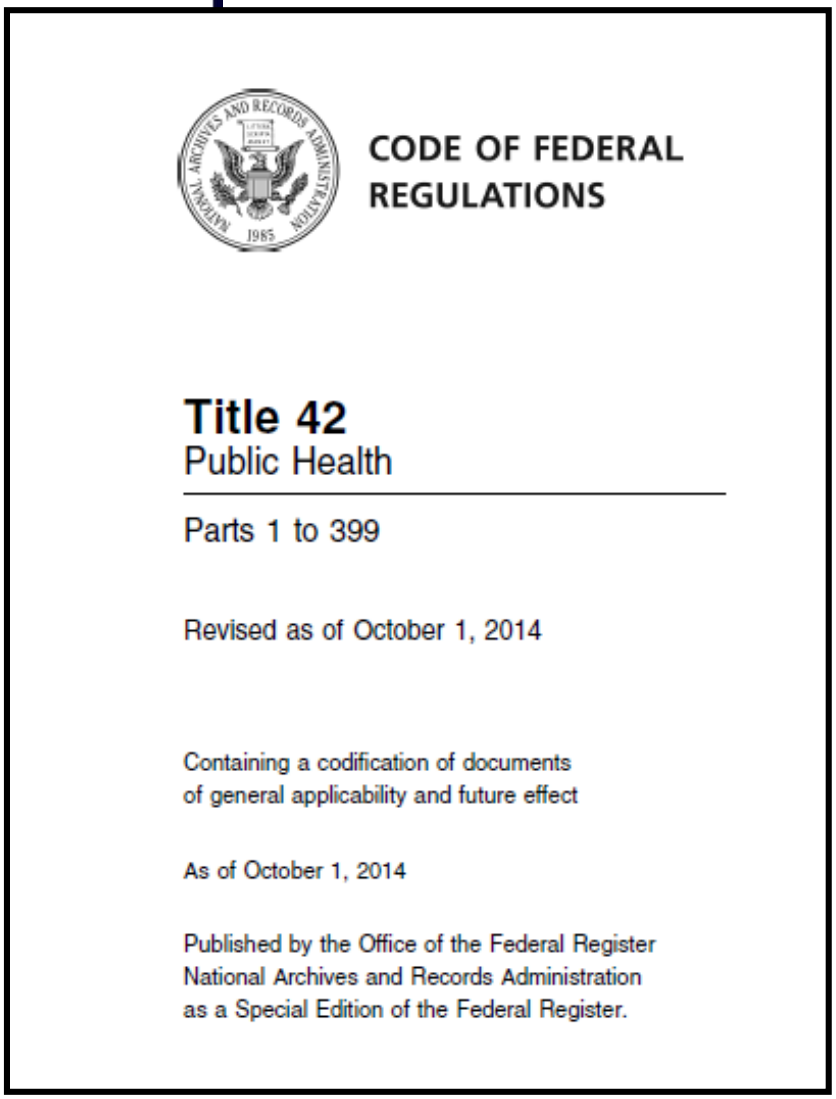
VARIATIONS OF A FINAL RULE

- Final Rule with Comment Period: A final rule is issued, but some provisions are open for public comment
  - Provisions may or may not be effective

- An Interim Final Rule may be issued without a proposed rule if agency determines that it has “good cause” to do so
  - Agency must explain “good cause” rationale in the preamble
  - Rule effective when issued, but open to public comment
  - Agency may later issue final rule responding to comments



http://www.ecfr.gov/cgi-bin/text-idx?SID=7240053f7e592cf7661d57cac5f519f2&tpl=/ecfrbrowse/Title42/42tab_02.tpl



http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR

Is the final rule the final word?

CORRECTION NOTICE

A Correction Notice may be posted and published in *Federal Register* if technical errors in proposed or final rule (e.g., erroneous numbers in tables, typo in regulatory text).

[FR Doc. 2014–23634 Filed 10–2–14; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, 415, 422, 424, 485, and 488

[CMS–1607–CN]

RINs 0938–AS11; 0938–AR12; and 0938–AR53

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program; Correction

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

ACTION: Final rule; correction.

SUMMARY: This document corrects technical and typographical errors in the final rule that appeared in the August 22, 2014 **Federal Register** titled ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program.''

DATES: *Effective date:* This document is effective October 1, 2014.

FOR FURTHER INFORMATION CONTACT: Ing Jye Cheng, (410) 786–4487, Operating Prospective Payment, Capital Prospective Payment, and New Medical Service and Technology Add-On Payment Corrections.

Donald Thompson, (410) 786–6504, Operating Prospective Payment, Wage Index, and Capital Prospective Payment Corrections.

James Poyer, (410) 786–2261, PPS-Exempt Cancer Hospital Quality Reporting and Hospital Inpatient Quality Reporting Corrections.

Mary Pratt, (410) 786–2261, Long-term Care Hospital Quality Data Reporting Corrections.

Kellie Shannon, (410) 786–0416, Administrative Appeals by Providers and Judicial Review Corrections.

Thomas Hamilton, (410) 786–6763, Organ Transplant Center Corrections.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2014–18545 which appeared in the August 22, 2014 **Federal Register** (79 FR 49853), titled ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program'' (hereinafter referred to as the FY 2015 IPPS/LTCH PPS final rule), there were a number of technical errors that are identified and corrected in section IV. of this correcting document. The provisions in this correction document are effective as if they had been included in the FY 2015 IPPS/LTCH PPS final rule that appeared in the August 22, 2014 **Federal Register**. Accordingly, the corrections are effective October 1, 2014.

II. Summary of Errors and Corrections to Tables Posted on the CMS Web Site

A. Summary of Errors in the Preamble

On page 49865, in our discussion of the summary of costs and benefits of the payment adjustment of the Hospital-Acquired Condition (HAC) Reduction Program for FY 2015, we made a technical error in the amount by which overall payments would decrease.

On page 49918, in our discussion of new technology add-on payments, we made an error in the amount of the maximum add-on payment for Voraxaze®.

On page 49940, we made an error in our discussion of the FY 2015 new technology add-on payment for the

CONGRESSIONAL REVIEW ACT*

- Before a final rule can take effect, the rule and any cost-benefit analysis must be filed with the House, the Senate, and the General Accountability Office (GAO)
- Major rules (as determined by OMB) may not be effective for at least 60 days after publication in the *Federal Register* or submission to Congress, whichever is later; GAO reports on agency compliance
- For any rule, a resolution of disapproval may be introduced in Congress within 60 days of receipt; expedited voting procedures
  - If enacted, resolution nullifies the rule, even if already in effect
  - President must sign resolution of disapproval
  - Rarely used to date; might apply best to "midnight rules" issued at end of an Administration (used by Bush to overturn Clinton OSHA ergonomics rule)
- Congress may also block implementation of regulation through appropriations bills or other legislation

*5 USC §§ 801-808, enacted March 1996

JUDICIAL REVIEW OF REGULATIONS

- Individuals negatively affected by a regulation may seek relief in the courts
- Court decides relevant questions of law, interprets constitutional and statutory provisions, and determines the meaning or applicability of the terms of a regulation (or other agency action)
- APA (5 U.S.C. §701–708) specifies when an agency action, findings, and conclusions can be held to be unlawful and set aside. Includes those that are:
  - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law
  - (B) contrary to constitutional right, power, privilege, or immunity
  - (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right
  - (D) without observance of procedure required by law
- *King v Burwell*: judicial review of how the IRS interpreted and implemented provisions of the ACA in regulation

Sub-regulatory Guidance

- Agency further clarifies and operationalizes regulatory policy
- Notice and comment rulemaking process does not apply
- Especially important in Medicaid and CHIP
  - State Medicaid Director and State Health Official Letters
  - Center for Medicaid & CHIP Services Informational Bulletins
- Medicare Advantage and Part D plans (annual process)
  - Advanced Notice of Changes in Methodology
  - Announcement of Capitation Rates and Policies
- Frequently Asked Questions (FAQs)
- Medicare manuals and transmittals
- Regtap.info (ACA Marketplace)

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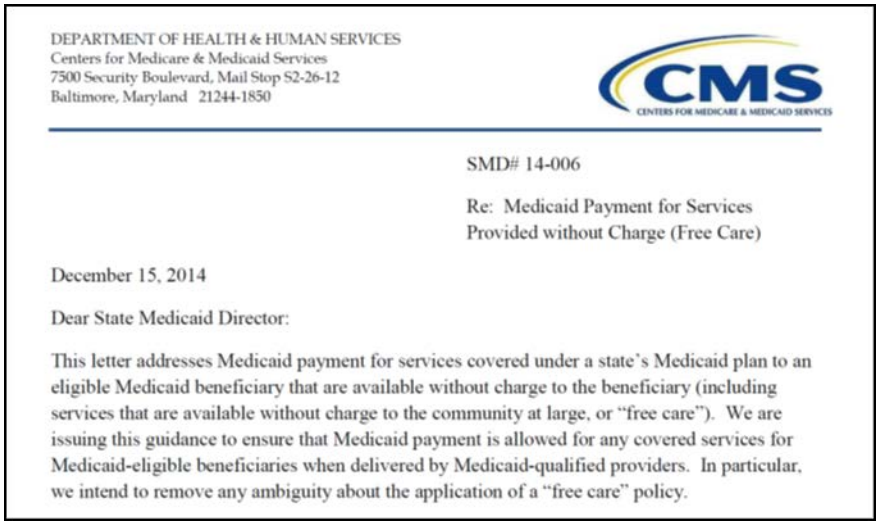
Federal Policy Guidance

As part of the state-federal partnership in administering the Medicaid and CHIP programs, the Centers for Medicare and Medicaid Services (CMS) issues guidance in the form of letters to State Medicaid Directors, letters to State Health Officials (often regarding CHIP policy or financing issues), Informational Bulletins, and Frequently Asked Questions to communicate with states and other stakeholders regarding operational issues related to Medicaid and CHIP. In addition, CMS issues federal regulations that codify statutory provisions and also policies that have been previously outlined in sub-regulatory guidance. The supporting documents are searchable on this page.



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

SMD# 14-006

Re: Medicaid Payment for Services Provided without Charge (Free Care)

December 15, 2014

Dear State Medicaid Director:

This letter addresses Medicaid payment for services covered under a state's Medicaid plan to an eligible Medicaid beneficiary that are available without charge to the beneficiary (including services that are available without charge to the community at large, or "free care"). We are issuing this guidance to ensure that Medicaid payment is allowed for any covered services for Medicaid-eligible beneficiaries when delivered by Medicaid-qualified providers. In particular, we intend to remove any ambiguity about the application of a "free care" policy.

http://medicaid.gov/federal-policy-guidance/federal-policy-guidance.html

INFLUENCING THE RULEMAKING PROCESS

- Ongoing dialogue with agency staff and officials
- Make agency aware of concerns before proposed rule issued
- Submit written comments during public comment period
- Meetings with agency staff after proposed rule is released offer opportunity to further explain concerns addressed in written comments
  - Not opportunity for dialogue with agency

Where to Learn More

- HHS Regulatory Tool Kit

http://www.hhs.gov/regulations/rulemaking-tool-kit.html

- Federal Register guide to rulemaking process

https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf

- Multiple resources on Regulations.gov
- http://www.regulations.gov/#!home;tab=learn
- Regmap annotated chart

http://www.reginfo.gov/public/reginfo/Regmap/index.jsp