



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

**Office of
Inspector
General**

Compendium of Unimplemented Recommendations

December 2012 Edition

OIG Organization

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) employs about 1,700 professional staff members who are deployed throughout the Nation in regional and field offices and in Washington, DC, headquarters. We conduct audits, evaluations, and investigations; provide guidance to industry; and, when appropriate, impose sanctions such as civil monetary penalties (CMP) and exclude individuals and entities from participation in Federal health care programs. We collaborate with HHS and its operating and staff divisions, the Department of Justice (DOJ) and other executive branch agencies, Congress, and States to bring about systemic changes, successful prosecutions, negotiated settlements, and recovery of funds. Following are descriptions of our mission-based components.

OAS

THE OFFICE OF AUDIT SERVICES (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

OEI

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OI

THE OFFICE OF INVESTIGATIONS (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in almost every State and the District of Columbia, OI actively coordinates with DOJ and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, or CMPs.

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The organizational entities described above are supported by the Immediate Office of the Inspector General and the Office of Management and Policy.

Introductory Message From the Office of Inspector General

The Department of Health & Human Services (HHS) Office of Inspector General (OIG) *Compendium of Unimplemented Recommendations* (Compendium) summarizes significant¹ monetary and nonmonetary recommendations that, when implemented, will result in cost savings and/or improvements in program efficiency and effectiveness. The recommendations result from audits and evaluations that are performed pursuant to the Inspector General Act of 1978, as amended.

What can you learn from the Compendium?

At the beginning of each fiscal year (FY) OIG follows up with HHS and its operating and staff divisions to determine their progress in implementing significant recommendations that were included in the preceding edition of the Compendium and in reports that were issued during the closed fiscal year. This edition of the Compendium updates the status of recommendations made through FY 2011 that were not fully implemented as of December 2012 and represent significant opportunities for action in FY 2013.

Each narrative in the Compendium contains for pertinent reports the open recommendations, background, progress of implementation, report titles, numbers, and issue dates. Related reports and testimony are listed under “See Also” at the end of each section.

OIG’s audits and evaluations do not routinely project the annual cost savings that could be realized at program level from implementing the recommendations. However, reports are indicative of the extent to which policies and methodologies may be less than effective and in need of corrective action.

How are OIG’s recommendations implemented?

Implementation generally requires one or more of three types of actions: legislative, regulatory, or administrative. Some issues involve more than one type of action. OIG relies on policy makers such as HHS and its operating and staff divisions, the Administration, Congress, and States to take the necessary steps to achieve optimal outcomes.

Although many OIG recommendations are directly implemented by organizations within HHS, some are acted on by States that collaborate with HHS to administer, operate, and/or oversee designated federally funded programs such as Medicaid. HHS and States sometimes do not immediately implement OIG’s recommendations for various reasons, including administrative complexities, the current policy environment, or a lack of statutory authority. In such cases, Congress may step in to incorporate OIG’s recommendations into legislative actions, resulting in substantial funds being put to better use and/or in improvements in areas such as quality of care, program integrity, or better information systems and processes.

¹ The Compendium does not include all unimplemented OIG recommendations. For example, it does not include recommendations that are only to collect improper payments or those that are addressed to specific non-Federal entities. It also does not include recommendations that are systemically significant but involve sensitive security issues.

What agencies, programs, and functions do our recommendations address?

The Compendium's structure mirrors HHS's organization and related programs.

Centers for Medicare & Medicaid Services Programs

The programs of the Centers for Medicare & Medicaid Services (CMS), which include Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), generally account for more than 80 percent of HHS's budget. The programs provide medical coverage for adults and children in certain statutorily defined categories.

Public Health and Human Service Programs and Other HHS-Related Issues

Public Health—Public Health-related agencies—including the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), and the National Institutes of Health (NIH)—promote biomedical research; prevent and cure diseases; ensure the safety and efficacy of marketed food, drugs, and medical devices; or conduct other activities designed to ensure the general health and safety of Americans.

Human Services—The Administration on Aging and the Administration for Children & Families (ACF) provide Federal direction and funding for State-administered efforts designed to promote stability, economic security, responsibility, and self-support for the Nation's families and to establish comprehensive community-based systems to help maintain dignity and quality of life.

Other HHS-Related Issues—Departmental functions include policies and procedures for financial accounting, information systems management, oversight of grants and contracts, and selected initiatives involving more than one HHS organizational entity.

Which recommendations are priorities?

Below is a list of open recommendations that we refer to as "priority recommendations" because in our view they represent the most significant opportunities to positively impact HHS's programs. The recommendations, are presented in the order in which they are found in the Compendium.

Medicare Part A and Part B—Traditional Medicare

Hospitals—Eliminate or Reduce Medicare Payments for Hospital Bad Debts. P. 4

Physicians—Adjust Global Surgery Fees To Reflect the Number of Evaluation and Management Services Actually Being Provided by Physicians. P. 12

Medical Equipment—Reduce the Rental Period for Medicare Home Oxygen Equipment. P. 17

Hospices—Ensure That Hospice Claims for Beneficiaries in Nursing Homes Comply With Medicare Coverage Requirements. P. 32

Independent Diagnostic Testing Facilities—Implement Unannounced Site Visits and Other Actions To Prevent Improper Payments (New). P. 35

Medical Equipment—Ensure That Claims for Lower Limb Prostheses Meet Requirements (New). P. 46

Medicare Part C —Medicare Advantage

Medicare Advantage Payment Amounts—Modify Payments to Medicare Advantage Organizations. P. 72

Medicare Advantage Aggressive Marketing—Ensure That New Enrollees Understand Plan Rules. P. 75

Medicare Part D—Prescription Drug Benefit

CMS—Develop a Comprehensive Safeguard Strategy for Overseeing Part D Prescription Drug Plans. P. 76

Sponsor Data—Ensure the Accuracy of Sponsors' Cost Estimates in Part D Bids. P. 84

Claims Processing—Ensure the Validity of Prescriber Identifiers on Claims. P. 92

Atypical Antipsychotic Drugs—Ensure That Part D Sponsors Have Information Needed To Make Accurate Coverage and Reimbursement Determinations (New). P. 94

Medicaid Reviews

Prescription Drugs—Develop National Pharmacy Acquisition Cost Data as a Benchmark for Reimbursing Prescription Drugs (New). P. 98

Prescriptions Drugs—Establish a Connection Between the Calculations of Medicaid Drug Reimbursements and Rebates. P. 104

Prescriptions Drug Rebates—Extend the Additional Rebate Payment Provisions for Brand-Name Drugs to Generic Drugs. P. 107

Payments to Public Providers—Limit Medicaid Payments to Costs and Require That Payments Returned by Public Providers Be Used To Offset the Federal Share. P. 111

Improve Medicaid Children's Utilization of Preventive Screening Services. P. 129

Public Health Reviews

Centers for Disease Control and Prevention—Improve States' and Localities' Medical Surge Preparedness for Pandemics. P. 133

Food and Drug Administration—Ethics Oversight—Ensure That Clinical Investigators Disclose All Financial Interests. P. 135

Food and Drug Administration—Food Safety—Improve and Strengthen Food Facilities' Compliance With Records Requirements for Traceability of Food Products. P. 138

Indian Health Service—Reduce Overpayments for Contract Health Services Hospital Claims and Cap Payments for Nonhospital Services at Medicare Rates. P. 148

National Institutes of Health—Ethics Oversight—Require NIH Grantee Institutions To Identify, Report, and Address Institutional Financial Conflicts of Interest (New). P. 152

If you have questions about this publication, please contact OIG's Office of External Affairs at 202-619-1343.

To report potential instances of waste, fraud, or abuse related to HHS's programs, you may contact the OIG Hotline by phone at 1-800-HHS-TIPS (1-800-447-8477) or via our Web site at <https://oig.hhs.gov>.

For information about mail, fax, and TTY options and the types of information needed in your report, please visit <https://oig.hhs.gov/fraud/hotline>.

OIG's Compendium and other key publications are available on our Web site at: <https://oig.hhs.gov/>

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Medicare Part A and Part B (Traditional Medicare)

❖ Avoid Wasteful Spending

Wasteful spending occurs when Medicare's laws, policies, and methodologies fail to ensure that program costs are reasonable and appropriate and reflect Medicare's role as a high-volume, prudent insurer/payer in the health care marketplace. The Office of Inspector General (OIG) designated avoiding waste in health care pricing methodologies as one of the top management and performance challenges facing the Department of Health and Human Services (HHS) in FY 2012. The recommendations in this section address the wasteful spending that arises from shortcomings in existing laws, policies, and methodologies.

"Waste" is a broad term that could apply to all situations in which Medicare pays more than it should. For example, when Medicare's payment policies and methodologies are not aligned with the marketplace, e.g. the costs incurred by a supplier to acquire a medical device, waste occurs. Sometimes Medicare's policies and methodologies also cause waste when unintended loopholes or other inherent problems invite exploitation or hinder consistent payment determinations. Medicare's supporting systems and practices sometimes cause waste by hindering timely and appropriate payment adjustments.

A separate section of the *Compendium* specifically addresses improper payments, which are also a form of wasteful spending. Improper payments occur when Medicare does not effectively identify and reduce erroneous, inappropriate, and fraudulent billing by providers and suppliers prior to payment.

OIG's audits and evaluations do not routinely project the annual cost savings that could be realized at program level from implementing the recommendations. However, reports are indicative of the extent to which policies and methodologies may be less than effective and in need of corrective action.

Acronyms and Abbreviations for Selected Terms Used in This Section

AMP	average manufacturer price	MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
ASP	average sales price	NLA	national limit amount
BBA	Balanced Budget Act of 2007	PPI	Producer Price Index (Bureau of Labor Statistics)
CBO	Congressional Budget Office	RHC	rural health clinic
DRA	Deficit Reduction Act of 2005	RUG	resource utilization group (code)
E&M	evaluation and management (services)	SCHIP	State Children's Health Insurance Program
ESRD	end stage renal disease	SNF	skilled nursing facility
MIPPA	Medicare Improvements for Patients and Providers Act of 2008	WAMP	widely available market price

Medicare A/B > Avoid Waste in Spending > Rural Health Clinics > Payment Methodology

Rural Health Clinics—Improve Medicare’s Reimbursement and Certification Rules

Recommendations To Be Implemented

We recommended that CMS

- improve the oversight and functioning of the rural health clinics (RHC) cost reimbursement system, with a long-term goal of implementing an improved method of reimbursement;
 - modify the RHC certification process to increase State involvement and ensure more strategic placement of RHCs (in conjunction with the Health Resources and Services Administration (HRSA));
 - issue regulations that respond to States' requests for guidance on monitoring and evaluating RHCs;
 - issue regulations to ensure that only RHCs that are determined to be essential providers remain certified as RHCs; and
 - seek legislative authority or administratively require RHC applicants to document the need for and the impact of the RHCs on access to health care in the rural underserved areas.
- Also, we recommended that HRSA publish regulations revising its shortage-designation criteria.

Savings probable but not estimated.

The recommendations would prevent the wasteful Medicare spending that occurs because Medicare’s cost-based reimbursement methodology for RHCs results in claims for costs that are difficult and sometimes impossible to verify or to audit without significant resource expenditures by the Government.

Waste also occurs when RHCs, which are intended to serve rural, underserved, and shortage-designated areas, may be inappropriately located in urban areas or in areas with no shortage of primary care providers.

- A July 1996 OIG report identified the cost-based reimbursement methodology as one of several factors driving RHC program growth. With certain requirements, Medicare pays RHCs on the basis of their costs. Cost reimbursement is well understood as an extremely vulnerable mechanism by which to pay providers of service. It contains little or no incentive for efficiency, provides opportunities for inflated and inappropriate payments (especially given the lack of itemized billing for most independent RHCS), is cumbersome and complex, and is difficult and

expensive to oversee. Generally, health care providers and suppliers in urban or nonshortage areas are paid under more accountable reimbursement methodologies, such as prospective payment systems or fee schedules.

- An August 2005 OIG report analyzed 279 questionable RHCs and found that 61 percent were located in areas that were not designated as shortage areas and 39 percent were located in urban areas. Ninety percent of RHCs had three or more primary care provider sites within 25 miles of their locations, indicating the areas may not qualify as underserved.

Progress of Implementation

CMS and HRSA have attempted to address our recommendations through various actions, for example:

- On February 28, 2000, CMS published a proposed rule, noting that both the General Accounting Office (now the Government Accountability Office) (GAO) and HHS OIG had concluded that the number of RHCs was growing out of proportion to the need, that some RHCs remained in the program after the need for payment incentives no longer existed, that the payment methodology for provider-based RHCs lacked sufficient cost controls, and that establishing payment limits and screens on reasonable costs for providers was needed. ([65 Fed. Reg. 10450](#).) The rule was intended to implement related amendments in the Balanced Budget Act of 1997 (BBA).
- The final rule was issued on December 24, 2003. ([68 Fed. Reg. 74791, 74792](#).) However, the rule was subsequently suspended on September 22, 2006, to revert to prior rules because more than 3 years had elapsed between the publication of the proposed and final rules. ([71 Fed. Reg. 55341](#) and MMA, § 902.)
- On February 29, 2008, HRSA issued a notice of proposed rulemaking on shortage designation criteria. ([73 Fed. Reg. 11232](#).) On July 23, 2008, HRSA subsequently said that it intended to post a new notice of proposed rulemaking before issuing a final rule. ([73 Fed. Reg. 42743](#).) The rule was not issued.
- On June 27, 2008, CMS issued a new proposed rule to clarify policies and to revise certain provisions concerning the payment methodology, nonphysician providers, waivers of staffing requirements, conditions for certification, and other matters. ([73 Fed. Reg. 36696](#).) The rule would have made Medicare payments equal to reasonable costs less aggregate coinsurance and deductible amounts billed (p. 36705). The rule was not finalized.
- In November 3, 2011, HRSA published a notice announcing an update of [shortage areas](#), available on the HRSA Web site. ([76 Fed. Reg. 68198](#).) The update used existing (not revised) criteria.

We encourage CMS and HRSA to follow through on their efforts to implement each of the recommendations we specified. We continue to monitor CMS's and HRSA's progress.

Primary OIG Reports

- 1996 JUL *Rural Health Clinics – Growth, Access, and Payment*. OEI-05-94-00040. [Full Text](#).
- 2005 AUG *Status of the Rural Health Clinic Program*. OEI-05-03-00170. [Full Text](#).

Medicare A/B > Avoid Waste in Spending > Hospitals > Bad Debt Payments

Hospitals—Eliminate or Reduce Medicare Payments to Hospitals for Bad Debt

Recommendations To Be Implemented

We recommend that the Centers for Medicare & Medicaid Services (CMS) seek legislation or legislative authority to

- eliminate (or reduce) Medicare payments to hospitals for bad debt associated with beneficiaries' failure to pay their deductibles and coinsurance and
- modify Medicare's bad debt policies.

Savings – An HHS *Budget in Brief for FY 2013* proposal to more closely align Medicare's bad debt policy with the private sector (which does not pay for bad debt) by reducing Medicare's bad debt payments to 25 percent for all providers that receive such payments estimated **\$35.9 billion** in savings over 10 years. (*Department of Health and Human Services Fiscal Year 2013 Budget in Brief*, p. 53.) The Congressional Budget Office's estimate of the 10-year savings for the same proposal was **\$23.6 billion**.

The recommendations would prevent the wasteful Medicare spending that occurs when hospitals fail to make a reasonable effort to collect unpaid deductibles and coinsurance from Medicare beneficiaries who can afford to pay or to collect from other sources (such as beneficiaries' other insurance or Medicaid) that would pay the amounts on their behalf.

In FY 2012, Medicare reimbursed 70 percent of hospitals' allowable bad debt from uncollected deductibles and coinsurance, amounting to billions of dollars.

A June 1990 OIG management advisory report stated that hospitals' path of least resistance was merely to submit the claims to Medicare. The report noted that prior OIG reviews found there was little incentive for hospitals to collect unpaid deductibles and coinsurance because Medicare would pay the amounts. One of our recommendations was that Medicare not pay hospitals for bad debts.

Additional Background >

A 1987 statutory moratorium prohibited the Secretary from changing any hospital bad debt policies that were in effect at that time. (Omnibus Budget Reconciliation Act of 1987, § 4008(c).) The moratorium, which effectively blocked administrative and regulatory adjustments to bad debt policy, was rescinded by the Middle Class Tax Relief and Job Creation Act of 2012, § 3201(d), as of FY 2013.

In several other OIG reviews since 2001, we have found recurring problems with hospital claims for bad debt reimbursement. For example, hospitals claimed Medicare reimbursement for bad debts that were not sufficiently documented, may not have been subjected to reasonable collection efforts, may not have met the definition of "uncollectible" when claimed as worthless, or were not derived from unpaid deductible and coinsurance amounts. Other problems included data entry and

calculation errors and hospitals' failure to reduce their bad debts by the amount that they recovered from previously written off bad debts as required.

Progress of Implementation

In a January 2012 update, CMS agreed that hospitals do not always follow Medicare bad debt policies and noted that the bad debt moratorium in effect since 1987 continued to prevent it from revising hospital bad debt policies. Various legislative actions and proposals have adjusted, or attempted to adjust, Medicare's payments for bad debts. For example:

- The Balanced Budget Act of 1997 (BBA), § 4451, reduced Medicare bad debt payments to hospitals to 55 percent as of FY 2000. However, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), § 541, increased reimbursement to 70 percent.
- An HHS *Budget in Brief for FY 2008* legislative proposal to eliminate Part A and Part B bad debt reimbursements over 4 years for all providers was estimated to save [\\$7.15 billion](#) over 5 years. CBO scored the 10-year savings for the provision at [\\$19.9 billion](#) beginning with FY 2009.
- An HHS proposal to reduce bad debt payments to 25 percent for all providers over 3 years beginning in 2013 was estimated to save [\\$35.88 billion](#) over 10 years. The Congressional Budget Office's estimate of the 10-year savings for the same proposal was [\\$23.6 billion](#).
- The Middle Class Tax Relief and Job Creation Act of 2012, [§ 3201](#), reduced Medicare bad debt payments to hospitals and skilled nursing facilities to 65 percent (from 70 percent) beginning with FY 2013. The new law also phases in over 3 years a reduction to 65 percent for certain other providers whose allowable bad debt was being paid at a 100-percent rate. According to a joint staff analysis by the House Committees on Ways and Means and Energy and Commerce, CBO scored savings from the reductions in § 3201 at [\\$6.9 billion](#) over 10 years. Section 3201, which is self-implementing, was included in a proposed rule published at [77 Fed. Reg. 40951](#) (July 11, 2012).

We continue to recommend eliminating or further reducing Medicare payments to hospitals for bad debt.

Primary OIG Report

1990 JUN *Options To Reform Payment for Medicare Bad Debts*. A-14-90-00339. [Full Text](#).

See Also

The following reviews revealed problems in hospital claims for bad debt reimbursement.

2010 JUN [A-04-09-00055](#); [A-04-09-00056](#); [A-04-09-00057](#); [A-04-09-00058](#).

2003 JAN [A-01-02-00515](#); [A-02-02-01031](#); [A-04-02-02016](#).

2002 OCT [A-04-02-02011](#); [A-05-02-00039](#); [A-05-02-00052](#); [A-06-02-00027](#).

2002 SEP [A-02-02-01016](#).

2002 JUL [A-03-01-00022](#); [A-09-02-00057](#).

2002 JUN [A-03-02-00002](#).

Medicare A/B > Avoid Waste in Spending > Hospitals > Part B Diagnostic Radiology

Hospitals—Implement a Uniform Claims Policy for Interpretations and Reports of Diagnostic Radiology Services in Outpatient Emergency Departments (New)

Recommendation To Be Implemented

We recommend that CMS

- adopt a uniform policy for single and multiple claims for interpretations and reports of diagnostic radiology services in hospital outpatient emergency departments to require that claimed services be contemporaneous with the beneficiary's diagnosis and treatment or, alternatively,
- identify circumstances in which noncontemporaneous interpretations may contribute to the diagnosis and treatment of the beneficiary.

Savings probable but not estimated.

The recommendation would prevent the wasteful Medicare Part B spending that occurs when Medicare's payment contractors do not ensure that paid services are reasonable and necessary for the diagnosis and treatment of the patient. (Social Security Act, §1862(a)(1)(A).)

In hospital emergency department settings, professional diagnostic radiology services (such as interpretations and reports by physicians) that are billed to Part B must be identifiable, direct, and discrete diagnostic or therapeutic services to an individual patient. (*Medicare Claims Processing Manual*, [Chapter 13](#), § 20.1.)

Generally, interpretations meeting this requirement occur while the patient is present in the emergency room. However, in practice, when only one claim for interpretation and report services is received, Medicare's payment contractors pay the claim without confirming that the interpretation was performed while the beneficiary was in the emergency room.

OIG found that many interpretations and reports, particularly those performed after the patients' discharge, did not contribute directly to the patients' diagnosis and treatment and were not allowable under the Part B fee-schedule methodology.

- A 1993 OIG report revealed that in 44 percent of the cases, radiologists reinterpreted x-rays in our sample at least 1 day after the emergency departments discharged the patients. The reinterpretations had no effect on the treatments provided to beneficiaries. No patient from the group reviewed was recalled to the hospital or referred elsewhere.
- An April 2011 OIG report found that in 2008 Medicare paid for interpretation and reports performed for 16 percent of x-rays (\$10 million) and 12 percent of CTs and MRIs (\$19 million) that were performed after beneficiaries left the emergency departments. For 25 percent of x-ray claims and 27 percent of CT and MRI claims, contemporaneity was difficult to establish because documentation was incomplete.

The April 2011 report noted that in 2009 the Senate Finance Committee released “*Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs*,” which indicated that the number of imaging services increased more than other Medicare physician services for the period under review.

Progress of Implementation

CMS’s 2012 update said that neither a single billed interpretation and report nor multiple billed interpretations and reports must in all cases be contemporaneous with the beneficiary’s diagnosis and treatment to contribute to that diagnosis and treatment. CMS said a case-by-case basis should be used to determine circumstances in which noncontemporaneous interpretations may contribute to the beneficiary’s diagnosis and treatment.

We maintain that ineligible claims have been routinely paid and that adopting a uniform policy would avoid waste in fee-schedule payments. As a step toward monitoring this condition, we have suggested that CMS institute service code modifiers for further analysis of instances in which emergency department diagnostic interpretations were performed after patients were discharged from emergency department care.

Primary OIG Reports

2011 APR *Medicare Payments for Diagnostic Radiology Services in Emergency Departments.*
OEI-07-09-00450. [Full Text.](#)

1993 JUL *Medicare’s Payment for Interpretations of Hospital Emergency Room X-rays.*
OEI-02-89-01490. [Full Text.](#)

Medicare A/B > Avoid Waste in Spending > Skilled Nursing Facilities > Higher Paying RUGs

Skilled Nursing Facilities—Monitor and Adjust Payments (New)

Recommendations To Be Implemented

We recommend that CMS

- monitor overall Medicare payments to skilled nursing facilities (SNF) and adjust rates as necessary,
- change the current methodology for determining the level of therapy that is needed and ensure appropriate payments,
- strengthen monitoring of SNFs that disproportionately bill for higher paying resource utilization groups (RUG), and
- follow up on the SNFs that are identified as having questionable billing practices.

Savings probable but not estimated.

The recommendations would curb the wasteful Medicare spending that occurs when incentives inherent in the current payment methodology for SNFs lead some SNFs to inappropriately bill for higher paying RUGs for therapy and other higher paying RUGs. Such higher levels of care may not be medically necessary.

Medicare pays SNFs under a prospective payment system. For billing purposes, SNFs categorize Medicare beneficiaries into RUGs based on their care and resource needs at various points during their stays. Changes to rates and methods could remove inappropriate incentives that may be driving questionable billing.

- A December 2010 OIG report revealed that SNFs' shift toward billing higher paying RUGs did not appear to be the result of changes in beneficiary characteristics, such as age and diagnosis. For example, SNFs' billing for ultra-high therapy increased by nearly 90 percent (\$5 billion), from 2006 to 2008.
- A July 2011 OIG report said that on the basis of FY 2010 and FY 2011 data, Medicare payment rates for therapy RUGs were more than 1½ times higher, on average, than the rates for nontherapy RUGs. The report highlighted the need to make RUGs and Medicare payments more consistent with beneficiaries' care and resource needs. Changes could include requiring SNFs to recalculate a beneficiary's RUG whenever his or her level of therapy changes substantially and reduce the overlap that occurs in assessment periods.

Additional Background >

The Medicare Payment Advisory Commission (MedPAC), in a March 2012 *Report to Congress* (p. 2), recommended that Congress direct the Secretary of HHS to revise the SNF payment system to

redistribute payments away from intensive therapy care that is unrelated to patient care needs and toward medically complex care. MedPAC made a similar recommendation in June 2008.

Progress of Implementation

Regulatory actions by CMS are supported by OIG's work. For example:

- On August 8, 2011, CMS issued a final rule adjusting rates in FY 2012 in response to a substantial increase in payments to SNFs in FY 2011. ([76 Fed. Reg. 48486](#).) The final rule, which refers to our July 2011 preliminary analysis of data for the first 6 months of FY 2011, said that CMS will continue to work with OIG to provide greater monitoring of SNF utilization and reporting trends.
- Though CMS made changes to the RUGs in FY 2011, more needs to be done to reduce the potentially inappropriate and significant increases in payments for ultra high therapy and other higher paying RUGs. CMS estimated that payments to SNFs increased by nearly \$4 billion in FY 2011.
- On August 2, 2012, CMS issued a notice, "Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2013," that describes CMS's monitoring of the impact of FY 2012 policy changes and certain SNF practices, including RUG distributions, group therapy allocations, and other elements. ([77 Fed. Reg. 46213](#).)

We remain concerned that the payment system continues to provide incentives to SNFs to bill for more therapy than is medically necessary, and we strongly encourage CMS to pursue the options we recommended to reduce this vulnerability. We continue to monitor CMS's progress.

Primary OIG Reports

2011 JUL *Changes in Skilled Nursing Facilities Billing in Fiscal Year 2011*. OEI-02-09-00204. [Full Text](#).

2010 DEC *Questionable Billing by Skilled Nursing Facilities*. OEI-02-09-00202. [Full Text](#).

Medicare A/B > Avoid Waste in Spending > Hospice Care in Nursing Facilities

Hospices—Modify the Payment System for Hospice Care in Nursing Facilities (New)

Recommendations To Be Implemented

We recommend that CMS

- modify the payment methodology for hospice care in nursing facilities (to reduce incentives for hospices to improperly seek out SNF beneficiaries), seeking statutory authority if necessary and
- monitor hospices that depend heavily on nursing facility residents.

Savings probable but not estimated.

The recommendations would curb the wasteful Medicare spending that occurs when incentives inherent in Medicare's hospice payment methodology lead some hospices to inappropriately seek out beneficiaries in nursing facilities.

Nursing facilities are already staffed with professional caregivers that provide personal care services similar to the hospice aide services. However, Medicare pays hospices the same rate for care provided in nursing facilities as it does for care provided in other settings, such as private homes.

A July 2011 OIG report revealed that hundreds of hospices had more than two-thirds of their beneficiaries residing in nursing facilities in 2009. Medicare spending on hospice care for nursing facility residents increased nearly 70 percent from \$2.55 billion in 2005 to \$4.31 billion in 2009. The number of Medicare hospice beneficiaries residing in nursing facilities increased 40 percent during the same period—considerably less than the increase in spending.

We found that hospices having a high percentage of their beneficiaries in nursing facilities received more Medicare payments per beneficiary than did other hospices because the nursing facility beneficiaries generally spent more time in care, increasing total reimbursements.

Additional Background >

Hospice care is provided to individuals and their families in various settings, including the home or other places of residence, such as a skilled nursing facility or other nursing facility. Upon a beneficiary's election of hospice care, the hospice assumes the responsibility for palliative, rather than curative, care for the beneficiary's terminal illness.

Medicare pays hospices an all-inclusive daily rate under Part A. The rate is paid to the hospice for each day that a beneficiary is in hospice care, regardless of the number of services furnished. Routine home care is the most common level of care.

A November 1997 OIG report examined contractual relationships between hospices and nursing facilities for the care of beneficiaries eligible for both Medicare and Medicaid (cited at the end of this section). We expect to issue new reports in FY 2013 about hospices' marketing materials and practices and their financial relationships with nursing facilities.

Progress of Implementation

In responding to our review, CMS said it concurred with our recommendations, agreed that incentives may exist in the current payment structure, and noted that the Affordable Care Act requires reforms to hospice payments.

- In its January 2012 update, CMS stated that it would share our report with its payment and recovery audit contractors. CMS also stated that it would instruct contractors to consider this issue when prioritizing their medical review strategies or other interventions.
- On July 27, 2012, CMS issued the Hospice Wage Index for Fiscal Year 2013. ([77 Fed. Reg. 44242](#).) The notice mentioned that over the past several years, MedPAC, GAO, and HHS OIG all recommended that CMS collect more comprehensive data in order to better understand the utilization of the Medicare hospice benefit and said that CMS would investigate the recommendations as well as other payment options. CMS is conducting hospice payment reform research and will develop payment model options.

We encourage CMS to focus its efforts on lessening the incentives for hospices to disproportionately seek out beneficiaries in nursing facilities. We maintain that the problem is rooted in the payment methodology which pays hospices the same rate for the care of patients whether the patient is in a nursing home or in other settings, such as at home. A change in methodology is warranted. We continue to monitor CMS's progress.

Primary OIG Report

2011 JUL *Medicare Hospices That Focus on Nursing Facility Residents*. OEI-02-10-00070. [Full Text](#).

See Also

- 2011 JUL OIG's [Spotlight on Medicare Hospice Care](#), available on our [Web site](#).
- 2009 SEP *Medicare Hospice Care for Beneficiaries in Nursing Facilities: Compliance With Medicare Coverage Requirements*. OEI-02-06-00221. [Full Text](#).
- 2009 SEP *Medicare Hospice Care: Services Provided to Beneficiaries Residing in Nursing Facilities*. OEI-02-06-00223. [Full Text](#).
- 2007 DEC *Medicare Hospice Care: A Comparison of Beneficiaries in Nursing Facilities and Beneficiaries in Other Settings*. OEI-02-06-00220. [Full Text](#).
- 1997 NOV *Hospice and Nursing Home Contractual Relationships*. OEI-05-95-00251. [Full Text](#).
- 1997 SEP *Hospice Patients in Nursing Homes*. OEI-05-95-00250. [Full Text](#).

Medicare A/B > Avoid Waste in Spending > Physicians > E&M Services

Physicians—Adjust Global Surgery Fees to Reflect the Number of Evaluation and Management Services Being Provided

Recommendations To Be Implemented

We recommend that CMS

- adjust the estimated number of evaluation and management (E&M) services within global surgery fees to reflect the number of E&M services actually being provided to beneficiaries or
- use the financial results of the audit, in conjunction with other information, during the annual updates of the physician fee schedule.

Savings – \$97.6 million per year. (Estimate based on CY 2005 data.)

The recommendations would curb the wasteful Medicare spending that occurs when Medicare’s fee schedule payments for global surgery do not align with the number of E&M services provided in such surgery.

A global surgery is a group of clinically related services, including the surgical service and related preoperative and postoperative services that are treated as a single unit for purposes of coding, billing, and reimbursement. E&M services are nonsurgical services provided for diagnosing and treating diseases or counseling and evaluating beneficiaries. Medicare compensates physicians for surgical services and the related E&M services included in the global fee regardless of the E&M services actually provided during the global surgery period.

An April 2009 OIG report estimated that Medicare paid \$97.6 million for E&M services in CY 2005 that were included in eye global surgery fees but were not provided during the global surgery periods. The report disclosed that physicians generally provided fewer E&M services than were included in the global surgery fees. In some instances, they provided more E&M services than were included in the fees. This high-priority audit was included in the Joint OIG-CMS Health Care Integrity Strategy.

Additional Background >

Medicare pays for physicians’ services on the basis of an established fee schedule that CMS updates annually. The fee schedule amounts, which are based on the resources, such as physician time and intensity of the work (measured in relative value units), involved with furnishing services, include global surgery fees for surgical services and the related preoperative and postoperative E&M services provided during the global surgery period.

Similar audits of musculoskeletal and cardiovascular global surgeries that were issued in 2012 are cited in the “See Also” section below.

Progress of Implementation

CMS indicated that it will continue to work in conjunction the American Medical Association Relative Value Update Committee and relevant specialty societies to identify potentially misvalued services. CMS annually reviews hundreds of codes, many of which are codes with global surgery periods. CMS said it will continue to consider the results of this report and several other relevant reports during its selection process for misvalued codes, noting that the process for identifying, reviewing, and updating values of a misvalued code takes years. CMS said it will continue to investigate whether adjustments to the number of E&M visits within global periods are necessary to appropriately value global surgical packages.

We are monitoring CMS's actions to address our recommendations and plan additional audits of industry practices related to the number of E&M services provided by physicians and reimbursed as part of the global surgery fee. We continue to recommend that CMS consider the results of our nationwide audit of eye surgeries during its periodic review and revision process.

Primary OIG Report

2009 APR *Nationwide Review of Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees for Calendar Year 2005.* A-05-07-00077. [Full Text.](#)

See Also

- 2012 JUN *Use of Electronic Health Record Systems in 2011 Among Medicare Physicians Providing Evaluation and Management Services.* OEI-04-10-00184. [Full Text.](#)
- 2012 JUN *Fletcher Allen Health Care Did Not Always Bill Correctly for Evaluation and Management Services Related to Eye Injection Procedures.* A-01-11-00515. [Full Text.](#)
- 2012 MAY *Musculoskeletal Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided.* A-05-09-00053. [Full Text.](#)
- 2012 MAY *Cardiovascular Global Surgery Fees Often Did Not Reflect the Number of Evaluation and Management Services Provided.* A-05-09-00054. [Full Text.](#)
- 2012 MAY *Medicare Coding Trends of Medicare Evaluation and Management Services.* OEI-04-10-00180. [Full Text.](#)

Medicare A/B > Avoid Waste in Spending > Laboratories > Cost Sharing

Laboratories—Reinstate Beneficiary Cost Sharing and Notices for Lab Tests and Evaluate the Fee Schedule for Lab Services

Recommendations To Be Implemented

We recommend that CMS

- reinstate beneficiary deductibles and coinsurance (and notifications of amounts paid on their behalf) as a means of controlling utilization and
- periodically evaluate the national fee schedule to ensure that reimbursement is aligned with the prices that physicians pay for clinical laboratory tests.

Savings – The Congressional Budget Office's (CBO) December 2008 *"Budget Options Volume I – Health Care"* (p. 159) estimated savings of \$23.8 billion over 10 years from reinstating standard deductible and coinsurance requirements, with annual savings of \$2.4 billion by 2014.

The recommendations would help prevent the wasteful Medicare spending known to occur because beneficiaries do not share in the cost of laboratory tests. Medicare pays for allowed laboratory charges at a rate of 100 percent, which is unlike its reimbursement rate for most other Medicare benefits.

Waste also occurs because Medicare's fee schedule methodology does not align reimbursements with the prices that physicians pay for clinical laboratory tests.

Beneficiary cost sharing is a standard provision of the Medicare program. A January 1996 OIG report said that if laboratory tests were subject to Medicare's deductible and the 20-percent coinsurance and beneficiaries received a notice of the amount paid on their behalf, there would be more participatory control over utilization and billing. CMS informally confirmed in 2011 that because beneficiaries do not pay a share of the charges, CMS has no global policy requiring its payment contractors to notify beneficiaries of the payments Medicare made to laboratories on their behalf. Notifications are an important program integrity safeguard.

With regard to reimbursements, a January 1990 OIG report noted that Medicare was paying substantially more than physicians paid for laboratory tests. Our detailed review of 4,120 billings to 211 physicians revealed that the Medicare payment rates were about 90 percent more than the amounts that were actually paid by physicians. The January 1996 report said that although Medicare reduced the national fee schedule after our 1990 report, the average amount billed per beneficiary had gone up.

The Medicare Improvement for Patients and Providers Act of 2008 (MIPPA), § 145(b) made adjustments to the laboratory reimbursement methodology, but did not resolve our concerns.

Progress of Implementation

Copayments—CMS said a legislative change would be necessary to reinstate deductibles and coinsurance.

- In December 2008, the Congressional Budget Office (CBO) estimated that **\$23.8 billion** could be saved over 10 years by reinstating standard deductible and coinsurance requirements through an option that would require independent laboratories to bill the providers who ordered the tests instead of billing Medicare and the enrollees separately. Providers, who already bill and collect fees from patients, would bill Medicare and collect the beneficiary copayments.
- The December 2008 option places the ordering physician (instead of laboratories) at the hub of Medicare billing for lab tests, and restoring deductibles and copayments would raise beneficiaries' awareness of claims filed on their behalf. *Budget Options, Volume 1: Health Care*. Option 86. "Impose a Deductible and Coinsurance for Clinical Laboratory Services Covered by Medicare," p. 159.

Reimbursements—With regard to reevaluating the fee schedule, CMS said it did not have access to physician or laboratory records that would enable it to determine the prices that laboratories charge other customers or the amounts that physicians are paying for laboratory tests. CMS noted in its annual updates that it was taking steps to reduce payments for laboratory tests and said it would continue to evaluate payment levels for laboratories. CMS has not provided specific information that would cause us to close out our recommendation on reimbursements.

- An October 14, 2011, MedPAC package of potential policies to offset the budgetary costs of repealing the sustainable growth rate system estimated that reducing clinical laboratory payments by 10 percent would save **\$10 billion** over 10 years.
- The Middle Class Tax Relief and Job Creation Act of 2012, **§ 3202**, reduced by 2 percent the fee schedules for 2013, and such reduced fee schedules will serve as the base for 2014 and subsequent years. According to a joint staff analysis of the House Committees on Ways and Means and Energy and Commerce, CBO estimated that § 3202 will reduce spending by **\$2.7 billion** over 10 years.

We encourage CMS to seek legislative authority to reinstate deductibles and copayments and, as it reviews billing patterns for codes for more complex lab tests, to consider appropriate adjustments to be made to reimbursements, seeking legislation if necessary.

Primary OIG Reports

- 1996 JAN *Follow-up to Report on Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests*. A-09-93-00056. January 1996. [Full Text](#).
- 1990 JAN *Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests*. A-09-89-00031. [Full Text](#).

See Also

- 2012 JUN *Medicare Memorandum Report: Coverage and Payment for Genetic Laboratory Tests*. OEI-07-11-00011. [Full Text](#).

Medicare A/B > Avoid Waste in Spending > Laboratories > Payment Methodology

Laboratories—Establish a New Process for Reimbursement of Laboratory Tests

Recommendation To Be Implemented

- We recommend that CMS seek legislative authority to establish a new process for setting accurate and reasonable payment rates for laboratory tests.

Savings probable but not estimated.

The recommendation would curb the questionable Medicare spending that is occurring because the data used in 1985 to establish and update the Clinical Laboratory Fee Schedule may not have reflected the actual costs of performing the lab tests. Also, the data may not have reflected real differences in costs from one geographic area to another, as would be expected.

A July 2009 OIG report indicated that in establishing rates in 1985, carriers used data on laboratory charges that may not have reflected costs. Since then, methods used to update carrier rates have incrementally added to variation in carrier rates. If CMS continues to use current methods for updating the Clinical Laboratory Fee Schedule, early formula calculations that do not reflect actual costs will remain and possibly increase over time. Therefore, a new process is needed for setting accurate and reasonable payment rates that would represent costs, adjusted for geographic differences.

Under current methodology, Medicare's payment contractors reimburse laboratories the lower of the laboratories' charges or the contractors' fee schedules for their geographic areas for each test, as capped by a national limit amount (NLA).

Progress of Implementation

CMS said it would consider our recommendation as it continues to monitor the effects of its payment policies for laboratories. Options may include instituting competitive bidding for laboratory services.

The HHS Budget in Brief for Fiscal Year 2009 proposed introducing competitive bidding for clinical laboratory services ([p. 54](#)). Specifically it proposed to expand the successful competitive acquisition policy to include clinical laboratory services. HHS estimated the savings at \$2.29 billion over 5 years, 2009–2013, [p. 59](#).

We encourage CMS to continue to pursue legislation that would set accurate and reasonable payment rates for laboratory tests.

Primary OIG Report

2009 JUL *Variation in the Clinical Laboratory Fee Schedule*. OEI-05-08-00400. [Full Text](#).

See Also

- 2002 JAN *Common Working File Edits for Unauthorized Laboratory Tests*. OEI-05-00-00050. [Full Text](#).
- 1996 JAN *Follow-up to Report on Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests*. A-09-93-00056. January 1996. [Full Text](#).
- 1990 OCT *Ensuring Appropriate Use of Laboratory Services*. OEI-05-89-89150. [Full Text](#).
- 1990 JAN *Changes Are Needed in the Way Medicare Pays for Clinical Laboratory Tests*. A-09-89-00031. [Full Text](#).
- 1989 MAR *Medicare Reimbursement for Outpatient Laboratory Services*. OAI-04-88-01080. [Full Text](#).

Medicare A/B > Avoid Waste in Spending > Medical Equipment > Oxygen Rental Period

Medical Equipment—Reduce the Rental Period for Home Oxygen Equipment

Recommendation To Be Implemented

- We recommend that CMS work with Congress to further reduce the rental period for oxygen equipment.

Savings – We calculated that if the rental period were 13 months instead of 36 months, Medicare and its beneficiaries would save approximately \$3.2 billion over 5 years. The Congressional Budget Office estimated savings at \$11 billion over 10 years. (See “Progress” section.)

The recommendation would curb the wasteful Medicare spending that occurs because Medicare’s and beneficiaries’ expenditures for rented oxygen equipment substantially exceed the purchase price of the equipment.

At the end of the capped rental period, ownership of the oxygen equipment transfers to the beneficiary. The current 36-month rental period causes excessive rental payments to occur prior to transfer of ownership.

A September 2006 OIG report estimated that Medicare would allow \$7,215 for 36 months for concentrators that cost only \$587, on average, to purchase. Beneficiaries would pay \$1,443 in coinsurance paid for the same \$587 concentrators. The beneficiaries’ coinsurance alone exceeds the average cost of two concentrators by \$269. A legislative change is needed to reduce the rental period.

Additional Background >

Medicare has reduced the payment rates for home oxygen equipment three times since 1989. A still shorter rental period is warranted, and HHS budget documents have recommended 13 months as an alternative.

In deliberations about whether to reduce the rental period, industry groups have commented on the related costs of servicing equipment. Our 2006 report indicated that suppliers perform only minimal servicing and maintenance for beneficiary-owned concentrators and portable equipment. When suppliers visit beneficiaries, they often perform services that beneficiaries have been trained to do themselves. For example, on the basis of our sample, 50 percent of the visits to service the concentrators included cleaning the external filter, which the beneficiary is trained to maintain. When we accompanied suppliers on their visits to beneficiaries' homes, we observed that routine maintenance for a concentrator consisted of checking the filter to make sure it was clean and checking the oxygen concentration and flow rate using handheld instruments—tasks that can be performed in less than 5 minutes.

Progress of Implementation

CMS stated that reducing the rental period for most oxygen equipment from 36 to 13 months requires a statutory change.

- In 2007, the Congressional Budget Office estimated that shortening the continuous rental period for oxygen equipment from 36 months to 13 months would save \$3.5 billion over 5 years and **\$11 billion** over 10 years, 2008 – 2017. *Budget Options, February 2007*, p. 193.
- The HHS *Budget in Brief for FY 2008* estimated that reducing the rental period for oxygen equipment from 36 to 13 months would save **\$2.38 billion** over 5 years (FY 2008 – FY 2012). (pp. 53 and 57.)
- The HHS *Budget in Brief for FY 2009* estimated that reducing the rental period for oxygen equipment from 36 to 13 months would save **\$3 billion** over 5 years (FY 2009 – FY 2013). (pp. 54 and 59.)
- In its 2012 update, CMS suggested that a statutory change may not be necessary given that unreasonable payment amounts for oxygen and oxygen equipment are addressed through the competitive bidding program for medical equipment and supplies.

While we support CMS's efforts to control pricing through competitive bidding, we do not believe the competitive bidding process alone will do enough to address the large difference between acquisition costs and Medicare's and beneficiaries' shared rental payments for oxygen equipment. We continue to encourage CMS to work with Congress to reduce the rental period for oxygen equipment.

Primary OIG Report

2006 SEP *Medicare Home Oxygen Equipment – Cost and Servicing*. OEI-09-04-00420.
[Full Text](#).

Medicare A/B > Avoid Waste in Spending > Medical Equipment > Power Wheelchairs

Medical Equipment—Adjust Reimbursements for Power Wheelchairs

Recommendation To Be Implemented

- We recommend that CMS determine whether Medicare’s fee schedule amounts for standard and complex rehabilitation power wheelchairs should be adjusted.

Savings probable but not estimated. In 2007, approximately 173,300 Medicare beneficiaries received standard and complex power wheelchairs, at a total cost of \$686 million. The 2009 Medicare fee schedule amount exceeded the average competitively bid price by \$568.

The recommendation would curb the wasteful Medicare spending that occurs because Medicare’s methodology for developing power wheelchair fee schedule amounts does not align reimbursements with supplier acquisition costs.

OIG evaluations found that consumers can purchase power wheelchairs in the marketplace at lower prices than Medicare and its beneficiaries pay.

An August 2009 OIG report compared acquisition costs to payments in 2007 and revealed that Medicare and its beneficiaries paid almost four times the average amount suppliers paid to acquire standard power wheelchairs and paid almost two times the average amount suppliers paid to acquire complex rehabilitation power wheelchair packages.

Additional Background >

At the time of our review, Medicare covered power wheelchairs under a capped rental arrangement. The beneficiary could choose to rent or purchase the power wheelchair. Medicare beneficiaries typically chose to purchase power wheelchairs. In the first half of 2007, new purchases accounted for 95 percent of all Medicare power wheelchair expenditures.

A report by the Congressional Research Service (CRS) stated that starting January 1, 2011, the Affordable Care Act, § 3136, restricted the lump-sum payment option for new or replacement chairs to only the complex, rehabilitative power wheelchairs. The lump-sum payment option is eliminated for all other wheelchairs. (The provision does not apply to competitive acquisition areas prior to January 1, 2011.) The CRS report said that starting January 1, 2011, the rental payment for power-driven wheelchairs is 15 percent of the purchase price for each of the first 3 months (instead of 10 percent) and 6 percent of the purchase price for each of the remaining 10 months of the rental period (instead of 7.5 percent). CBO scored savings from § 3136 at \$800 million over 10 years. (Congressional Research Service (CRS) Report [R41196](#), p. 45.)

Progress of Implementation

In responding to our review, CMS said that it planned to use information from the Competitive Bidding Acquisition Program for its analysis of whether Medicare’s fee schedule amounts for

standard and complex rehabilitation power wheelchairs should be adjusted and will consider seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes. CMS noted that it is not likely to use its authority to adjust fee schedule amounts until the results of the supplier bids for power wheelchairs under the Competitive Bidding Acquisition Program have been assessed.

Subsequently, the Affordable Care Act, § 3136, was passed, making the changes described under the “Additional Background” section above. See CMS Manual System [Change Request 7116](#), October 15, 2010, and *MLN Matters*, MM7116, *Elimination of Lump Sum Purchase Payment for Standard Power Wheelchairs Furnished on or after January 1, 2011 due to the Affordable Care Act*.

We encourage CMS to provide documentation of the extent to which our recommendation regarding fee schedule payments is being implemented. We continue to monitor improvements in this area.

Primary OIG Report

2009 AUG *Power Wheelchairs in the Medicare Program – Supplier Acquisition Costs and Services*. OEI-04-07-00400. [Full Text](#).

See Also

2011 OIG’s [Spotlight on Power Wheelchairs](#), available on our Web site.

2009 JUL *Miscoded Claims for Power Wheelchairs in the Medicare Program*. OEI-04-07-00403. [Full Text](#).

2009 DEC *Medicare Power Wheelchair Claims Frequently Did Not Meet Documentation Requirements*. OEI-04-07-00401. [Full Text](#).

2004 APR OIG Testimony Before the Senate Committee on Finance – “Abuses of the Medicare Wheelchair Benefit.” [Testimony](#).

Medicare A/B > Avoid Waste in Spending > Medical Equipment > Wound Therapy Pumps

Medical Equipment—Monitor Growth in the Negative Pressure Wound Therapy Pump Market

Recommendations To Be Implemented

We recommend that CMS

- continue to monitor the growth of new negative pressure wound therapy pumps in the marketplace and
- follow up on the claims that we identified that may be inappropriate.

Savings probable but not estimated.

The recommendations would curb the wasteful Medicare spending that occurs when Medicare's payment rates for rentals of negative pressure wound therapy pumps (pump) results in reimbursements that do not align with supplier acquisition costs.

The pumps are portable or stationary devices used to treat ulcers or wounds that have not responded to traditional wound treatment methods. Medicare's rental fee was based on a purchase price that was established when there was only one manufacturer in the market. Since then, a number of manufacturers have introduced new pump models to the market and are charging substantially less for them.

A March 2009 OIG report revealed that Medicare's purchase price for the original model was more than four times the average price paid by suppliers for the new pump models. Although CMS included pumps in Round 2 competitive bidding in 2012 and is implementing adjustments to payments, additional monitoring of the growing pump market is needed to ensure that Medicare reimbursements are appropriately aligned going forward.

Additional Background >

Medicare covers pumps under a capped rental arrangement. Under this arrangement, Medicare pays suppliers a monthly fee schedule amount for each month that they rent the pumps to beneficiaries. Between 2001 (when Medicare started covering pumps) and 2007, Medicare payments for the pumps increased 583 percent, from \$24 million to \$164 million.

Our 2009 report also revealed that beneficiaries' coinsurance payments for pumps covered a substantial portion of the average cost of a new pump model. After just 4 months of rental, a beneficiary's coinsurance of \$1,286 covered over one-third (36 percent) of the average cost of a new pump model to the supplier.

Progress of Implementation

CMS included the pumps under the competitive bidding program for medical equipment and supplies. For bidding that began in 2012, revised payment amounts will take effect on July 2, 2013. The revised prices for pumps will implement a prior, short-term OIG recommendation to align Medicare's reimbursements for the pumps with prices in the current marketplace.

CMS said it will consider whether it would be able to gather valid and reliable data to make a determination when the payment amount for pumps is grossly deficient or excessive and to establish, if needed, a new amount that is realistic and equitable. CMS said it will monitor and track trends in utilization of pumps and track the market share among pump suppliers. CMS concurred with our recommendation to follow up on pump claims that may be inappropriate and said it is working with its contractors to strengthen oversight in this area.

We encourage CMS to follow through on its efforts. We request that CMS describe the mechanisms it has in place to collect and analyze data on pump market prices. We continue to monitor CMS's progress in implementing our recommendations.

Primary OIG Report

2009 MAR *Comparison of Prices for Negative Pressure Wound Therapy Pumps.*
OEI-02-07-00660. [Full Text.](#)

Medicare A/B > Avoid Waste in Spending > Part B Drugs > ASP Data Collection

Part B Drugs—Improve Collection of Average Sales Price Data

Recommendations To Be Implemented

We recommend that CMS

- develop an automated system for collecting average sales price (ASP) data and
- seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASP data.

Savings probable but not estimated.

The recommendations would prevent the wasteful Medicare spending that occurs when Medicare's ineffective data collection practices and processing methods hinder timely and appropriate payment adjustments.

ASPs serve as the basis of Medicare payment for Part B-covered drugs. The increased efficiencies that would result from implementing an automated system for collecting ASP data would facilitate appropriate adjustments to Medicare payments.

A February 2010 OIG report identified several potential issues with the ASP data reporting process, including the timeliness of manufacturer reporting, the largely manual process CMS uses to collect and analyze manufacturer-reported data, and the legal requirements for manufacturer reporting. Each of these issues introduces the potential for inefficiency and errors. Administrative and legislative changes are needed.

Additional Background >

The ASP is derived from a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program

Some manufacturers of Part-B-covered drugs are not required to report ASPs. CMS should work with Congress to develop legislation that would directly require all manufacturers of Part B-covered drugs to submit ASPs. This would ensure that Medicare payment amounts were reflective of all Part B-covered drugs.

Progress of Implementation

CMS supported developing an automated system for the collection of ASP data and said that as it continues to monitor the effects of current payment policies, it would consider seeking a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs.

We encourage CMS to follow through on its plan as a way to ensure that Medicare payment amounts are reflective of all Part-B-covered drugs. We continue to monitor CMS's implementation of our recommendations.

Primary OIG Report

2010 FEB *Average Sales Prices – Manufacturer Reporting and CMS Oversight.*
OEI-03-08-00480. [Full Text.](#)

Medicare A/B > Avoid Waste in Spending > Part B Drugs > Payment Adjustments

Part B Drugs—Exercise a Statutory Option To Reduce Payments

Recommendations To Be Implemented

We recommend that CMS

- reduce Medicare reimbursement amounts for Part B drugs that meet a statutory 5-percent threshold,
- expand its price substitution policy to include certain drug codes with partial average manufacturer price (AMP) data, and
- seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit both average sales prices (ASP) and average manufacturer prices (AMP).

Savings – \$13.2 million for 32 drug codes over 4 calendar quarters.

The recommendations would eliminate the wasteful Medicare spending that occurs when Medicare fails to optimally exercise a statutory option to reduce payments for Part B-covered drugs under specified conditions.

When the ASP of a drug exceeds the AMP or the WAMP by a certain threshold (currently 5 percent), the Secretary of HHS may disregard the ASP for the drug when setting reimbursement amounts.

A November 2011 OIG report estimated that if reimbursement amounts for 32 drug codes with complete AMP data had been lowered to 103 percent of the AMPs during the applicable quarters, Medicare expenditures would have been reduced by \$13.2 million between the third quarter of 2010 and the second quarter of 2011. Although the opportunity to save Medicare dollars exists, in practice the option has not been used.

Additional Background >

Federal law requires OIG to conduct reviews comparing ASPs to AMPs and widely available market prices (WAMP). OIG's November 2011 report ([link below](#)) provides more detail on our recommendations.

Progress of Implementation

CMS has taken steps to ensure that manufacturers report certain pricing data in a timely manner, including terminating manufacturers' rebate agreements for failure to report AMPs and referring manufacturers with nontimely AMPs to OIG for evaluating civil monetary penalties (CMP). In 2011, CMS published an AMP substitution policy in the Federal Register at [76 Fed. Reg. 42772, 42828](#) (July 19, 2011). Details of the AMP substitution policy were described in the final rule with comment period published at [76 Fed. Reg. 73026, 73287-96](#) (November 28, 2011).

We continue to recommend that Medicare reimbursements for eligible drug codes be lowered and will continue to assist CMS in developing a price substitution policy and taking appropriate action against manufacturers that fail to comply with reporting requirements.

Primary OIG Reports

- 2011 Nov *Comparison of ASP to AMP: An Overview of 2010*. OEI-03-11-00410. [Full Text](#).
- 2011 APR *Comparison of ASP to AMP: An Overview of 2009*. OEI-03-10-00380. [Full Text](#).
- 2010 FEB *Comparison of ASP to AMP: An Overview of 2008*. OEI-03-09-00350. [Full Text](#).
- 2008 DEC *Comparison of ASP to AMP: An Overview of 2007*. OEI-03-08-00450. [Full Text](#).

See Also

- 2012 AUG *Impact on Reimbursement for Second Quarter 2012*. OEI-03-12-00410. [Full Text](#).
- 2012 JAN *Comparison of ASP to WAMP*. OEI-03-10-00280. [Full Text](#).
- 2012 JAN *Impact on Reimbursement for Fourth Quarter 2011*. OEI-03-12-00020. [Full Text](#).
- 2011 AUG *Impact on Reimbursement for Third Quarter 2011*. OEI-03-11-00540. [Full Text](#).
- 2011 JUL *Impact on Reimbursement for Second Quarter 2011*. OEI-03-11-00360. [Full Text](#).
- 2011 MAY *Impact on Reimbursement for First Quarter 2011*. OEI-03-11-00160. [Full Text](#).
- 2011 FEB *Impact on Reimbursement for Fourth Quarter 2010*. OEI 03-11-00030. [Full Text](#).
- 2010 NOV *Impact on Reimbursement for Third Quarter 2010*. OEI 03-10-00440. [Full Text](#).
- 2010 SEP *Manufacturers' Reporting Requirements*. OEI-03-09-00060. [Full Text](#).
- 2010 JUL *Impact on Reimbursement for Second Quarter 2010*. OEI 03-10-00350. [Full Text](#).
- 2010 APR *Impact on Reimbursement for First Quarter 2010*. OEI 03-10-00150. [Full Text](#).
- 2010 FEB *Manufacturer Reporting and CMS Oversight of ASP*. OEI-03-08-00480. [Full Text](#).
- 2010 JAN *Impact on Reimbursement for Fourth Quarter 2009*. OEI-03-09-00640. [Full Text](#).
- 2009 AUG *Impact on Reimbursement for Third Quarter 2009*. OEI-03-09-00490. [Full Text](#).
- 2009 AUG *Impact on Reimbursement for Second Quarter 2009*. OEI-03-09-00340. [Full Text](#).
- 2009 APR *Impact on Reimbursement for First Quarter 2009*. OEI-03-09-00150. [Full Text](#).
- 2009 FEB *Impact on Reimbursement for Fourth Quarter 2008*. OEI-03-09-00050. [Full Text](#).
- 2008 DEC *Impact on Reimbursement for Third Quarter 2008*. OEI-03-08-00530. [Full Text](#).

2006 JUL OIG Testimony Before the House Committee on Ways and Means, Subcommittee on Health – “Part B Reimbursement for Prescription Drugs and the Average Sales Prices (ASP) Used To Set This Reimbursement.” [Testimony](#).

Medicare A/B > Avoid Waste in Spending > Part B Drugs > Newly Available Generic Drugs

Part B Drugs—Adjust Payments for Drugs With Newly Available Generic Versions To Accurately Reflect Market Prices

Recommendations To Be Implemented

We recommend that CMS

- ensure that the Medicare payments for drugs with newly available generic versions accurately reflect market prices and
- work with Congress to require manufacturers of first generics to submit monthly ASP data during the period of initial generic availability.

Savings – \$111 million for 16 drugs over three quarters.

The recommendations would curb the wasteful Medicare spending that occurs because the current payment methodology causes Medicare and its beneficiaries to miss out on immediate savings when a drug’s ASP declines.

The vulnerability involves a two-quarter lag between the time that manufacturers lower the ASP of a drug and Medicare’s corresponding payment adjustment. This occurrence is especially relevant when generic versions of a drug first become available.

A January 2011 OIG report revealed that if there had been no two-quarter reimbursement lag during the period of initial generic availability for 16 selected drugs, Medicare and its beneficiaries could have saved a conservatively estimated \$111 million in the three quarters under review. Administrative and legislative changes are needed.

An August 2008 OIG report compared the first-quarter 2008 Medicare payment amount to manufacturer prices for irinotecan hydrochloride (irinotecan), an injectable drug used to treat patients with colorectal cancer. The Medicare payment amount for irinotecan was more than double the average manufacturer sales price we calculated. Medicare expenditures for the drug could have been reduced by \$6.5 million in that month alone.

Additional Background >

According to FDA, 26 of the 48 top dollar-volume brand-name drugs covered under Part B either already have or could have generic versions approved for the first time in the next several years. Also, the Affordable Care Act, [§ 7002](#), created a new approval pathway for generic biologics.

Therefore, the impact of the two-quarter lag will likely continue to grow if CMS does not make changes to its Part B payment system.

Progress of Implementation

CMS stated that the ASP methodology reflects market-based prices over time. CMS's comments and our responses about monthly ASP reporting begin on [p. 20](#) of the August 2011 report.

We encourage CMS to implement the recommendations we specified. We continue to monitor CMS's progress.

Primary OIG Reports

2011 JAN *Medicare Payments for Newly Available Generic Drugs*. OEI-03-09-00510. [Full Text](#).

2008 AUG *Medicare Payment for Irinotecan*. OEI-03-08-00310. [Full Text](#).

Medicare A/B > Avoid Waste in Spending > Physicians > Chemotherapy Administration

Part B Drugs—Specify Drugs That Qualify for the Chemotherapy Administration Rate and Ensure That Claims Are Correctly Paid

Recommendations To Be Implemented

We recommend that CMS

- establish a process to determine the specific drugs that qualify for the chemotherapy administration payment rate and
- ensure that drug administration claims are coded and paid correctly.

Savings probable but not estimated.

The recommendations would control the wasteful Medicare spending that occurs because Medicare has not established a process to specify the drugs that qualify for the chemotherapy administration payment rate.

The lack of specifications hinders consistent determinations of whether claims for chemotherapy administration are appropriate for reimbursement.

A June 2009 OIG report revealed that Medicare's payment contractors have implemented inconsistent chemotherapy administration coding policies and review procedures. Medicare paid \$1.9 billion for chemotherapy administration services between 2005 and 2007.

Additional Background >

Medicare pays physicians about twice as much to administer chemotherapy drugs as it pays them to administer nonchemotherapy drugs. Medicare also pays the chemotherapy rate for administering certain types of nonchemotherapy drugs with particularly complex preparation and delivery issues.

Medicare leaves the determinations of qualifying drugs to the individual payment contractors that process Part B physician claims.

Progress of Implementation

CMS said that the current procedural terminology guidance represents the best consensus from the medical community and CMS. CMS also said that it believes the current variations in carrier definitions of qualifying drugs may be because of required practice variations in the conditions for which a drug is used and that these variations may decrease as a consequence of contracting reform.

We continue to encourage CMS to establish a process to determine which specific drugs qualify for the chemotherapy administration payment rate and that CMS ensure that drug administration claims are coded correctly and paid appropriately. We continue to monitor CMS's progress.

Primary OIG Report

2009 JUN *Medicare Part B Chemotherapy Administration – Payment and Policy.*
OEI-09-08-00190. [Full Text.](#)

Medicare A/B > Avoid Waste in Spending > Dialysis Facilities > Payment Adjustments

Dialysis-Related Drugs—Develop a More Accurate Method for Estimating Changes in the Prices of End Stage Renal Disease Drugs

OIG Recommendation

- We recommend that CMS develop a more accurate method for estimating changes in the prices of end stage renal disease (ESRD) drugs.

Savings are probable but not estimated.

The recommendations would prevent the wasteful Medicare spending that occurs when Medicare uses the Bureau of Labor Statistics Producer Price Index (PPI) for the ESRD drugs portion of the ESRD new bundled rate when estimating price changes.

A September 2010 OIG report established that the PPI is not an accurate tool for the purpose. The report revealed that during a period when facilities' acquisition costs for many ESRD drugs decreased, the PPI increased by 39 percent. This method will unnecessarily cost Medicare and its beneficiaries hundreds of millions of dollars a year.

We calculated that if CMS had used the PPI to update payment amounts for the ESRD drug epoetin alfa since 2003, total program payments to all independent dialysis facilities for the drug in the first quarter of 2009 alone would have been 33 percent higher than the actual payments made under the prior ASP-based system. In contrast, facility acquisition costs for the drugs that account for the

majority of Medicare expenditures in independent dialysis facilities actually decreased during the same period.

Additional Background >

In August 2010, CMS published an ESRD final rule, “Medicare Program End-Stage Renal Disease Prospective Payment System,” that implemented a case-mix adjusted bundled prospective payment system (PPS) for Medicare outpatient end-stage renal disease (ESRD) dialysis facilities beginning January 1, 2011 (ESRD PPS). ([75 Fed. Reg. 49030](#) (August 12, 2010).) CMS said in the final rule that it agreed “with the commenters” [on the earlier proposed rule] about the need for an update in ASP prices for Part B drugs and the need to use the PPI for the update. CMS estimated that an update using the PPI would result in a 3.9-percent increase in Medicare reimbursement for the top 11 separately billable Part B Drugs from 2010 to 2011 ([p. 49079](#)).

Progress of Implementation

CMS did not concur with our recommendation to develop a more accurate method for estimating changes in the prices of ESRD drugs under the bundled rate but said it will monitor the ESRD program to ensure that growth trends in the PPI represent an appropriate price proxy when compared to growth trends in ASP.

We continue to monitor CMS’s implementation of the recommendation we specified. We will review payments for ESRD drugs under the new bundled rate system. We also will compare facility acquisition costs for certain drugs to inflation-adjusted cost estimates and determine how costs for the drugs have changed since our last review.

Primary OIG Report

2010 SEP *End Stage Renal Disease Drugs – Facility Acquisition Costs and Future Medicare Payment Concerns*. OEI-03-09-00280. [Full Text](#).

❖ Identify and Reduce Improper Payments

Improper payments occur when Medicare does not effectively identify and reduce erroneous and inappropriate billing by providers and suppliers prior to payment. OIG designated improper payments as one of the top management and performance challenges facing HHS in FY 2012. Improper payments include both overpayments and underpayments. Some (but certainly not all) overpayments are fraudulent.

Improper payments are associated with claims-based or claims-processing-based deficiencies. Commonly, the items or services billed are not supported by the documentation in the providers’ medical files, are not medically necessary, or were not covered by Medicare. Also, administrative errors may be associated with the claims. Many claims are questioned and disallowed because providers do not maintain required documentation or the documentation is not sufficient to support the services and amounts claimed.

Recommendations in this section include that CMS and/or Medicare contractors conduct prepayment and postpayment reviews of medical records (including third-party records, such as ordering providers’ records) as appropriate; conduct unannounced site visits of providers; implement system edits to detect and reject questionable entries on claims; develop data sets and

other tools to assist in proper billing; track billing histories for capped items and services; establish risk-based levels for screening and reviewing providers; monitor historically vulnerable provisions, procedures, providers, benefit categories, and system codes; ensure effective guidance and communications among CMS, its payment contractors, and the provider community; and impose sanctions, such as penalties, suspensions, and revocations, on providers with serious deficiencies.

OIG's audits and evaluations do not routinely project the annual cost savings that could be realized at program level from implementing the recommendations. However, reports are indicative of the extent to which policies and methodologies may be less than effective and in need of corrective action.

Acronyms and Abbreviations for Selected Terms Used in This Section

CCI	Correct Coding Initiative	MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
DPNA	denial of payment for new admissions	NPI	national provider identifier
DRA	Deficit Reduction Act of 2005	SNF	skilled nursing facility
IDTF	independent diagnostic testing facility	UPIN	unique physician identifier number

Medicare A/B > Reduce Improper Payments > Practitioners > Modifier 59

Claims Processing—Monitor the Use of Service Code Modifier 59 and Ensure Correct Payments

Recommendations To Be Implemented

We recommend that CMS

- encourage Medicare's payment contractors to conduct prepayment and postpayment reviews of the use of service code modifier 59 and
- ensure that the payment contractors' claims processing systems pay claims with modifier 59 only when the modifier is billed with the correct service code.

Savings – We estimated that \$27 million was improperly paid in FY 2003 because modifier 59 was attached to the wrong service codes on claims.

The recommendations would prevent the improper payments that occur when the billing providers (physicians and other eligible practitioners) inappropriately enter service code modifier 59 on claims for Medicare reimbursement. Medicare does not automatically detect misuses of modifier 59 before paying the claims.

Providers use Modifier 59 to indicate that the provider performed a distinct procedure or service for a beneficiary along with another procedure or service that generally would not be billed together on the same date of service. Modifier 59 allows both service codes to be paid. A modifier

is a two-digit code that further describes the service performed. Thirty-five modifiers can be used to bypass Correct Coding Initiative (CCI) edits. Modifier 59 is one of the modifiers.

A November 2005 OIG report estimated \$59 million in improper Medicare payments occurred in FY 2003 because the service code pairs with which Modifier 59 was used did not meet certain program requirements. We estimated an additional \$27 million was improperly paid because the modifier was attached to the wrong service code on the claim.

The report also revealed that most Medicare payment contractors did not conduct special reviews of claims with modifier 59. For those that did, the providers had an error rate of 40 percent or more for the services they billed with modifier 59.

Additional Background >

In January 1996, the Centers for Medicare & Medicaid Services (CMS) began the Correct Coding Initiative (CCI). This initiative was developed to promote correct coding by providers and to prevent Medicare payment for improperly coded services. The initiative consists of automated edits that are part of the carriers' claims processing systems.

Specifically, the CCI edits contain pairs of Healthcare Common Procedure Coding System codes (i.e., code pairs) that generally should not be billed together by a provider for a beneficiary on the same date of service.

Progress of Implementation

CMS concurred with our recommendations to encourage carriers to conduct prepayment and postpayment reviews of the use of modifier 59 and to ensure that carriers' claims processing systems pay claims only when modifier 59 is billed with the secondary code. However, at the time of the report, CMS said that it was unable to implement system edits to ensure correct coding.

- In April 2006, CMS published clarifying guidance to chapter 4 of the *Medicare Claims Processing Manual*, which includes the use of modifier 59 (CR 4388).
- In April 2008, CMS issued an *MLN Matters* article (classified as Special Edition 0810) to provide continuing education to physicians on how to bill modifier 59 appropriately.
- In its December 2009 update, CMS indicated that it would explore the development of a system edit for modifier 59. However, upon further analysis in this area, CMS concluded that the implementation of an edit for modifier 59 would likely result in increased appeals volume.
- In its update for 2011, CMS indicated that it will continue to explore alternative solutions to ensure correct coding.

We continue to monitor CMS's progress to ensure correct coding and use of Modifier 59.

Primary OIG Report

2005 NOV *Use of Modifier 59 To Bypass Medicare's National Correct Coding Initiative Edits.*
OEI-03-02-00771. [Full Text.](#)

Medicare A/B > Reduce Improper Payments > Skilled Nursing Facilities > Denial of Payment

Skilled Nursing Facilities—Ensure the Appropriate Processing of Denial-of-Payment Remedies for Noncompliant Facilities

Recommendation To Be Implemented

We recommend that CMS manage skilled nursing facility denial-of-payment remedies for new admissions (DPNA) cases by timely sending DPNA instructions to contractors and ensuring that the contractors retrospectively review cases that are processed late to correct any payment errors. Specifically, CMS should

- address communication breakdowns by implementing a standard format to notify Medicare's payment contractors that a DPNA remedy will be in effect and
- require confirmation that instructions are received and understood.

Savings probable but not estimated.

The recommendations would prevent the improper payments that occur because Medicare does not have consistent procedures in place to identify and correctly process SNF new admissions claims that are subject to DPNA disallowances.

DPNA is an enforcement remedy that CMS may use to address noncompliance with Federal quality-of-care standards in SNFs.

A May 2008 OIG report revealed that CMS and its payment contractors incorrectly processed 74 percent of the SNF DPNA actions we reviewed. Forty percent of the cases resulted in overpayments to the SNFs in an amount exceeding \$5 million in FY 2004. Causes of the DPNA processing errors included CMS's failure to provide its contractors with DPNA instructions on a timely basis or at all, CMS's provision of information to the wrong contractors, and contractors' misinterpretation of CMS's instructions.

Additional Background >

CMS is required to impose a denial of payment for new admissions (DPNA) under two circumstances: extended noncompliance and repeated instances of substandard quality of care, for example, a string of unrelated, low-level deficiencies that create a potential for harm to beneficiaries as well as for the most severe instances of immediate jeopardy, which pose serious injury, harm, impairment, or death to beneficiaries.

CMS is responsible for imposing denial of payment remedies but relies on its payment contractors to actually identify and reject the relevant Medicare claims.

Progress of Implementation

CMS outlined specific actions to address each recommendation and indicated that it would develop internal procedures to effectively communicate DPNA instructions to claims processing contractors

and create a protocol so contractors could notify CMS that a DPNA had been implemented as requested.

- In April 2009, CMS told OIG that it had established a workgroup to improve practices to reduce improper payments to nursing homes subject to DPNA. According to CMS, the workgroup was developing a formal administrative policy guidance memorandum for internal use by CMS and MACs about consistency in effectuating DPNAs. The guidance was scheduled to be issued in summer 2009, but as of January 2011, it had not been issued.
- In its update for 2011, CMS said that no updates were available on the guidance concerning DPNA instructions and protocols with contractors. CMS said that it would provide this information as soon as possible after it becomes available.
- CMS had not provided subsequent updates as of August 2012.

We continue to monitor CMS's progress in implementing the recommendations we specified.

Primary OIG Report

2008 MAY *Nursing Home Enforcement – Processing Denials of Medicare Payment.*
OEI-06-03-00390. [Full Text](#).

See Also

2007 JUL OIG Testimony Before the Senate Special Committee on Aging – “Elder Abuse and Noncompliant Nursing Homes.” [Testimony](#).

Medicare A/B > Reduce Improper Payments > Hospices > Noncompliance

Hospices—Ensure That Hospice Claims for Beneficiaries in Nursing Homes Comply With Medicare Coverage Requirements

Recommendation To Be Implemented

- We recommend that CMS strengthen its monitoring practices for hospice claims for beneficiaries in nursing homes by using targeted medical reviews and other oversight mechanisms.

Savings probable but not estimated.

The recommendation would prevent the improper payments that occur because Medicare cannot determine on the basis of hospice claims alone whether key coverage requirements are met before paying claims. Claims associated with noncompliance with Medicare's requirements are considered improper and unallowable.

Additional monitoring of hospice claims for beneficiaries in nursing homes is needed.

Two OIG reports issued together in September 2009 quantified the number of beneficiaries enrolled in hospice and the types of services being provided to them and, on the basis of medical reviews, concluded that CMS's oversight procedures for hospice claims were inadequate and that it must do more to ensure that Medicare coverage requirements are met. We found that 82 percent of claims we reviewed for hospice beneficiaries in nursing facilities did not meet at least one Medicare coverage requirement. Medicare paid about \$1.8 billion for the claims.

Additional Background >

The Tax Equity and Fiscal Responsibility Act of 1982, § 122, created the Medicare hospice benefit for eligible beneficiaries under Medicare Part A. Pursuant to regulations, to be covered for payment by Medicare, hospice services must be reasonable and necessary for the palliation or management of the terminal illness as well as related conditions. Hospices must establish and maintain a clinical record for each beneficiary receiving services. The record must contain evidence that certain requirements are met.

Progress of Implementation

CMS said that it shared our report with providers but has not offered evidence that it has changed its oversight practices.

- In its update for 2011, CMS said that it would instruct Medicare contractors to consider the coverage requirements in our report when prioritizing its medical review strategies or other interventions. CMS also said that it is collecting more data on hospice claims and has added edits to reject claims that do not comply. A change request for new edits, CR 6778, was issued on February 5, 2010. Additionally, CMS said it began conducting provider outreach calls in 2010 to improve compliance with Medicare requirements regarding hospice claims.
- In its 2012 update, CMS said that it is exploring preliminary requirements to begin the implementation of the Affordable Care Act, [§ 3132\(b\)](#), which requires reviews of hospices with a certain percentage of its population having lengths of stay greater than 180 days.

We continue to monitor CMS's implementation of the recommendation we specified.

Primary OIG Reports

2009 SEP *Medicare Hospice Care for Beneficiaries in Nursing Facilities: Compliance With Medicare Coverage Requirements.* OEI-02-06-00221. [Full Text.](#)

2009 SEP *Medicare Hospice Care: Services Provided to Beneficiaries Residing in Nursing Facilities.* OEI-02-06-00223. [Full Text.](#)

See Also

2011 JUL *Medicare Hospices That Focus on Nursing Facility Residents.* OEI-02-10-00070. [Full Text.](#)

1997 SEP *Hospice Patients in Nursing Homes.* OEI-05-95-00250. [Full Text.](#)

Medicare A/B > Reduce Improper Payments > Chiropractors > Noncovered Services

Chiropractors—Prevent Payments for Chiropractic Maintenance Therapy

Recommendation To Be Implemented

- We recommend that CMS implement and enforce policies to prevent payments for maintenance therapy.

Savings probable but not estimated.

The recommendation would prevent the improper payments that occur when chiropractors inappropriately enter an acute treatment service code modifier (AT modifier) on claims for Medicare reimbursement.

Medicare's controls are not sufficient to detect misuses of the modifier before paying the claims. Claims associated with noncompliance with Medicare's requirements are considered improper and unallowable.

The AT Modifier identifies services that are active/corrective treatments that meet Medicare's requirements for payment. Medicare denies service codes without the AT modifier as being noncovered maintenance therapy. The AT Modifier allows the claim to be paid.

A May 2009 OIG report revealed that a lack of initial visit dates in claims data contributes to Medicare's inability to identify noncovered maintenance therapy. On the basis of medical reviews, we estimated that Medicare inappropriately paid 47 percent of allowed chiropractic claims in a 2006 sample. Chiropractors improperly submitted claims for maintenance therapy with the AT modifier even though all 16 Medicare payment contractors we reviewed indicated that they provided education to chiropractors on the correct use of the modifier.

Additional Background >

Medicare pays only for medically necessary chiropractic services, which are limited to active/corrective manual manipulations of the spine to correct subluxations. When further improvement cannot reasonably be expected from continuing care, the services are then considered maintenance therapy, which is not medically necessary and therefore not payable under Medicare. When submitting claims, chiropractors must use the AT Modifier to identify services that are active/corrective treatments that meet Medicare's requirements for payment (i.e., for subluxations) and must document services pursuant to CMS's *Medicare Benefit Policy Manual*.

Previous OIG work found significant vulnerabilities existed in connection with chiropractic claims, particularly concerning Medicare payments for maintenance therapy.

Progress of Implementation

CMS indicated it is working through the policy and operational implications of requiring an additional service code modifier and will consider implementing one if feasible.

We continue to monitor CMS's efforts regarding the feasibility of requiring an additional modifier or other potential policy solutions.

Primary OIG Report

2009 MAY *Inappropriate Medicare Payments for Chiropractic Services*. OEI-07-07-00390. [Full Text](#).

See Also

2005 JUN *Chiropractic Services in the Medicare Program: Payment Vulnerability Analysis*. OEI-09-02-00530. [Full Text](#).

2000 JUN *Chiropractic Care—Comparison of Medicare Managed Care and Fee-For-Service*. OEI-04-97-00495. [Full Text](#).

1999 NOV *Utilization Parameters for Chiropractic Treatments*. OEI-04-97-00496. [Full Text](#).

1998 SEP *Chiropractic Care—Controls Used by Medicare, Medicaid, and Other Payers*. OEI-04-97-00490. [Full Text](#).

1998 SEP *Chiropractic Care—Medicaid Coverage*. OEI-06-97-00480. [Full Text](#).

Medicare A/B > Reduce Improper Payments > Other Suppliers > IDTFs > Noncompliance

Independent Diagnostic Testing Facilities—Implement Unannounced Site Visits and Other Actions To Prevent Improper Payments (New)

Recommendations To Be Implemented

We recommend that CMS

- periodically conduct unannounced site visits to independent diagnostic testing facilities (IDTF),
- take action against the noncompliant IDTFs identified by our site visits in Los Angeles,
- impose a moratorium on the enrollment of IDTFs in the Los Angeles area, and
- stop payments to noncompliant IDTFs whose billing privileges are being revoked.

Savings probable but not estimated.

The recommendations would prevent the questionable payments that occur when IDTFs bill Medicare for services but, as confirmed by site visits, do not maintain their physical facilities at the locations on file with CMS and are not open during business hours as required. Claims associated with noncompliance with Medicare's requirements are considered improper and unallowable.

IDTFs, a type of Medicare service supplier, offer diagnostic services and are independent of a physician's office or hospital.

OIG issued two reports in August 2011 on IDTFs in Los Angeles, California and Miami, Florida. Our work revealed that of the 224 actively enrolled IDTFs in the two selected cities, 73 were not open during regular business hours at the location on file. IDTFs that do not comply with Medicare standards are subject to administrative actions, including revocation of their Medicare billing privileges.

Additional Background >

IDTFs, which were formerly called Independent Physiological Laboratories, have historically been vulnerable to abuse. In site visits in 1997, we found that 20 percent of IDTFs were not at the locations on file with CMS. A June 2006 OIG report of IDTF claims in 2001 projected \$71.5 million in improper Medicare payments to IDTFs. Medicare allowed almost \$1 billion for IDTF claims for 2.4 million beneficiaries in 2010.

Progress of Implementation

In response to the Los Angeles report, CMS said it anticipates increasing the frequency of unannounced site visits and that it will take appropriate administrative actions against the IDTFs identified in the report. CMS did not concur with the recommendation to impose a moratorium. However, CMS said it would take the recommendation under strong consideration. In response to the Miami report, CMS said it anticipates increasing the frequency of unannounced site visits to IDTFs. CMS also said it is exploring options to use payment suspensions in conjunction with revocation actions for providers and suppliers that are found to be nonoperational.

Given the conditions disclosed by our review, we maintain that all the specific corrective actions we recommended be implemented. We continue to monitor CMS's progress.

Primary OIG Reports

2011 AUG *Miami Independent Diagnostic Testing Facilities' Compliance With Medicare Standards.* OEI-05-09-00560. [Full Text.](#)

2011 AUG *Los Angeles Independent Diagnostic Testing Facilities' Compliance With Medicare Standards.* OEI-05-09-00561. [Full Text.](#)

See Also

2012 MAR *Questionable Billing for Medicare Independent Diagnostic Testing Facility Services.* OEI-09-09-00380. [Full Text.](#)

2011 AUG OIG's [Spotlight](#) on Independent Diagnostic Testing Facilities, available on our Web site.

2006 JUN *Review of Claims Billed by Independent Diagnostic Testing Facilities for Services Provided to Medicare Beneficiaries During Calendar Year 2001.* A-03-03-00002. [Full Text.](#)

1998 AUG *Independent Physiological Laboratories: Vulnerabilities Confronting Medicare.* OEI-05-97-00240. [Full Text.](#)

Medicare A/B > Reduce Improper Payments > Medical Equipment > Provider Identifiers

Medical Equipment—Ensure That Claims Have Valid and Active Identifiers for Suppliers and the Providers Who Ordered the Items or Services

Recommendations To Be Implemented

We recommend that CMS

- Implement claims processing system changes to ensure that national provider identifiers (NPI) for both referring physicians and suppliers listed on medical equipment and supply claims are valid and active and
- determine the earliest date to end the provision that allows suppliers to submit claims without referring physician NPIs while maintaining beneficiary access to services.

Savings probable but not estimated.

The recommendations would prevent the questionable payments that occur because a temporary CMS instruction allows medical equipment suppliers to substitute their own NPIs for ordering providers' NPIs on claims (i.e., use identical NPIs for both), thus creating a program vulnerability.

CMS allows the practice when suppliers cannot obtain valid, active NPIs from the ordering providers. Thus, claims are being paid without any indicator that the ordering providers are eligible to order medical equipment and supplies for the beneficiaries as required.

A February 2009 OIG report noted and expressed concern about the temporary provision, which became effective May 23, 2008. An OIG followup report in April 2010 revealed that Medicare paid \$87 million from May 23, 2008, through September 2009 for medical equipment claims with identical NPIs for suppliers and ordering providers. CMS plans to implement system edits that will deny payments when the NPI of the ordering provider does not match Medicare's provider enrollment data, but CMS has not announced a date for activating the edits. Meanwhile, questionable payments continue.

Additional Background >

In May 2008, NPIs became the exclusive identifier to be used on medical equipment and other Medicare claims. We remain concerned that longstanding vulnerabilities we found with UPINs (an earlier identifier) may be perpetuated with NPIs, and new challenges, such as the temporary measure described above, may be affecting the integrity of the claims processing system.

Progress of Implementation

Following are links describing CMS's temporary measure, its final rule on related statutory requirements, and its claims processing procedures, accessed on its Web site in June 2012.

- Temporary measure allowing suppliers to substitute their NPI for the ordering providers' NPIs on claims. (CMS's *Program Integrity Manual*, [ch. 14, § 14.5](#), "NPIs for Secondary Providers." Accessed on June 26, 2012 at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c14.pdf>.)
- Final rule. Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements. ([77 Fed. Reg. 25284](#) (April 27, 2012).) Effective June 26, 2012, the interim final rule amending 42 CFR parts 424 and 431 published on May 5, 2010 ([75 FR 24437](#)) is confirmed as final with [changes](#).
- Phase 2 of Ordering and Referring Requirement. (*MLN Matters* article, [SE1221](#) (June 2012).)

Although CMS has taken a number of steps to implement the NPI, it has not operationally implemented the recommendations we specified.

Primary OIG Reports

2010 APR *Medicare Payments for Medical Equipment and Supply Claims With Identical Referring Physician and Supplier National Provider Identifiers*. OEI-04-10-00110. [Full Text](#).

2009 FEB *Medicare Payments in 2007 for Medical Equipment and Supply Claims With Invalid or Inactive Referring Physician Identifiers*. OEI-04-08-00470. February 2009. [Full Text](#).

See Also

2008 JUL OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, Permanent Subcommittee on Investigations. "Unique Physician Identifiers on Medical Equipment and Supply Claims and Related Issues." [Testimony](#).

2002 SEP *Durable Medical Equipment Ordered with Surrogate Physician Identification Numbers*. OEI-03-01-00270. [Full Text](#).

2002 MAY *Accuracy of Unique Physician Practitioner Identification Number Registry Data*. OEI-03-01-00380. [Full Text](#).

2001 NOV *Medical Equipment and Supply Claims with Invalid or Inactive Physician Numbers*. OEI-03-01-00110. [Full Text](#).

1999 OCT *Accuracy of Unique Physician Identification Number Data*. OEI-07-98-00410. [Full Text](#).

Medicare A/B > Reduce Improper Payments > Medical Equipment > Nursing Home Stays

Medical Equipment—Ensure That Part B Claims for Medical Equipment Used During Beneficiaries’ Non-Part-A Nursing Home Stays Are Allowable

Recommendations To Be Implemented

We recommend that CMS

- Designate and maintain information on which nursing facilities and distinct parts of Medicaid nursing homes primarily provide skilled care and thus would not qualify as a beneficiary’s home for medical equipment payment purposes and
- implement a process or processes to identify patients entering nursing homes with rented medical equipment.

Savings probable but not estimated.

The recommendations would prevent the improper Medicare Part B payments that occur when suppliers inappropriately submit a “home” place-of-service code on medical equipment claims but the nursing homes in which the beneficiaries are staying do not qualify as the beneficiaries’ homes for Medicare payment purposes.

Part B pays for medical equipment only if it is used in beneficiaries’ homes or institutions that qualify as their homes. Claims associated with noncompliance with Medicare’s requirements are considered improper and unallowable.

A July 2009 OIG report revealed that Medicare Part B inappropriately allowed \$30 million in 2006 for medical equipment provided during non-Part A stays in Medicare-certified skilled nursing facilities (SNF). Also, nearly all of \$11.9 million that Medicare allowed for medical equipment provided during stays in Medicaid nursing facilities (NF) and distinct parts of NFs was inappropriate. As with the SNF claims, the inappropriately allowed NF claims nearly always (97 percent) erroneously identified the place of service as the beneficiary’s home.

We found that medical equipment suppliers and Medicare’s payment contractors lack reliable listings of which Medicaid nursing facilities (NF) and distinct-part nursing homes primarily provide skilled care; facilities primarily providing skilled care generally do not qualify as beneficiaries’ homes. CMS and States reported that they do not maintain primary level-of-care designations for nursing homes. Such designations would facilitate accurate claim submission by suppliers and proper claim adjudication by payment contractors.

Additional Background >

The BIPA requires OIG to monitor Medicare Part B payments during non-Part A nursing home stays. Medicare Part A covers nursing home care (including use of medical equipment) for up to 100 days in an SNF. If nursing home care is needed after the 100 days (or the beneficiary did not qualify for a Part A SNF stay), Medicare Part B may cover certain medical and other health services. However,

Part B does not pay for medical equipment provided to beneficiaries in nursing homes unless the nursing homes qualify as the beneficiaries' homes. Very few nursing homes qualify as beneficiaries' homes.

Progress of Implementation

CMS has not provided specific information regarding steps it plans to take to identify nursing homes in which medical equipment should not be paid for because the nursing homes provide primarily a skilled level of care. In its 2012 update, CMS cited that criteria already exist for identifying nursing homes that meet the basic SNF definition. CMS also noted that it is State survey agencies' responsibility to assess individual institutions against these criteria. However, our study showed that States and CMS do not maintain this information. For Medicare to recoup payments and for DME suppliers to determine a facility's status, this determination needs to be made. We continue to believe that CMS is the appropriate entity to do so.

Additionally, CMS has not proposed a process to identify patients entering a nursing home with rented medical equipment.

We continue to monitor CMS's progress in implementing the recommendations we specified.

Primary OIG Report

2009 JUL *Part B Services During Non-Part A Nursing Home Stays – Durable Medical Equipment.* OEI-06-07-00100. [Full Text](#).

See Also

1996 MAR *Durable Medical Equipment Payments in Nursing Homes.* OEI-06-92-00862. [Full Text](#).

Medicare A/B > Reduce Improper Payments > Medical Equipment > Capped Rental Repairs

Medical Equipment—Track Accumulated Repair Costs for Capped Rental Medical Equipment

Recommendation To Be Implemented

- We recommend that CMS require its Medicare payment contractors to track accumulated repair costs of capped rental medical equipment.

Savings probable but not estimated.

The recommendation would prevent the questionable payments that occur when medical equipment suppliers bill Medicare for repairs to equipment rented or owned by Medicare beneficiaries but the claims exceed certain limits or the repairs are not covered.

Medicare cannot always detect that the repairs may not qualify for payment because Medicare does not have a mechanism for tracking accumulated repair costs of capped rental durable medical equipment.

An August 2010 OIG report revealed that from 2006 to 2008, Medicare improperly allowed nearly \$4.4 million for noncovered repairs for beneficiary-rented capped rental equipment. In 2007, Medicare allowed nearly \$27 million for repair claims for beneficiary-owned capped rental equipment that failed to meet payment requirements and allowed nearly \$29 million for questionable repair claims.

Tracking accumulated repair costs would enable Medicare's payment contractors to identify and prevent improper payment for repairs that exceed 100 percent of the purchase price for replacement capped rental medical equipment. This same technique could be used to identify claims for accumulated repairs that exceed a designated percentage of the purchase price for replacement capped rental medical equipment. We recommend that the Medicare payment contractors obtain serial numbers of repaired equipment and track accumulated repair costs of capped rental equipment in the same way Medicare tracks repair costs of prosthetics.

Additional Background >

The term "capped rental" refers to equipment for which Medicare contractors pay suppliers a fee schedule amount that is "capped" after a certain number of continuous months of rental to a Medicare beneficiary. Ownership of the equipment is then transferred to the beneficiary. Examples of capped rental equipment include power mobility devices, hospital beds, continuous positive airway pressure devices, commodes, and walkers. Medicare will pay for maintenance and servicing, including repairs, depending on when the capped rental equipment was first rented, who owns the equipment, and what types of repairs need to be made.

The implementation effective January 1, 2006 of the DRA of 2005 altered Medicare coverage of routine maintenance and servicing of capped rental medical equipment. When ownership of a capped rental item is transferred to the beneficiary, Medicare pays for repairs only when the repairs are necessary to make it serviceable. Medicare does not cover routine, periodic maintenance of beneficiary-owned equipment, such as testing, cleaning, and regulating of equipment. Medicare also does not pay for parts and labor covered by a supplier or manufacturer warranty.

Both before and after the implementation of the DRA, Medicare did not cover maintenance and servicing during rental periods because medical equipment suppliers recover the expenses they incur in maintaining the equipment in working order from the rental charge.

Progress of Implementation

CMS responded positively to each of six original recommendations in the August 2010 report and has implemented all recommendations except for requiring its payment contractors to track accumulated repair costs of capped rental medical equipment. CMS agreed to consider the feasibility of requiring its payment contractors to obtain serial numbers of repaired equipment and track accumulated repair costs. However, it has not implemented the actions.

We continue to monitor CMS's implementation of the final recommendation for this report.

Primary OIG Report

2010 AUG *Review of Claims for Capped Rental Durable Medical Equipment*. OEI-07-08-00550.
[Full Text](#).

See Also

2002 JUN *Maintenance Payments for Capped Rental Equipment*. OEI-03-00-00410. [Full Text](#).

Medicare A/B > Reduce Improper Payments > Medical Equipment > Power wheelchairs

Medical Equipment—Ensure That Claims for Power Wheelchairs Meet Medical Necessity Criteria (New)

Recommendations To Be Implemented

We recommend that CMS

- review records from sources in addition to the supplier, such as the prescribing physician, to determine whether power wheelchairs are medically necessary and
- enhance reenrollment screening standards for current suppliers of durable medical equipment, prosthetics, orthotics, and supplies at a risk level of “high” upon reenrollment.

Savings – The HHS *Budget in Brief for Fiscal Year 2012* projected that conducting prepayment or earlier reviews of power wheelchair claims would reduce improper payments and prevent fraud. HHS estimated such reviews would save \$240 million over 10 years. (See Progress section.)

The recommendations would prevent the improper payments that occur when medical equipment suppliers bill Medicare for power wheelchairs that do not meet Medicare’s medical necessity criteria. Claims associated with noncompliance with Medicare’s requirements are considered improper and unallowable.

By reviewing prescribing physicians’ records along with suppliers’ records, Medicare could better determine whether claims meet the criteria for payment. Medicare contractors are not required to review the prescribing physician’s records.

A July 2011 OIG report revealed that on the basis of medical record reviews, 61 percent of claims Medicare allowed for power wheelchairs provided in the first half of 2007 were not medically necessary or the claims were not sufficiently documented to determine medical necessity. Medicare and its beneficiaries paid \$95 million for the claims. A power wheelchair is medically necessary when a beneficiary’s mobility deficit cannot be addressed using other types of mobility-assistive equipment, such as a cane, manual wheelchair, or scooter.

Although CMS has taken steps since 2007 to decrease errors among suppliers of power wheelchairs and other medical equipment and supplies, Medicare has paid significantly more in recent years for power wheelchairs than it did in 2007.

Additional Background >

Two previous OIG reports based on the same sample of power wheelchairs found problems with coding and with documentation requirements. Across all three reports, 80 percent of claims for power wheelchairs did not meet Medicare's coverage criteria.

Given the overall 80-percent error rate for power wheelchair claims, which reinforced the findings of multiple other OIG reports that identified substantial vulnerabilities in the medical equipment and supplies benefit, we also recommended that all current medical equipment suppliers be subject upon reenrollment to screening at the risk level of "high."

In August 2012, CMS announced a 3-year Medicare Prior Authorization for Power Mobility Device (PMD) Demonstration for certain PMD codes in seven States where there have been high incidences of fraudulent claims and improper payments. The demonstration will provide CMS with valuable data through which, working with its partners, CMS can develop new avenues for combating the submission of fraudulent claims to for PMDs. The prior authorization demonstration is expected to have a secondary benefit of helping to identify and reduce improper payments, recognizing that many improper payments are not the result of willful fraud. (77 Fed. Reg. 46439 (August 3, 2012).) The demonstration, which was originally announced in November 2011, was scheduled to begin in September 2012. [Fact Sheet](#).

Progress of Implementation

CMS said it will continue to emphasize the need for proper documentation from the prescribing physician to determine medical necessity.

The HHS *Budget in Brief for Fiscal Year 2012*, p. 63, proposed to require prepayment or earlier review for all power wheelchair claims. HHS estimated savings at \$240 million over 10 years (2012 – 2021), p. 65. However, the proposal was not enacted.

With regard to screening medical equipment suppliers at the risk level of "high" upon reenrollment, CMS said that existing authorities allow it the flexibility to combat fraud, waste, and abuse among existing suppliers effectively and that it has tools in place that allow for better monitoring and regulation of existing suppliers.

We continue to monitor CMS's progress in preventing payments for medically unnecessary power wheelchairs. We also maintain that all current medical equipment suppliers should be subject to the screening standards of the "high" risk level upon reenrollment.

Primary OIG Report

2011 July *Most Power Wheelchairs in the Medicare Program Did Not Meet Medical Necessity Guidelines*. OEI-04-09-00260. [Full Text](#).

See Also

- 2011 OIG's [Spotlight on Power Wheelchairs](#), available on our Web site.
- 2009 DEC *Medicare Power Wheelchair Claims Frequently Did Not Meet Documentation Requirements*. OEI-04-07-00401. [Full Text](#).
- 2009 AUG *Power Wheelchairs in the Medicare Program – Supplier Acquisition Costs and Services*. OEI-04-07-00400. [Full Text](#).
- 2009 JUL *Miscoded Claims for Power Wheelchairs in the Medicare Program*. OEI-04-07-00403. [Full Text](#).

2004 APR *Medicare Payments for Power Wheelchairs*. OEI-03-02-00600. [Full Text](#).

Medicare A/B > Reduce Improper Payments > Medical Equipment > Support Surfaces

Medical Equipment—Ensure That Claims for Pressure-Reducing Support Surfaces Meet Coverage Criteria

Recommendations To Be Implemented

We recommend that CMS

- ensure that claims for group 2 support surfaces meet Medicare coverage criteria and are paid appropriately and
- take action regarding the claims in our sample that were inappropriate.

Savings probable but not estimated.

The recommendations would prevent the improper Medicare payments that occur when medical equipment suppliers bill Medicare for support surfaces that do not meet coverage requirements and inappropriately enter a special service code modifier (KX modifier) that allows the claim to be paid without review.

Suppliers use the KX modifier to indicate that a claim meets Medicare coverage criteria and that adequate documentation exists. Claims associated with noncompliance with Medicare's requirements are considered improper and unallowable.

An August 2009 OIG report revealed that all but one of the claims in our sample included the KX modifier, even though we found that 80 percent of the claims did not meet clinical coverage criteria. Support surfaces are used in treating pressure ulcers (bedsores). Our report showed that 86 percent of group 2, which covers 80 percent of all support surface payments, did not meet Medicare coverage criteria for the first half of 2007. This resulted in an estimated \$33 million in inappropriate payments.

Additional Background >

Pressure ulcers occur commonly among the elderly and individuals with spinal cord injuries. Support surfaces are covered under Medicare Part B as durable medical equipment. If a physician determines that a support surface is medically necessary, the physician writes a prescription indicating the type of support surface the beneficiary needs. Once a support surface is selected, prescribed, and ordered, a medical equipment supplier delivers the item to the beneficiary and bills Medicare monthly for the rental.

For the August 2009 report, we considered a claim as not meeting Medicare coverage criteria if it either did not meet Medicare's clinical coverage requirements or did not meet Medicare's supplier documentation requirements.

An April 2012 OIG report summarized four audits of claims with KX modifiers for therapeutic shoes for diabetics, continuous positive airway pressure systems, respiratory assist devices, and pressure reducing support surfaces. We made unannounced visits to review suppliers' files for a sample of claims with the KX modifier and CY 2007 dates of service. We estimated that Medicare paid about \$316.4 million to suppliers that, despite having entered the KX modifier on the claims, did not have the required documentation on file to support the claims.

Progress of Implementation

CMS initially said that it is reviewing the utility and use of the KX modifier as a safeguard, including its application in durable medical equipment claims.

- CMS's 2011 update said that it had tasked a contractor with conducting additional medical review on claims for pressure-reducing support services. As part of the study, the contractor reviewed the KX modifier. Since this update, the contractor completed its review of claims.
- In its 2012 update, CMS said it shared the results with the pertinent Medicare payment contractors. CMS also said that once it reviews the inappropriate claims and better understands their nature, it will forward them to the payment contractors for action.

CMS did not provide documentation to support the actions it described. We encourage CMS to provide OIG with evidence of its corrective actions. Until then, the recommendations remain open.

Primary OIG Report

2009 AUG *Inappropriate Medicare Payments for Pressure Reducing Support Surfaces.*
OEI-02-07-00420. August 2009. [Full Text](#).

See Also

2012 APR *Claim Modifier Did Not Prevent Medicare From Paying Millions in Unallowable Claims for Selected Durable Medical Equipment.* A-04-10-04004. April 2012.
[Web Summary](#). [Full Text](#).

Medicare A/B > Reduce Improper Payments > Medical Equipment > Lower Limb Prostheses

Medical Equipment—Ensure That Claims for Lower Limb Prostheses Meet Requirements (New)

Recommendations To Be Implemented

We recommend that CMS ensure that claims for lower limb prostheses meet requirements by taking the following actions:

- implement additional claims processing edits to prevent inappropriate payments,
- strengthen monitoring of billing for lower limb prostheses using the measures discussed in our report,
- implement requirements for face-to-face encounters [between physicians and beneficiaries] to establish beneficiaries' need for prostheses,
- revise requirements in local coverage determinations to ensure that prostheses are matched to beneficiaries' needs and that CMS contractors can assess the medical necessity of these devices,
- enhance screening for currently enrolled suppliers of lower limb prostheses and place these suppliers into the risk level of "high," and
- take appropriate action on suppliers with questionable billing.

Savings - \$43 million. The estimate is based on our review of 2009 claims.

The recommendations would prevent the improper payments that occur when medical equipment suppliers bill Medicare for lower limb prostheses that do not meet requirements specified in the local coverage determination and Medicare cannot readily identify the deficiencies.

Claims associated with noncompliance with Medicare's requirements are considered improper and unallowable. Lower limb prostheses are designed to replace, as much as possible, the function of a missing limb.

An August 2011 OIG report revealed that \$43 million (about 6.6 percent) in payments for a sample of lower limb prostheses did not meet Medicare requirements and could have been prevented by using claims processing edits. The \$43 million was based solely on an analysis of claims data and did not include payments that a medical record review may have found to be unreasonable or unnecessary. By implementing additional coverage-based edits and taking the other steps we recommended, Medicare could better determine whether claims meet criteria for payment. Between 2005 and 2009, Medicare spending for lower limb prostheses increased 27 percent (from \$517 million to \$655 million) while the number of Medicare beneficiaries receiving lower limb prostheses decreased by 2.5 percent.

We also found that Medicare paid \$61 million for beneficiaries for whom no claims were filed by the referring physicians, raising questions about whether the physicians ever evaluated the beneficiaries and whether these devices were medically necessary. Suppliers frequently billed for unusual combinations of prostheses or for beneficiaries who had no history of amputation or missing limb.

Progress of Implementation

CMS said it would instruct the pertinent Medicare payment contractors to implement consistent claims processing edits based on local coverage determination requirements and consider the measures used in the OIG review as supplemental criteria for detecting high-risk suppliers. CMS said it would also encourage the contractors to consider developing thresholds for these measures while prioritizing their workloads. CMS's comments on the specific recommendations included the following:

CMS agreed that face-to-face encounters between the physician and beneficiary are important. The Affordable Care Act, [§ 6407](#), authorizes a face-to-face documentation requirement for designated medical supplies and for other items and services for which payment is provided under title XVIII of the Social Security Act on the basis of a finding that such an decision would reduce the risk of waste, fraud, or abuse.

CMS said it has sufficient tools for increased scrutiny of existing suppliers.

In March 2012, CMS issued an *MLN Matters* Special Edition Article outlining our concerns and CMS's responses. The article was intended for providers that bill Medicare for lower limb prostheses. While the MLN article may have increased awareness about vulnerabilities highlighted in our report, the article did not address any related OIG recommendations. ("Questionable Billing by Suppliers of Lower Limb Prostheses." *MLN Matters*. [SE 1213 Revised](#). Issued March 26, 2012, Revised June 7, 2012.)

We encourage CMS to follow through on its implementation plans and include in its efforts all the recommendations we specified. We continue to monitor CMS's progress.

Primary OIG Report

2011 AUG *Questionable Billing by Suppliers of Lower Limb Prostheses*. OEI-02-10-00170. [Full Text](#).

See Also

2011 DEC *Program Integrity Problems With Newly Enrolled Medicare Equipment Suppliers*. OEI-06-09-00230. [Full Text](#).

Medicare A/B > Reduce Improper Payments > Medical Equipment > Appeals of Revocations

Medical Equipment—Develop Evidence Criteria for Appeals To Reinstate Medical Equipment Suppliers’ Billing Privileges

Recommendation To Be Implemented

- We recommend that CMS strengthen the appeal process by developing criteria on the types of evidence required for hearing officers to reinstate medical equipment suppliers’ billing privileges.

Savings probable but not estimated.

The recommendation would prevent the improper payments that could occur when medical equipment suppliers with revoked or inactivated billing privileges are reinstated to Medicare by hearing officers who have not been provided guidance from Medicare on the types of evidence to be considered.

An October 2008 OIG report revealed that two-thirds of the suppliers we reviewed whose billing privileges were reinstated by hearing officers had their privileges revoked or inactivated again and that some individuals connected to the reinstated suppliers had been indicted.

We found that hearing officers reinstated billing privileges for 91 percent of the medical equipment suppliers we reviewed who appealed revocation of their billing privileges. Hearing officers reinstated the suppliers’ billing privileges on the basis of a variety of evidence submitted by the suppliers.

Additional Background >

All suppliers whose billing privileges have been denied or revoked may appeal and request a hearing. This is an important process to ensure that only billing privileges for suppliers that fail to meet the supplier standards remain denied or revoked. For suppliers that request a hearing, hearing officers generally accept all documentation submitted as legitimate, unless they have reason to believe otherwise.

Progress of Implementation

CMS agreed that it should consider establishing guidelines for the evaluation of evidence that a hearing officer would review. However, CMS said that guidance should not impinge on a hearing officer’s ability to make an independent determination or with a supplier’s ability to submit any evidence that it believes would support the reversal of a revocation or denial decision. In late 2010, CMS indicated that it would establish guidelines for evaluating evidence and participate in a workgroup to develop evidentiary criteria for inclusion in regulatory guidance for hearing officers.

We agree that CMS should develop criteria that maintain the independence of hearing officers and suppliers’ ability to submit evidence. We suggest that CMS develop a list of evidence that it believes

would support the need for overturning various types of revocation and that such evidence be germane to the reason for revocation.

Primary OIG Report

2008 OCT *South Florida Durable Medical Equipment Suppliers – Results of Appeals.*
OEI-03-07-00540. [Full Text.](#)

❖ Ensure Patient Safety and Quality of Care

Medicare faces challenges in ensuring the safety and quality of care rendered to its beneficiaries. Despite increased attention to patient safety, quality problems persist.

Tools to ensure patient safety and quality include ensuring that providers meet all Medicare conditions for coverage and participation; ensuring that health care professionals meet qualification and licensure requirements; strengthening policies for provider accountability for quality of care; imposing appropriate sanctions, including denying payments for services of such low quality that they are virtually worthless; excluding providers that fail to meet basic quality standards; and adopting electronic health records and electronic prescribing, which should improve quality of care, reduce medication errors, and otherwise promote patient safety.

CMS develops Conditions of Participation (CoP) and Conditions for Coverage (CfC) that health care organizations must meet in participate in and receive payment from the Medicare and Medicaid programs. These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries. CMS also ensures that the standards of accrediting organizations recognized by CMS (through a process called "deeming") meet or exceed the Medicare standards set forth in the CoPs / CfCs. Medicare contracts with State health agencies, otherwise referred to as State survey agencies, to perform survey and review functions on behalf of Medicare and certify that providers comply with Federal requirements. The types of health care organizations subject to CoP and CfC are listed on CMS's [Web site](http://www.cms.gov) at <http://www.cms.gov>.

Acronyms and Abbreviations for Selected Terms Used in This Section

ASC	ambulatory surgical center	HHA	home health agency
CfC	conditions for coverage	MIPPA	Medicare Improvements for Patients and Providers Act of 2008
CoP	conditions of participation	OBRA	Omnibus Budget Reconciliation Act
CPM	Clinical Performance Measure	QAPI	quality assessment and performance improvement (program)
ESRD	end stage renal disease		
FISMA	Federal Information Security Management Act of 2002		

Medicare A/B > Safety and Quality of Care > Hospitals > Noncompliance With CoPs

Hospital Survey and Certification—Provide Guidance to State Survey Agencies on Assessing Hospital Tracking of Adverse Events

Recommendation To Be Implemented

- We recommend that CMS provide interpretative guidelines for State survey agencies to assess hospitals' compliance with Federal requirements to track and monitor adverse events.

The recommendation would prevent the vulnerabilities that arise when State survey agencies that certify hospitals' compliance with Medicare conditions of participation (CoP) and other requirements lack guidance from CMS about how to assess hospitals' systems for tracking and monitoring adverse events (events that cause harm to a patient as a result of medical care or otherwise occurs in a health care setting).

The absence of interpretive guidance undermines Medicare's oversight of provider accountability for safety and quality.

A March 2010 OIG report revealed deficiencies in two critical information sources that could impact Medicare payment requirements and CoP—inaccurate patient diagnosis codes and missing hospital incident reports. Hospitals did not generate incident reports for 93 percent of the identified events, including some of the most serious events involving disability or death.

Additional Background >

Federal regulations require that hospitals, as a Medicare CoP, develop and maintain quality assessment and performance improvement (QAPI) programs. As a part of the QAPI program, hospitals must measure, analyze, and track quality indicators, including adverse events. To accomplish this, hospitals must track medical errors and adverse events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

State health agencies, otherwise referred to as State survey agencies, perform survey and review functions on behalf of Medicare and certify that hospitals comply with Federal requirements. However, CMS's *State Operations Manual*, through which CMS provides guidance to State survey agencies that assess hospital compliance with Federal regulations, contains no interpretive guidelines regarding hospitals' tracking of medical errors and adverse events. Therefore, when State agencies perform standard compliance surveys and surveys based on complaints, it is unclear how surveyors are to assess hospital operations for tracking the errors and events that result in harm to patients.

Progress of Implementation

In its initial response to our March 2010 report, CMS indicated that it will ensure that the *State Operations Manual* includes full guidance for surveyors to assess hospital QAPI systems and strengthen CMS surveyor-training programs to enhance surveyors' abilities to evaluate compliance with the QAPI requirements. CMS has drafted guidance to State survey agencies regarding tracking and monitoring adverse events; however, the new guidance has not been published in final.

We continue to monitor CMS's progress on publishing guidance in the *State Operations Manual*.

As a separate matter related to our review, to promote proper coding, we encourage CMS to continue to publish coding advice regarding hospital-acquired conditions and reporting of present-on-admission indicators in the *Coding Clinic for ICD-9-CM*. This publication is used by all hospitals and reviewers, as it is recognized as the official CMS-approved source of coding instructions.

Primary OIG Report

2010 MAR *Adverse Events in Hospitals – Methods for Identifying Events*. OEI-06-08-00221. [Full Text](#).

See Also

2011 OCT *Adverse Events in Hospitals: Medicare's Responses to Alleged Serious Events*. OEI-01-08-00590. [Full Text](#).

2010 NOV *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*. OEI-06-09-00090. [Full Text](#).

2010 JAN *Adverse Events in Hospitals: Public Disclosure of Information About Events*, OEI-06-09-00360. [Full Text](#).

2008 DEC *Adverse Events in Hospitals: Overview of Key Issues*. OEI-06-07-00470. [Full Text](#).

2008 DEC *Adverse Events in Hospitals: State Reporting Systems*. OEI-06-07-00471. [Full Text](#).

2008 DEC *Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries in Two Counties*. OEI-06-08-00220. [Full Text](#).

Medicare A/B > Safety and Quality of Care > Ambulatory Surgical Centers > Standards

Ambulatory Surgical Center Recertifications—Implement a Minimum Survey and Certification Cycle

Recommendations To Be Implemented

We recommend that CMS

- determine an appropriate minimum cycle for surveying ambulatory surgical centers (ASC) certified by State survey agencies and
- hold State agencies and accreditors fully accountable to the Medicare program and the public for their performance in overseeing ASCs.

The recommendations would prevent the vulnerabilities that arise when ASCs are infrequently reviewed for their compliance with Medicare's conditions for coverage (CfC) and when Medicare does little to hold accreditors and State survey agencies accountable to the program and the public for their oversight of ASCs.

In February 2002, OIG issued three reports on ASC quality oversight. Our work revealed that one-third of ASCs certified by State agencies had not been recertified in 5 or more years when the review was performed in 2000. CMS had done little to hold accreditors and State survey agencies accountable to the Medicare program and the public.

At the time of our review, ASCs were one of the fastest growing settings for ambulatory surgery in Medicare. Quality oversight of ASCs revolves around the ASC CfC, which are Medicare's set of minimum health and safety requirements. CMS requires that an ASC become Medicare certified by a State survey and certification agency or be privately accredited to show that it meets the CfC. Although ASCs are free to choose which route they take, over 90 percent elect to become certified by State agencies rather than through private accreditation.

Progress of Implementation

After our 2002 report, CMS initiated administrative and regulatory steps to improve oversight of ASCs but has not sufficiently documented its actions with regard to frequency of survey and certification and the accountability of State surveyors and accrediting agencies.

- In May 2004, CMS updated its *State Operations Manual*, § 2008F, to say that "resurveys are generally conducted annually, but depending on national initiatives and budget constraints, the cycle may vary."
- On November 18, 2008, CMS issued a final rule implementing revised ASC conditions for coverage but did not prescribe frequency of survey and certification. ([73 Fed. Reg. 68502](#).)
- In 2009, the American Recovery and Reinvestment Act (Recovery Act) allotted funds to allow States to survey one-third of all nonaccredited ASCs in fiscal year (FY) 2010.

- In its 2012 update of our 2002 recommendations, CMS stated that it now requires States to survey nonaccredited ASCs every 4 years and expects to maintain that level of frequency.

We are reviewing CMS documentation to determine whether the 4-year survey requirement is in effect. We continue to monitor CMS's implementation of the recommendations we specified, including holding State survey agencies and accreditors accountable to Medicare and the public.

Primary OIG Reports

- 2002 Feb *Quality Oversight of Ambulatory Surgical Centers – A System in Neglect.*
OEI-01-00-00450. [Full Text.](#)
- 2002 Feb *The Role of Certification and Accreditation, Supplemental Report 1.*
OEI-01-00-00451. [Full Text.](#)
- 2002 Feb *The Role of Certification and Accreditation, Supplemental Report 2.*
OEI-01-00-00452. [Full Text](#)

Medicare A/B > Safety and Quality of Care > Hospices > Standards

Hospice Recertifications—Establish Specific Requirements for the Frequency of Certification Surveys

OIG Recommendation

- We recommend that CMS seek regulatory or statutory changes to establish specific requirements for the frequency of hospice recertification.

The recommendation would prevent the vulnerabilities that arise when hospices are infrequently surveyed and recertified for compliance with Medicare's Conditions of Participation (CoP) or other program standards. ([73 Fed. Reg. 32088](#), June 5, 2008.)

Medicare payments for hospice care increased from \$3.6 billion in 2001 to \$12.08 billion in 2009. Despite the rapid growth of the hospice industry and the vulnerability of the seriously ill patients it serves, surveys of hospices' compliance with Medicare CoP generally occur only once every 6.5 years.

An April 2007 OIG report noted that the frequency of hospice surveys is budget driven and is less frequent than the surveys conducted for other providers of services to seriously ill patients. Because of budgetary constraints, CMS changed its hospice survey frequency from 6 years in 2005 to every 8 years in 2006. Subsequently CMS reset the frequency to every 6.5 years. We found that hospices past due for recertification (14 percent) in 2005 had not been surveyed for 9 years, on average. In contrast, the industry standard, as practiced by accrediting organizations, is to survey hospices every 3 years. Medicare nursing facilities and home health agencies, which also care for seriously ill patients, are certified at least every 15 months and every 3 years, respectively.

Staff from two professional associations knowledgeable about hospice issues told us they support more frequent hospice certifications. CMS policy has consistently assigned a higher priority to

certification surveys of hospitals, nursing homes, and home health agencies than it has to certification surveys of hospices. However, the issues at hospices are no less critical than those at nursing homes. CMS could change the frequency of surveys by regulation, but stability of funding for the surveys may require legislation.

Additional Background >

As defined by CMS, hospice care focuses on relief of pain and uncomfortable symptoms for terminally ill patients, rather than curative care or life-prolonging treatment. Medicare hospice services include nursing care, counseling, and home health aide services, as well as drugs and medical supplies. Hospice care is provided either by freestanding hospices or by hospices owned or operated by home health agencies, hospitals, and skilled nursing facilities.

CoP are minimum standards for hospices with which hospices must comply to participate in Medicare. State survey agencies conduct surveys of hospices to assess their compliance with the CoP. The results of State survey agencies' certification surveys, complaint investigations, and recommendations for termination are CMS's primary sources of information about hospice performance. Neither statute nor regulation specifies survey frequency for hospices.

Progress of Implementation

CMS said that it believed frequency of hospice certification should not be addressed in regulation and that it was primarily a statutory issue for consideration by Congress. CMS said it believed that the only effective statutory change would be one that automatically correlated the expected frequency and number of surveys with the resources to accomplish the mission.

We continue to recommend that CMS seek statutory changes for the frequency of hospice certification.

Primary OIG Report

2007 APR *Medicare Hospices – Certification and Centers for Medicare & Medicaid Services Oversight.* OEI-06-05-00260. [Full Text.](#)

See Also

- 2011 JUL *Medicare Hospices That Focus on Nursing Facility Residents.* OEI-02-10-00070. [Full Text.](#)
- 2009 SEP *Medicare Hospice Care for Beneficiaries in Nursing Facilities Compliance with Medicare Coverage Requirements.* OEI-02-06-00221. [Full Text.](#)
- 2009 SEP *Medicare Hospice Care: Services Provided to Beneficiaries Residing in Nursing Facilities.* OEI-02-06-00223. [Full Text.](#)
- 2008 MAR *Hospice Beneficiaries' Use of Respite Care.* OEI-02-06-00222. March 2008. [Full Text.](#)
- 2007 DEC *Medicare Hospice Care: A Comparison of Beneficiaries in Nursing Facilities and Beneficiaries in Other Settings.* OEI-02-06-00220. [Full Text.](#)
- 1998 APR *Medicare Hospice Beneficiaries: Services and Eligibility.* OEI-04-93-00270. [Full Text.](#)
- 1997 NOV *Hospice and Nursing Home Contractual Relationships.* OEI-05-95-00251. [Full Text.](#)
- 1997 SEP *Hospice Patients in Nursing Homes.* OEI-05-95-00250. [Full Text.](#)

Medicare A/B > Safety and Quality of Care > Home Health > Standards

Home Health Agency Recertifications—Implement Intermediate Sanctions for Noncompliance With Conditions and Standards

Recommendation To Be Implemented

- We recommend that CMS implement intermediate sanctions against noncompliant home health agencies (HHA) as directed by the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987).

The recommendation would allow less severe sanctions that would offer CMs a more appropriate response to certain instances of noncompliance, such as certain deficiencies detected by a State survey agency.

Currently, termination from the Medicare program is CMS's only available Federal sanction to address an HHA's failure to comply with Medicare conditions and standards. An extreme remedy, termination is used only rarely. In 2006, termination was applied only 21 times.

OBRA of 1987 authorized intermediate sanctions. CMS issued a proposed rule for intermediate sanctions on August 2, 1991, but never finalized the regulation. Intermediate sanctions may include civil money penalties, suspension of all or part of Medicare payments, and appointment of temporary management for cyclically deficient HHAs. Expanding CMS's oversight options to allow intermediate sanctions would allow CMS to respond to detected deficiencies and promote compliance in a manner that allows continued delivery of services to beneficiaries and minimizes disruption of care.

A July 2008 OIG report revealed that of the cyclically deficient HHAs we identified, 42 percent repeated at least two of the same citations on each of their three most recent surveys and 5 percent repeated the same five or more citations. Our July 2008 report also revealed that as of January 2007, 15 percent of HHAs in our sample had repeated at least one deficiency citation on each of their three most recent surveys. Many cyclically deficient HHAs repeated more than one deficiency citation across multiple surveys. Most cyclically deficient HHAs repeated standard-level citations.

The repeatedly noncompliant HHAs received, on average, twice as many deficiency citations per survey compared with HHAs without repeated citations. Furthermore, HHAs with repeated deficiencies performed worse on subsequent surveys. In such cases, intermediate sanctions are an appropriate oversight option.

Additional Background >

All HHAs participating in Medicare must comply with 15 Medicare Conditions of Participation (CoP), 12 of which are subdivided into standards that address specific aspects of the condition. CMS is responsible for ensuring that the CoP and their enforcement are adequate to protect the health

and safety of individuals receiving home health services. To fulfill this duty, CMS contracts with State survey agencies to conduct initial HHA certification and recertification reviews.

Progress of Implementation

CMS concurred with the recommendation to implement intermediate sanctions as directed by OBRA 1987 and said that it had initiated the rulemaking process numerous times but that other demands had impeded promulgation of a final rule.

- In December 2009, CMS said that it had drafted an alternative sanction proposal that was under review.
- In 2010 CMS developed a new proposed rule that would require unannounced and extended surveys of HHAs and the imposition of intermediate sanctions when HHAs are found to be out of compliance with the Medicare standards.
- On July 13, 2012, CMS published its proposed rule for intermediate sanctions. The proposal would create new subpart I, which would provide survey and certification guidance, while new subpart J would outline the basis for enforcement of compliance standards for HHAs that are not in substantial compliance with Medicare participation requirements. The rule includes a number of related provisions, including setting forth rules for certification, documentation of findings, periodic review of compliance and approval, certification of noncompliance, determining compliance, frequency of surveys, surveyor qualifications, general rules for enforcement actions, factors to be considered in selecting sanctions, and available sanctions. (77 Fed. Reg. 41548, 41575.) On November 8, 2012, CMS published a final rule implementing intermediate sanctions for HHAs. However, the effective date for implementing the intermediate sanctions is July 1, 2014, to provide time to develop associated interpretive guidance. (77 Fed. Reg. 67068, 67137.)

We encourage CMS to issue interpretive guidance on intermediate sanctions. We continue to monitor the extent to which the corrective actions implement our recommendation.

Primary OIG Report

2008 JUL *Deficiency History and Recertification of Medicare Home Health Agencies.* OEI-09-06-00040. [Full Text.](#)

See Also

2012 MAR *Intermediate Sanctions for Noncompliant Home Health Agencies.* OEI-06-11-00401. [Full Text.](#)

Medicare A/B > Safety and Quality of Care > Nonphysicians

Physicians—Revise the "Incident-to" Rule and Implement a Service Code Modifier To Improve Oversight

Recommendations To Be Implemented

We recommend that CMS

- seek legislative revisions to Medicare's "incident to" rule; and
- require physicians who bill services to Medicare that they do not personally perform to identify such services on their Medicare claims using a service code modifier.

The recommendations would reduce the vulnerabilities that arise when physicians bill Medicare for services but, on the basis of the claim alone, Medicare cannot detect whether some or all of the services were performed by nonphysicians.

"Incident to" services are required to meet Medicare's general criteria for medical necessity, documentation, and quality of care. However, such services may be vulnerable to overutilization or to delivery by persons unqualified to perform the services and may put beneficiaries at risk of receiving services that do not meet professionally recognized standards of care.

Medicare's "incident to" rule allows physicians to bill for services performed by any personnel, licensed or unlicensed, that are performed incident to the physicians' services.

A September 2009 OIG report revealed that when Medicare allowed physicians more than 24 hours of services in a day, half of the services were not performed personally by the billing physicians. We found that nonphysicians performed almost two-thirds of the invasive services (which involve entry into the living body, as by incision or by insertion of an instrument). Our review disclosed that for 21 percent of all services performed by nonphysicians as "incident to," the nonphysicians did not possess the necessary licenses or certifications, had no verifiable credentials, or lacked the training to perform the services.

Additional Background >

This problem may be more widespread than we were able to report. Our sample included only those physicians who billed for more than 24 hours of services in a day. The sample was a proxy for physicians who billed "incident to." However, we have no reason to believe that the issues identified in this review are unique to the sampled physicians. Physicians who bill Medicare for fewer than 24 hours of services in a day also bill for "incident to" services, some of which may be performed by unqualified nonphysicians.

Progress of Implementation

CMS initially said it would provide improved guidance for documenting the qualifications of the person performing the services that were billed to Medicare by physicians and nonphysician

practitioners who may bill services “incident to” physicians’ services. On October 9, 2009, CMS issued limited guidance (CR Transmittal 574) to its payment contractors stating that the contractors should use the information in our September 2009 report and should follow the processes and procedures already in CMS’s *Program Integrity Manual* concerning data analysis, contractor strategies, and the progressive corrective action process.

CMS did not concur with our recommendation to create a service code modifier to identify physicians’ claims for services that physicians do not personally perform and has not provided updates on further guidance or revisions.

We continue to monitor CMS’s implementation of the recommendations we specified.

Primary OIG Report

2009 SEP *Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services*. OEI-09-06-00430. [Full Text](#).

❖ Oversight of Medicare Contractors

As the program manager for Medicare, CMS carries out claims processing and program integrity functions with the assistance of various types of contractors. For Part A and Part B claims processing, CMS has used contractors called “intermediaries” and “carriers,” which are being replaced by Medicare Administrative Contractors (MAC). Benefit integrity functions originally conducted by carriers and intermediaries were replaced several years ago by program safeguard contractors (PSC). PSC functions are now being transitioned to Zone Program Integrity Contractors (ZPIC). Also, Recovery Audit Contractors (RAC) conduct postpayment reviews to identify underpayments and overpayments. RACs may also identify potential fraud and refer such claims to CMS for assessment and possible referral to OIG.

Acronyms and Abbreviations for Selected Terms Used in This Section

CMS ARTS	Analysis , Reporting, and	PSC	program safeguard contractor
Tracking	System	RAC	Recovery Audit Contractor
HIPAA	Health Insurance Portability and	ZPIC	Zone Program Integrity Contractor
	Accountability Act of 1996		

Medicare Part A/B > Oversight of Medicare Contractors > Benefit Integrity Contractors Performance

Benefit Integrity Contractor Performance—Improve the Performance Evaluation Process to Include Quantitative Data

Recommendation To Be Implemented

- We recommend that CMS address benefit integrity contractors' results in their performance evaluation reports, to include quantitative as well as qualitative information.

The recommendation, which was made on the basis of a review of program safeguard contractors (PSC) (a type of benefit integrity contractor), would provide a more comprehensive picture of PSCs' performance and provide valuable data for making contract renewal decisions.

If, for example, certain contractor activities are saving money for the Medicare program, the activity and the amount of money saved should be included in the performance evaluation reports.

A March 2006 OIG report revealed that performance evaluation reports issued by CMS from 1999 to 2004 to PSCs contained only minimal information about the contractors' achievements in detecting and deterring fraud and abuse under benefit integrity task orders. Because these reports were limited in their description of the results that the contractors may have been achieving, they provided limited information on which to base task order renewal decisions. Only 5 of 32 final reports were issued 3 months before the task orders ended, which is the time by which CMS was required to notify the contractors of whether the contracts would be renewed.

Additional Background >

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), § 202, authorized CMS to contract out program integrity functions for Medicare and required a competitive process for awarding contracts. The first entities awarded such contracts were called PSCs. Once under contract, PSCs were awarded task orders to carry out specific duties. Prior to HIPAA, Medicare anti-fraud and abuse activities were conducted by fraud units housed in the Medicare claims processing contractors (fiscal intermediaries and carriers).

Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS is replacing PSCs with Zone Program Integrity Contractors (ZPIC). A November 2011 OIG report revealed that Medicare's performance evaluations of ZPICs contained few workload statistics.

Progress of Implementation

In its initial response to the results of our March 2006 review, CMS noted that in 2007 it assigned quantitative measures, as appropriate, to each rating in its performance evaluations. These measures allowed for more objective and consistent scoring across all evaluations. In its February 2011 update, CMS stated it continues to collect and track quantitative data from PSCs in its CMS Analysis, Reporting, and Tracking System (CMS ARTS) database. However, the data collected are not

being included in performance evaluations because CMS believes that quantifying output can create negative incentives and undermine the value of the contractors' work.

OIG believes quantitative data can be included in ways that do not create negative incentives. We continue to monitor CMS's progress.

Primary OIG Report

2006 MAR *Medicare's Program Safeguard Contractors – Performance Evaluation Reports.* OEI-03-04-00050. March 2006. [Full Text](#).

See Also

2012 JUN OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: Medicare Contractors' Efforts To Fight Fraud—Moving Beyond "Pay and Chase." [Full Text](#).

2011 DEC *Addressing Vulnerabilities Reported by Medicare Benefit Integrity Contractors.* OEI-03-10-00500. [Full Text](#).

2011 NOV *Zone Program Integrity Contractors' Data Issues Hinder Effective Oversight.* OEI-03-09-00520. [Full Text](#).

2010 MAY *Medicare Overpayments Identified by Program Safeguard Contractors.* OEI-03-08-00031. [Full Text](#).

2010 MAY *Collection Status of Medicare Overpayments Identified by Program Safeguard Contractors.* OEI-03-08-00030. [Full Text](#).

2010 MAY *Collection Rate for Overpayments Made to Medicare Suppliers in South Florida.* OEI-03-09-00570. [Full Text](#).

2009 OCT *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse.* OEI-03-08-00420. [Full Text](#).

2007 JUL *Medicare's Program Safeguard Contractors: Activities to Detect and Deter Fraud and Abuse.* OEI-03-06-00010. [Full Text](#).

1998 NOV *Fiscal Intermediary Fraud Units.* OEI-03-97-00350. [Full Text](#).

1996 NOV *Carrier Fraud Units.* OEI-05-94-00470. [Full Text](#).

Medicare Part A/B > Oversight of Medicare Contractors > Variation in Overpayment Referral Rates

Overpayment Referrals—Determine Why Medicare Overpayment Referral Rates Vary Among Contractors

Recommendations To Be Implemented

We recommend that CMS

- determine why some PSCs refer low levels of overpayment dollars for collection compared with their oversight responsibility and
- determine why some PSCs refer low Part A overpayment dollars for collection compared to the Part B overpayment dollars they refer for collection.

The recommendations would help Medicare better evaluate benefit integrity contractor efforts compared with the dollars and benefit categories at risk. CMS's contractor performance evaluations provide very few quantitative details about contractors' achievements in detecting and deterring fraud and abuse.

A May 2010 OIG report revealed that of 18 PSCs we reviewed in 2007, only 2 were responsible for 62 percent of the \$835 million referred. The amounts of the 18 PSCs' overpayment referrals differed substantially—from \$3 million to \$266 million with a median of \$15 million.

The May 2010 report also revealed that although Part B payments represented 29 percent of PSCs' oversight responsibility, Part B overpayments accounted for 89 percent of the overpayment dollars referred for collection. Conversely, although Part A payments represented 71 percent of PSCs' oversight responsibility, Part A overpayments accounted for only 11 percent of overpayment dollars referred for collection.

Additional Background >

We have also found significant variation in fraud detection activities among the new ZPICs that are replacing PSCs. We noted that while one would expect that contractors would differ somewhat from one another in activity levels, the variation in results cannot always be explained by the size of the contractors' budget or oversight responsibility.

Progress of Implementation

CMS said that the change to its new ZPIC benefit integrity strategy should address OIG's concerns. CMS is transitioning benefit integrity functions from PSCs to ZPICs. Each ZPIC is responsible for all claim types in its geographic zone. As of September 2011, CMS had awarded all ZPIC contracts.

OIG will monitor CMS's implementation of our recommendations, including whether its contracting strategy will address our recommendations.

Primary OIG Report

2010 MAY OIG Report—*Medicare Overpayments Identified by Program Safeguard Contractors*. OEI-03-08-00031. [Full Text](#).

See Also

2012 JUN OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: Medicare Contractors' Efforts To Fight Fraud—Moving Beyond "Pay and Chase." [Full Text](#).

Medicare Part A/B > Oversight of Medicare Contractors > Status of Overpayment Collections

Overpayment Referrals—Implement Controls To Track the Status of Overpayments Referred for Collection

Recommendations To Be Implemented

We recommend that CMS

- require benefit integrity contractors and claims processors to have controls in their tracking systems to ensure that all overpayment referrals and data related to their collection status can be found and
- determine what happened to the 1,060 overpayments that PSCs referred to claims processors in 2007 for which claims processors could not provide any collection information.

The recommendations would reduce the risk that the Medicare program might not recover the overpaid funds that benefit integrity contractors identify and refer to Medicare's claims processing contractors.

CMS, as the program manager of Medicare, is responsible for ensuring that PSCs, ZPICs, and claims processors perform their overpayment identification and referral functions effectively. To accomplish this, CMS must have complete and accurate information about overpayment referrals and the collection status of the referrals.

A May 2010 OIG report revealed that PSCs were not required to keep track of the amount that claims processors collected on their overpayment referrals. We found that overpayments referred for collection by PSCs in 2007 did not result in significant recoveries to Medicare. Only 7 percent of the referred amounts had been collected by claims processors as of June 2008. Fifty-three percent of the referred amount was sent to the Department of the Treasury's cross-servicing program for collection. However, the Treasury program does not have a high rate of return. Claims processors reported that collection was not complete for 5 percent of the overpayments, and another 5 percent will not likely be collected by claims processors because the providers stopped billing, filed for

bankruptcy, went out of business, or were deceased. For 17 percent of the referred amount, collection was on hold pending investigation or appeal.

As of June 2008, 6 percent of the PSC overpayment amount was no longer owed by providers because of revisions that claims processors made to the amounts and appeal decisions that were favorable to providers. Finally, claims processors could not provide data for one in four PSC overpayment referrals, which accounted for 8 percent of the PSC overpayment dollars. Claims processors reported that they did not receive or could not provide any collection information for 1,060 of 4,239 overpayments.

Progress of Implementation

According to CMS's 2012 status update, it now has a reporting system that enables it to identify the overpayments that PSCs and ZPICs refer to claims processors for collection and that the system also enables CMS to identify the status of the overpayments. CMS recently added the number of overpayments recovered to CMS ARTS.

We continue to monitor CMS's implementation of our recommendations, including any controls in place to ensure that all overpayment referrals and data related to their collection status can be found. In addition, we continue to monitor the status of the 1,060 overpayments identified by the May 2010 OIG report.

Primary OIG Report

2010 MAY *Collection Status of Medicare Overpayments Identified by Program Safeguard Contractors*. OEI-03-08-00030. [Full Text](#).

See Also

2012 JUN OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: Medicare Contractors' Efforts To Fight Fraud—Moving Beyond "Pay and Chase." [Full Text](#).

2102 MAY *Obstacles to Collection of Millions in Medicare Overpayments*. A-04-10-03059. [Full Text](#).

Medicare Part A/B > Oversight of Medicare Contractors > Recovery Audit Contractor Fraud Referrals

Fraud Referrals—Implement a System To Track Recovery Audit Contractors' Referrals of Potentially Fraudulent Claims

Recommendations To Be Implemented

- We recommend that CMS implement a system to track all fraud referrals it receives from Recovery Audit Contractors (RAC).

The recommendation would provide continuously quantifiable measures of the extent to which RACs identify potential fraud in conducting their claims payment reviews.

RACs conduct postpayment reviews of Medicare claims to identify overpayments and underpayments and attempt to recoup any overpayments they identify. The Affordable Care Act, [§ 6411](#), expanded the RAC program.

A February 2010 OIG report revealed that between March 2005 and March 2008 (a RAC 3-year demonstration project), RACs referred only two cases of potential fraud to CMS. RACs receive contingency fees based on the amount of improper payments identified (overpayments and underpayments). However, RACs do not receive any contingency fees for the cases they refer that are determined to be fraud. Thus, there may be a disincentive for RACs to refer cases of potential fraud to CMS.

Additional Background >

RACs are not responsible for reviewing claims for fraudulent activity; however, they are responsible for referring to CMS any cases of potential fraud identified during their reviews. During the demonstration project, RACs received no formal training from CMS regarding the identification and referral of potential fraud. About 40 percent of the improper payments that RACs identified during the demonstration period were found in medical necessity reviews. Lack of medical necessity is a common issue in fraudulent billing investigations.

Progress of Implementation

In its update for 2011, CMS noted that it had developed a Memorandum of Understanding (MOU) with OIG regarding fraud referrals as well as a referral template for the Medicare fee-for-service recovery audit program. CMS said that it has used the referral template to send fraud referrals to OIG. CMS also said that it has an internal database to track all such fraud referrals to OIG.

We believe that CMS should track all fraud referrals it receives from RACs, not just those passed on to OIG. We will continue to monitor CMS's implementation of our recommendation.

Primary OIG Report

2010 FEB *Recovery Audit Contractors' Fraud Referrals*. OEI-03-09-00130. [Full Text](#).

❖ Other Management and Systems Issues

This section addresses CMS's supporting systems, administrative responsibilities, and other requirements not directly related to the preceding sections.

Acronyms and Abbreviations for Selected Terms Used in This Section

CMP	civil monetary penalty	HRSA	Health Resources and Services Administration
FFMIA	Federal Financial Management Improvement Act of 1996	LEP	limited English proficiency
FMFIA	Federal Managers' Financial Integrity Act of 1982	NPDB	National Practitioner Data Bank
HIPDB	Healthcare Integrity and Protection Data Bank	OCR	Office for Civil Rights
		OMB	Office of Management and Budget
		OMH	Office of Minority Health
		SOSI	Statement of Social Insurance

Medicare A/B > Reduce Improper Payments > Hotline Complaints

1-800-HHS-TIPS Hotline—Upgrade the System for Processing Complaints (New)

Recommendation To Be Implemented

- We recommend that CMS upgrade its information system for processing hotline complaints.

Savings probable but not estimated.

The recommendations would prevent the improper payments that occur when long timeframes and inefficient processes delay starting work on hotline complaints and when a lack of guidance and an inadequate information system hinder complaint processing.

A March 2011 OIG report revealed that CMS resolved the majority of hotline complaints within at least 1 year after OIG received them through the 1-800-HHS-TIPS hotline, but 12 percent remained unresolved. CMS and contractor staff reported the need for written guidance for processing hotline complaints.

The availability of the hotline is widely publicized in HHS and CMS publications and Web sites. Given the hotline's prominence, it is vital that information reported to the hotline be thoroughly reviewed and appropriately addressed in a timely fashion. OIG hotline staff refer to CMS for resolution the complaints received. CMS staff, as well as staff at Medicare claims processing contractors, process the complaints referred by OIG.

Progress of Implementation

CMS said it will use Enterprise Content Management to integrate the OIG hotline database with 1-800-MEDICARE (a toll-free line for issues that fall outside OIG's jurisdiction or that do not rise to the level of a complaint) to provide an end-to-end automated system. CMS said that with the added functionality of tracking user activity, contractor assignments, and the status of complaints, the investment in an integrated platform and approach obviates previously planned tactical database upgrades.

We encourage CMS to follow through on its efforts to upgrade its hotline processing system. We continue to monitor implementation of our recommendation in terms of resolving the conditions found in our review.

Primary OIG Report

2011 MAR *CMS Processing of Complaints Received Through the 1-800-HHS-TIPS Hotline*.
OEI-07-09-00020. [Full Text](#).

Our report of this review to Congress in FY 2011 included a related recommendation concerning CMS's issuance of written guidance to its own and its contractor staffs for processing hotline complaints. That recommendation has since been resolved. (*Semiannual Report to Congress*, October 2010 – March 2011.)

Medicare Part A/B > Other Management and Systems Issues > Financial Reporting

Financial Management—Improve CMS’s Financial Reporting and Related Processes

Recommendations To Be Implemented

We recommend that CMS

- establish specific policies and procedures and a protocol to address situations or transactions that require the involvement of more than one CMS functional unit to ensure that CMS’s interim and year-end financial statements are accurate and complete (FY 2010);
- continuously monitor the State Medicaid draws and improve grant oversight activities to ensure that States do not overdraw funds (new FY 2011);
- establish a process to perform a claims-level detailed lookback analysis of Medicaid Entitlement Benefits Due and Payable to determine the reasonableness of the methodology used to estimate the accrual (FY 2010 and FY 2011);
- continue to improve the integrity and efficiency of the various error rate development and analysis tools (FY 2010 and FY 2011);
- continue to implement an integrated financial management system to promote consistency and reliability in accounting and financial reporting (FY 2010 and FY 2011);
- continue to enhance its process related to the development, documentation, and validation of critical accounting matters and to delegate the responsibility of the centers or offices to provide robust analyses on a routine and recurring basis (FY 2010 and FY 2011); and
- continue discussions with key stakeholders and standard-setting bodies on the presentation of the statement of social insurance (SOSI) (FY 2010 and FY 2011).

The recommendations (two of which apply to specifically to Medicaid), would help ensure that CMS’s financial management systems will process and record financial events effectively and efficiently and provide complete, timely, and reliable financial information.

Except for the second recommendation above on Medicaid draws, all recommendations were carried forward from the FY 2010 CMS financial statement audit and remain to be fully implemented.

The recommendation on Medicaid draws was reported in the FY 2011 CMS financial statement audit. CMS’s efforts to continuously monitor the State Medicaid draws and perform grant oversight activities should be improved. Routine and timely review of the draws would ensure that the States

do not overdraw funds. Medicaid grant awards should be finalized timely and settled on a periodic basis. CMS should ensure that the grant closeout process occurs timely and consistently to eliminate any erroneous draws to grant awards with remaining authority. The FY 2010 and FY 2011 audits are referenced under “OIG Reports” below.

Additional Background >

Financial management in the Federal Government requires accountability by financial and program managers, control over the Federal Government’s financial resources, and protection of Federal assets. The Office of Management and Budget’s (OMB) Circular A-127, *Financial Management Systems*, prescribes the policies and standards that each agency should follow in developing, operating, evaluating, and reporting on financial management systems.

CMS relies on a decentralized organizational structure and complex financial management systems—not only within its central office and regional offices’ processes, but also within many of the Medicare contractor organizations—to accumulate data for its financial reporting.

Progress of Implementation

In FY 2011, CMS continued to improve its financial management performance in many areas and continues to focus its efforts to address the remaining significant deficiencies.

As part of our financial statement audits, we will review CMS’s corrective action plan to ensure that it adequately addresses the findings and recommendations.

Primary OIG Reports

- 2011 NOV *CMS Financial Report, Fiscal Year 2011*. Audit Opinion Section. Daniel R. Levinson, Inspector General, *Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2011*, pp. [103](#), [127](#). A-17-11-02011. [Full Text](#).
- 2010 NOV *CMS Financial Report, Fiscal Year 2010*. Audit Opinion Section. Daniel R. Levinson, Inspector General, *Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2011*, pp. [89](#), [114-115](#). A-17-11-02010. [Full Text](#).

Medicare Part A/B > Other Management and Systems Issues > Data Integrity and Security

Data Integrity and Security—Improve Medicare Information Systems Controls

Recommendations To Be Implemented

We recommend that CMS

- proactively monitor Medicare fee-for-service contractor compliance with its directives for data access and for controlling changes made to shared systems;
- ensure that consistent, current, and complete system security plans are prepared by all system owners, Medicare fee-for-service claims processing contractors, enterprise data centers, and system software maintainers; and
- ensure that appropriate segregation of duties is established in all systems that support CMS's programs, including Medicare fee-for-service claims and related financial processing at claims processing contractors and enterprise data centers to prevent excessive or inappropriate access.

The recommendations would help ensure that Medicare's critical system assets are protected from unauthorized usage and that only authorized personnel are granted access to data and programs.

CMS's information systems controls were considered a significant deficiency in the FY 2011 financial statement audit because CMS did not ensure that configuration management controls were in effect at the single testing contractor; the single testing contractor's required system security plan was not current or complete and did not reflect an assessment of risk that the single testing contractor faces in its role supporting CMS; and there was inconsistent and incomplete execution of CMS's directives and guidance over information security controls by the Medicare claims processing contractors.

Additional Background >

The Federal Financial Management Improvement Act of 1996 (FFMIA) requires Federal agencies to maintain acceptable accounting systems. Also, the Federal Managers' Financial Integrity Act of 1982 (FMFIA) requires agencies to develop, maintain, and test their internal controls and financial management systems and to report any material weaknesses and planned corrective actions.

A substantial portion of CMS transactions and administration of programs is performed by geographically dispersed contractors. The contracts between CMS and its contractors that have IT responsibilities include provisions requiring the contractors to follow security standards detailed in CMS's *Business Partners Systems Security Manual*. Specific security standards followed by a contractor are to be documented in the contractor's System Security Plan.

Progress of Implementation

According to CMS's Financial Report for FY 2011, CMS has continued making progress to remediate specific information security weaknesses and continues to focus its efforts in on addressing the remaining significant deficiencies. The Chief Financial Officers audit for FY 2011 noted that

improvement was made concerning the FY 2010 significant deficiency associated with Medicare systems controls. In addition, OIG attended CMS's monthly Risk Management meetings that discussed and tracked the progress of CMS's corrective action plans.

As part of the FY 2012 financial statement audit, CMS's corrective action plan will be reviewed to ensure that it adequately addresses the FY 2011 recommendations. We continue to monitor CMS's progress.

Primary OIG Report

2011 NOV *CMS Financial Report, Fiscal Year 2011*. Audit Opinion Section. Daniel R. Levinson, Inspector General, *Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2011*, pp. 103, 119-120 . A-17-11-02011. November 2011.

Medicare Part A/B > Other Management and Systems Issues > Quality of Data for Oversight > HIPDB

Quality of Data for Oversight—Improve CMS Reporting to the Healthcare Integrity and Protection Data Bank

Recommendations To Be Implemented

- We recommend that CMS report all adverse actions to the Healthcare Integrity and Protection Data Bank (HIPDB) as required. To accomplish this, CMS should educate staff and contractors about the types of adverse actions required to be reported and the timeframes for reporting.

The recommendation would help ensure that HIPDB data are accurate and can be successfully used in monitoring or preventing the participation of potentially fraudulent or abusive health care providers in Medicare and other health care programs and environments.

The HIPDB is a national data bank containing reports of adverse actions against health care practitioners, providers, and suppliers. Federal and State government agencies and health plans are required to report to the HIPDB. CMS imposes a variety of sanctions that are required to be reported to the HIPDB, including revocations and suspensions of laboratory certifications; terminations of providers from participation in Medicare; and civil monetary penalties (CMP) against all types of providers, managed care plans, and prescription drug plans.

A September 2010 OIG report revealed that CMS took adverse actions against providers, but did not report them to the HIPDB as required. CMS did not report any actions between 2001 and 2008.

We identified a number of adverse actions imposed against laboratories in 2007 and against managed care and prescription drug plans between January 1, 2006, and July 31, 2009, that were not reported to the HIPDB. None of the adverse actions against medical equipment suppliers taken after 2008 had been reported to the HIPDB at the time of our review. However, as of April 30, 2009,

5,125 adverse actions against medical equipment suppliers imposed from 1998 through 2008 had been added to the databank. None of the nursing homes terminated from participating in Medicare from 2004 through 2008 were reported to the HIPDB until 2009, well after the required reporting timeframe.

Additional Background >

The HIPDB is maintained by the Health Resources and Services Administration (HRSA). HRSA also maintains a similar database of adverse actions against practitioners, the National Practitioner Data Bank (NPDB).

The Affordable Care Act, § 6403, requires the elimination of duplicative data reporting and access requirements between the NPDB and the HIPDB. The Secretary of HHS is required to establish a transition period to transfer all data in the HIPDB to the NPDB and, once the transition is completed, to cease operations of the HIPDB. Information previously collected and disclosed through the HIPDB will continue to be collected and disclosed through the NPDB. Therefore, CMS should continue its efforts to report all adverse actions as required—currently to the HIPDB and, when it ceases operation, to the NPDB. See proposed rule at 77 Fed. Reg. 9138 (February 15, 2012).

Progress of Implementation

CMS concurred with our recommendation. It described planned efforts to report adverse actions imposed against nursing facilities, laboratories, and medical equipment suppliers, including working with HRSA, to develop technical procedures and educating staff and contractors about HIPDB reporting.

In its update for 2011, CMS reported that the HIPDB records on revocations among medical equipment suppliers had been updated through August 2010. However, CMS did not provide information on its efforts to report adverse actions against provider types other than medical equipment suppliers (e.g., Medicare providers, nursing facilities, laboratories, managed care plans, and prescription drug plans).

We continue to monitor CMS's implementation of our recommendation.

Primary OIG Report

2010 SEP *CMS Reporting to the Healthcare Integrity and Protection Data Bank.*
OEI-07-09-00290. [Full Text.](#)

See Also

2012 SEP *Recommendation Followup Memorandum Report: CMS Reporting to the Healthcare Integrity and Protection Data Bank.* OEI-07-09-00292. [Full Text.](#)

Medicare Part C (Medicare Advantage)

The Balanced Budget Act of 1997 (BBA) established the Medicare+Choice (M+C) program to provide a wider range of health plan choices to Medicare beneficiaries. The BBA also modified the payment methodology under the program with the intent of correcting excess payments, reducing geographic variations in payments, and aligning payments to reflect beneficiaries' health status. However, because some of the BBA's provisions may not have been implemented as intended, their benefits were not realized.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) redesignated the M+C program as Medicare Advantage (MA). Despite evidence that MA organizations were receiving more than sufficient reimbursements, the MMA increased Medicare's payments to MA organizations.

OIG's audits and evaluations do not routinely project the annual cost savings that could be realized at program level from implementing its recommendations. However, reports are indicative of the extent to which policies and methodologies may be less than effective and in need of corrective action.

Medicare Part C > Avoid Wasteful Spending > MA Capitation Payments

Medicare Advantage Payment Amounts—Modify Payments to Medicare Advantage Organizations

Recommendation To Be Implemented

- We recommend that CMS modify monthly capitation rates to a level fully supported by empirical data.

Savings probable but not estimated. We found multiple issues that are being addressed incrementally. An HHS proposal to adopt competitive bidding for managed care was estimated to save **\$177.2 billion** over 10 years (2010 – 2019). (*HHS Budget in Brief for Fiscal Year 2010.*)

This longstanding recommendation would curb the wasteful spending that has occurred because factors that were known to negatively impact the reasonableness of Medicare reimbursements for managed care were not timely addressed.

A September 2000 OIG report summarized several factors causing Medicare's payments for managed care to be higher than necessary. Such factors included a high (14-percent) fee-for-service error rate that inflated the 1997 capitation base rate and was carried forward unadjusted into future years. Other factors included high Medicare-funded administrative costs and the

unaccounted-for interest revenue that managed care organizations earned on Medicare's prospective payments (prepayments).

The report also noted that the cost estimates used to establish the 1997 base rate for calculating payments to MCOs were overstated because of actuarial assumptions by 3.1 percent—about \$1.2 billion annually. The overstatement was never remedied. It negated the impact of intended reductions, and the effect carried forward into subsequent years' calculations. We estimated the cumulative effect of this overstatement alone would cost Medicare about \$21.7 billion over 10 years (FY 2000 through FY 2009).

The 2000 report described additional factors placing Medicare's managed care payment methodology in question. For example, the Balanced Budget Act of 1997, which created the Medicare+Choice (M+C) program, was intended to correct excesses in prior managed care payment methods; however, after implementation, payments were even higher. The BBA established payments at 95 percent of fee-for-service (FFS) payments to account for presumed efficiencies in the managed care sector. However, the BBA also included a minimum 2-percent annual increase for participating organizations and the Balanced Budget Refinement Act of 1999 (BBRA) delayed full implementation of BBA-authorized risk adjustments that would have saved costs. The net effect was that the provisions provided higher funding to participating managed care organizations than had the BBA and BBRA not been implemented.

The report also noted that MCOs were avoiding costs through beneficiaries' use of nonnetwork providers, favorable selection of healthier beneficiaries, and overcharging Medicare for certain special categories of beneficiaries.

We concluded that the implementation of a comprehensive risk adjustment system based on encounter data from sites of service in addition to inpatient hospital care would further reduce payments.

Progress of Implementation

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) redesignated the M+C program as Medicare Advantage. Despite evidence that MA organizations were receiving more than sufficient reimbursements, the MMA increased Medicare's payments to MA organizations.

- The Deficit Reduction Act of 2005 (DRA), [§ 5301](#), as summarized by the Congressional Budget Office (CBO), required the Secretary to temporarily modify the risk adjustment process. CBO estimated Medicare would save [\\$6.5 billion](#) from 2008 through 2010.
- The HHS *Budget in Brief for Fiscal Year 2010*, [p. 55](#), proposed to establish a competitive bidding system. The approach (which was not enacted) would have allowed the market, not Medicare, to set MA payment rates. HHS estimated savings as [\\$177.2 billion](#) over 10 years (2010 – 2019), [p. 59](#).
- The Health Care and Education Reconciliation Act of 2010, §§ 1102 and 1103, froze MA payments in 2011, extended CMS's authority to adjust risk scores relative to FFS, and limited administrative costs.

We continue to monitor CMS's progress in ensuring that Medicare Advantage capitation rates and adjustments are implemented and calculated in a manner that reflects appropriate empirical data.

Primary OIG Report

2000 SEP *Adequacy of Medicare's Managed Care Payments After the Balanced Budget Act of 1997.* A-14-00-00212. [Full Text](#)

See Also

2012 SEP *Risk Adjustment Data Validation of Payments Made to Paramount Care, Inc., for CY 2007 (Contract No. H3653).* A-05-09-00044. [Full Text](#).

2012 MAY *Risk Adjustment Data Validation of Payments Made to PacifiCare of Texas for Calendar Year 2007 (Contract Number H4590).* A-06-09-00012. [Full Text](#).

2012 FEB *Medicare Advantage Organizations' Identification of Potential Fraud and Abuse.* OEI-03-10-00310. [Full Text](#).

2011 JAN *Rollup Review of Impact on Medicare Program of Investment Income That Medicare Advantage Organizations Earned and Retained From Medicare Funds in 2007.* A-07-10-01080. [Full Text](#).

2002 JUL *Audit of Medicare Adjusted Community Rate Proposals Submitted by 55 Medicare+Choice Organizations for Contract Year 2000.* A-09-01-00051. [Full Text](#).

2001 NOV *Summary Results of Review of the Administrative Cost component of the Adjusted Community Rate Proposal at Ten Medicare+Choice Organizations for the 2000 Contract Year.* A-03-01-00017. [Full Text](#).

2000 AUG *Results of the Audit of Investment Income Earned by Managed Care Organizations with Risk-Based Contracts.* A-02-98-01005. [Full Text](#).

2000 FEB *Review of Payments to Medicare Managed Care Risk Plans for Deceased Beneficiaries.* A-07-99-01283. [Full Text](#).

2000 JAN *Review of the Administrative Cost Component of the Adjusted Community Rate Proposal at Nine Medicare Managed Care Organizations for the 1997 Contract Year.* A-03-98-00046. [Full Text](#).

2000 JAN *Administrative Costs Reflected on the Adjusted Community Rate Proposals Are Inconsistent Among Managed Care Organizations.* A-14-98-00210. [Full text](#).

1999 DEC *Review of Medicare Overpayments to Managed Care Organizations Due to Overstated Capitation Rates.* A-05-99-00025. [Full Text](#).

1999 APR *Review of Medicare Managed Care Payments for Beneficiaries With Institutional Status.* A-05-98-00046. [Full Text](#).

1998 SEP *Capitation Rates for Medicare Managed Care Plans Are Inflated Due to Improper Payments Included in Rate Calculations.* A-14-97-00206. [Full Text](#).

1998 JUL *Administrative Costs Submitted by Risk-Based Health Maintenance Organizations on the Adjusted Community Rate Proposals Are Highly Inflated.* A-14-97-00202. [Full Text](#).

1997 JUN *Systems and Overpayment Issues--End Stage Renal Disease Payments to Health Maintenance Organizations.* A-14-96-00203. [Full Text](#).

Medicare Part C > Beneficiary Protection > MA Marketing Activities

Medicare Advantage Aggressive Marketing—Ensure That New Enrollees Understand Plan Rules

Recommendation To Be Implemented

- We recommend that CMS issue (and enforce) regulations requiring plan sponsors to contact all new enrollees to ensure that they understand plan rules.

The recommendation would help protect beneficiaries who, under the influence of sales marketers, may make uninformed or misinformed decisions about their choice of MA plans. Aggressive marketing tactics may not include clear information about the cost and scope of benefits and plan rules.

A March 2010 OIG report revealed that although CMS regulations require sales agents to pass a marketing test on Medicare regulations annually and be State licensed, no plan sponsor we reviewed had a policy to contact Medicare beneficiaries enrolled through unqualified sales agents.

The report noted that in August 2009, CMS issued revised marketing guidance instructing plan sponsors to contact all new enrollees to ensure that Medicare beneficiaries understand plan rules. To protect beneficiaries and ensure that they understand their new plans' rules, we recommended that CMS codify this guidance in regulations.

Progress of Implementation

CMS responded that new regulations are unnecessary because CMS had already used existing regulations as the basis for its 2009 guidance, which requires outbound enrollment verification calls to ensure that newly enrolled Medicare beneficiaries understand plan rules.

We are concerned that the guidance may not be sufficient to hold plan sponsors accountable. We maintain that CMS should reconsider formalizing the guidance as regulations after monitoring plan sponsors' implementation of outbound enrollment verification calls. We continue to monitor CMS's implementation of the recommendation we specified.

Primary OIG Report

2010 MAR *Beneficiaries Remain Vulnerable to Sales Agents' Marketing of Medicare Advantage*. OEI-05-09-00070. [Full Text](#).

See Also

2006 AUG *Medicare Advantage Marketing Materials for Calendar Year 2005*. OEI-01-05-00130. [Full Text](#).

Medicare Part D (Prescription Drug Program)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Part D prescription drug benefit. Effective January 1, 2006, Part D provides an optional outpatient prescription drug benefit to Medicare beneficiaries. CMS administers the Part D program and contracts with private companies, known as plan sponsors, to provide Part D prescription drug coverage. Beneficiaries can enroll in a stand-alone prescription drug plan that covers drugs only or a Medicare Advantage prescription drug plan that integrates drug coverage with other health care services.

Since the inception of the Part D program in 2006, OIG has developed a body of work to review program integrity and payment accuracy safeguards that are in place to protect the program from fraud, waste, and abuse. To date, OIG's work has demonstrated that the Part D program oversight by the Centers for Medicare & Medicaid Services (CMS), its benefit integrity contractors, and the Part D plan sponsors has been limited. As a result, the program is vulnerable to fraud, waste, and abuse. There are opportunities to significantly enhance Part D oversight.

❖ Preventing and Detecting Fraud and Abuse

Within Medicare, the responsibility for ensuring integrity in the Part D prescription drug program is shared between Part D plan sponsors, benefit integrity contractors, and CMS. The program is large and complex. With more than \$50 billion at risk in the program each year, it is important that all having programmatic and oversight responsibilities collaborate to ensure that program vulnerabilities are identified and resolved. The recommendations in this section are directed to improving the way CMS, its contractors, and the Part D sponsors prevent and detect fraud and questionable billing in Part D.

Medicare Part D > Fraud and Abuse > CMS Safeguard Strategy

CMS—Develop a Comprehensive Safeguard Strategy for Overseeing Part D Prescription Drug Plans

Recommendation To Be Implemented

- We recommend that CMS develop a comprehensive safeguard strategy for overseeing Medicare Part D plans with specific activities and target dates and ensure that all activities are progressing in a timely manner.

Savings probable but not estimated.

The recommendation would help reduce the vulnerabilities that could arise from Medicare's lack of a documented comprehensive safeguard strategy. Overall, OIG's reviews of Part D indicate that program integrity efforts have been limited in scope and may not sufficiently protect the program.

An October 2007 OIG report revealed that although CMS had begun implementation activities in several safeguard areas we reviewed, CMS had not developed a comprehensive, written strategy document and CMS staff could not provide timelines for implementation. Our recommendation included that CMS make Part D safeguard activities a sufficient priority in the budgeting process to support their timely and effective administration. Of foremost concern were the commencement of required financial audits, having sufficient benefit integrity contractors to investigate fraud complaints, and pursuing innovative data-driven techniques to identify potential fraud and abuse.

Additional Background

CMS is statutorily required to perform financial audits of Part D plan sponsors, which provide Part D benefits to Medicare beneficiaries. CMS also can conduct a number of other types of audits of plan sponsors, including bid audits, program audits, benefit integrity audits, and compliance plan audits. Also, CMS contracts with Medicare Drug Integrity Contractors (MEDICs) to perform integrity functions, such as identifying and investigating potential fraud, waste, and abuse in Part D. MEDICs are the cornerstone of CMS's program integrity efforts.

Part D and its beneficiaries may be exposed to a wide range of fraud, waste, and abuse, including inappropriate billings, payments for excluded drugs, drug diversion, improper bid submissions, excessive premiums, and illegal marketing schemes. Such vulnerabilities put Medicare resources at risk.

Progress of Implementation

Although CMS has taken several steps to implement safeguards in Part D, it has not provided documentation of a comprehensive strategy with actions tied to timelines.

In responding to our review, CMS reported that it had developed a corrective action plan to address OIG's recommendation, it had implemented a regional MEDIC structure, and it was rewriting the MEDIC USOW to further refine CMS's coordination and oversight of the MEDICs. Additional safeguard plans included improving MEDICs' access to data and developing guidance and clarification that sponsors must apply training on fraud, waste, and abuse to all entities with which they are partnering.

CMS also stated that the MEDIC task orders and Umbrella Statement of Work (USOW) represented CMS's comprehensive safeguard strategy for Part D. Although OIG agrees that the task orders and USOW provide an important framework for implementing many safeguard activities, these documents are specific to the MEDIC activities and do not address the broad coordination needed between different groups within CMS that each have a role to play in safeguarding Part D.

We encourage CMS to follow through on its oversight efforts and implement the recommendation we specified. We continue to monitor CMS's progress in developing the documents.

Primary OIG Report

2007 OCT *CMS's Implementation of Safeguards During Fiscal Year 2006 To Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans.* OEI-06-06-00280. [Full Text](#).

See Also

- 2011 DEC [CMS] *Audits of Medicare Prescription Drug Plan Sponsors*. OEI-03-09-00330. [Full Text](#).
- 2011 NOV *Review of the Centers for Medicare & Medicaid Services' Audits of Part D Sponsors' Financial Records*. A-03-10-00007. [Full Text](#).
- 2010 MAR OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, "Oversight Challenges in the Medicare Prescription Drug Program." [Testimony](#).
- 2008 NOV *Centers for Medicare & Medicaid Services Audits of Medicare Part D Bids*. OEI-05-07-00560. [Full Text](#).
- 2008 OCT *CMS's Oversight of Prescription Drug Plan Sponsors' Compliance Plans*. OEI-03-08-00230. [Full Text](#).

Medicare Part D > Fraud and Abuse > MEDICs' Identification of Fraud

MEDICs—Authorize Medicare Drug Integrity Contractors To Directly Obtain the Information They Need To Investigate Fraud and Abuse

Recommendation To Be Implemented

- We recommend that CMS authorize Medicare drug integrity contractors (MEDIC) to directly obtain from certain entities the information they need to identify and investigate potential fraud and abuse, seeking legislation if needed.

Savings probable but not estimated.

The recommendation would help reveal improper and fraudulent claims that currently go undetected because Medicare's benefit integrity contractors are not the authorized to directly obtain the information they need to facilitate their mission.

An October 2009 OIG report revealed that MEDICs' lack of authority to directly obtain information such as prescriptions and medical records from pharmacies, pharmacy benefit managers, and physicians hindered MEDICs' ability to investigate potential fraud and abuse incidents. In addition, MEDICs may not have been aware of some potential fraud and abuse incidents because plan sponsors were not required to refer such incidents to MEDICs. Finally, CMS had not given MEDICs approval to conduct audits of plan sponsors' compliance plans as of our review in FY 2008.

Additional Background >

According to the MEDICs' statement of work and their individual task orders, their responsibilities include, but are not limited to, identifying potential Part D fraud and abuse through external sources and proactive methods; fulfilling requests for information from law enforcement agencies; investigating potential Part D fraud and abuse; referring cases and making immediate advisements

regarding potential Part D fraud or abuse to OIG; recommending appropriate administrative actions to CMS; identifying program vulnerabilities; and auditing the fraud, waste, and abuse programs that are part of plan sponsors' compliance plans.

Progress of Implementation

In responding to our review, CMS said it believes that the current arrangement is appropriate given the structure of the Part D program and the contractual relationship with the plans. In its update for 2011, CMS stated that it does not have the authority to permit MEDICs to collect information directly from pharmacies, pharmacy benefit managers, and physicians due to contracts between the entities and the Part D plan sponsors. Through compliance plan requirements, CMS holds plan sponsors accountable for the actions of these entities.

OIG understands that CMS currently does not have the authority to allow a MEDIC to directly obtain information from the necessary entities. However, we continue to recommend that CMS seek statutory authority if needed. We continue to monitor CMS's implementation of the recommendation.

Primary OIG Report

2009 OCT *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse.* OEI-03-08-00420. October 2009. [Full Text](#).

See Also

2012 JUN OIG Testimony Before the House Committee on Energy and Commerce, "Medicare Contractors' Efforts to Fight Fraud – Moving Beyond Pay and Chase." [Testimony](#).

2011 DEC *Addressing Vulnerabilities Reported by Medicare Benefit Integrity Contractors.* OEI-03-10-00500. [Full Text](#).

2011 NOV *Zone Program Integrity Contractors' Data Issues Hinder Effective Oversight.* OEI-03-09-00520. [Full Text](#).

2010 MAR OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, "Oversight Challenges in the Medicare Prescription Drug Program." [Testimony](#).

Medicare Part D > Program Integrity > Sponsors' Compliance Plans

Sponsors—Determine the Effectiveness of Plan Sponsors' Antifraud Programs

Recommendations To Be Implemented

We recommend that CMS

- review Part D plan sponsors to determine why certain sponsors have especially high or low volumes of potential fraud and abuse incidents,
- determine whether the Part D plan sponsors that found potential fraud and abuse initiated inquiries and corrective actions and made referrals for investigations as recommended by CMS,
- require Part D plan sponsors to maintain and report information about the results of their fraud and abuse programs, and
- use this information to help determine the effectiveness of the programs.

Savings probable but not estimated.

The recommendations would facilitate Medicare's oversight of Part D sponsors' antifraud programs. Improper and fraudulent claims may go undetected when Part D plan sponsors lack effective compliance plans and antifraud processes and procedures.

An October 2008 OIG report analyzed data for the first 6 months of 2007 from 86 of 91 stand-alone drug plan sponsors. We found that 28 percent did not report any potential fraud and abuse incidents. Most incidents were identified by a small number of plan sponsors; and not all sponsors that identified potential fraud and abuse conducted inquiries, initiated corrective actions, or made referrals for further investigation. One sponsor identified 67 percent of all incidents reported. Inappropriate billing was the most prevalent type of potential fraud and abuse and pharmacies were associated with most of the incidents, e.g., submitting claims for drugs not provided.

Additional Background >

CMS requires that Part D sponsors have compliance plans in place to protect the integrity of the program. Plans must include certain elements.

- A December 2006 OIG report revealed that while all plan sponsors had compliance plans, these plans did not fully address all of CMS' s requirements and, in some cases, contained only the broad outlines of a fraud and abuse plan and did not describe specific compliance and anti-fraud processes.
- A January 2010 OIG report of one sponsor's internal controls revealed that although most internal controls were adequate, there were several internal control weaknesses that compromised the plan sponsor's ability to detect, correct, and prevent fraud, waste, and abuse in Part D.

Progress of Implementation

CMS has taken steps toward implementing the recommendations we specified. In its 2011 update, CMS said it provided our findings to the MEDICs, but it did not report to us the results of the MEDICs' reviews. CMS revised the reporting requirements to provide the Part D sponsors with specific guidance for tracking and properly labeling any incidents.

We continue to monitor CMS's progress to determine whether the results of the MEDICS' reviews addressed our recommendations.

Primary OIG Report

2008 OCT *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse.* OEI-03-07-00380. [Full Text.](#)

See Also

2011 JUL *Medicare Prescription Drug Sponsors' Training To Prevent Fraud, Waste, and Abuse.* OEI-01-10-00060. [Full Text.](#)

2010 AUG *Review of Sterling Life Insurance Company's Internal Controls To Guard Against Fraud, Waste, and Abuse for the Medicare Part D Program.* A-07-09-03136. [Full Text.](#)

2010 MAR OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, "Oversight Challenges in the Medicare Prescription Drug Program." [Testimony.](#)

2010 JAN *Review of SilverScript Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for the Medicare Part D Program.* A-07-09-03124. [Full Text.](#)

2006 DEC *Prescription Drug Plans Sponsors' Compliance Plans.* OEI-03-06-00100. [Full Text.](#)

Medicare Part D > Program Integrity > Sponsor Training of Pharmacies

Sponsors—Improve Sponsors’ Training of Pharmacies To Prevent Fraud, Waste, and Abuse (New)

Recommendations To Be Implemented

We recommend that CMS

- reiterate to sponsors their responsibilities as the entities accountable for network pharmacies’ training to prevent Part D fraud, waste, and abuse,
- use its monitoring authority to determine compliance with training requirements, and
- ensure that sponsors are providing effective training and education to prevent fraud, waste, and abuse.

Savings probable but not estimated.

The recommendations would help reduce instances of pharmacy-based fraudulent or abusive behavior. OIG reviews of Medicare prescription drug plans have shown that pharmacies are at risk for fraud, waste, and abuse from beneficiaries, employees, prescribers, and drug manufacturers.

A July 2011 OIG report revealed that nearly all Part D network pharmacies received sponsor training to prevent fraud, waste, and abuse in 2009, but some sponsors failed to document the training. With a few exceptions, the content and source of most training materials reflected Medicare guidance, but most sponsors could not determine the extent to which the training of pharmacies was effective. Forty-one percent of all sponsors did not assess the training’s effectiveness. More than a third of the training materials failed to include information on the Health Insurance Portability and Accountability Act (HIPAA), and more than half of the materials were developed by pharmacies’ corporate offices, despite CMS guidance stating that pharmacies should not develop their own materials.

Additional Background >

As a condition for contracting with CMS to offer Part D benefits, sponsors must have compliance plans that help them follow Federal regulations and prevent fraud, waste, and abuse. Such plans must include effective annual training and education for network pharmacies to prevent fraud, waste, and abuse.

Progress of Implementation

In August 2011, CMS hosted its first annual Part C and Part D program integrity conference for plan representatives and law enforcement for the purpose of sharing and developing best practices and tools to identify and fight fraud and abuse. In responding to our review, CMS said that a Part C/D fraud training module will be made available through its training Web site, MEDLearn, and CMS planned to issue guidance to the plans regarding this module and instructions for documenting the

Web-based training. CMS said it continues to explore new ways of measuring effectiveness in the Part D compliance programs through audits, reviews, and qualitative and quantitative analysis.

We encourage CMS to follow through on its proposed actions and report the results to OIG. We continue to monitor CMS's progress in addressing the recommendations we specified.

Primary OIG Report

2011 JUL *Medicare Prescription Drug Sponsors' Training To Prevent Fraud, Waste, and Abuse.* OEI-01-10-00060. [Full Text](#).

See Also

2012 MAY *Medicare Retail Pharmacies With Questionable Part D Billing.* OEI-02-09-00600. [Full Text](#).

2008 OCT *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse.* OEI-03-07-00380. [Full Text](#).

❖ Accuracy of Data for Payments and Reconciliations

CMS makes payments to plan sponsors on a monthly basis through estimated subsidy payments and, as needed, at yearend as a result of the payment reconciliation process. The reconciliation process compares estimated subsidy payments made to plan sponsors throughout the year with the cost data submitted by plan sponsors through Prescription Drug Event (PDE) records and direct or indirect remuneration data to determine whether any residual payments are required by CMS to plan sponsors or plan sponsors to CMS. The reconciliation process relies on four major data sources: the sum of payments made to plan sponsors throughout the year, final updated plan enrollment, PDE records from plan sponsors, and remuneration estimates.

Medicare Part D > Accuracy of Payments > Sponsor Cost Estimates

Sponsor Data—Ensure the Accuracy of Sponsors’ Cost Estimates in Part D Bids

Recommendations To Be Implemented

We recommend that CMS

- ensure that sponsors’ bids more accurately reflect the cost of providing benefits to Medicare beneficiaries;
- hold sponsors more accountable for inaccuracies in the bids;
- determine whether changes to the reconciliation risk corridors¹ are appropriate, seeking legislative changes if needed; and
- determine whether alternative methodologies would better align payments with costs for the low-income cost-sharing and reinsurance subsidies.

Savings probable but not estimated.

The recommendations would result in more accurate sponsor estimates of costs and expected profits in their Part D bids, thus ensuring more appropriate levels of Medicare and beneficiary spending for Part D prescription drugs during the plan year. The recommendations would also help ensure more accurate yearend reconciliation of payments with actual costs.

A September 2009 OIG report revealed that 71 percent of sponsors we reviewed made unexpected profits large enough to trigger risk sharing at yearend reconciliation for 2007. When sponsors owe money to Medicare for risk sharing at reconciliation, it means that they overestimated the cost of providing the benefit when they submitted their bids.

¹ The plan’s allowable risk-corridor costs are its actual covered Part D drug costs incurred minus direct and indirect remuneration and the catastrophic coverage reinsurance subsidy paid by Medicare.

CMS uses sponsors' bids to determine beneficiary premiums and the monthly subsidy payments (prepayments) that CMS pays to each sponsor. When costs are overstated in bids, Medicare calculates prepayments and beneficiary premiums that are higher than necessary. Medicare recoups a portion of these higher payments because of risk-sharing requirements in reconciliation. However, beneficiaries do not directly recoup any of the money that they pay in higher premiums.

Progress of Implementation

In its initial response to the September 2009 report, CMS described a number of steps it was taking, planned to take, or was considering. In 2011, CMS issued 19 compliance actions related to bid submission compliance concerns. In its 2012 Medicare Advantage and Part D Call Letter, CMS said that, in general, commenters supported the risk corridors it proposed for 2012.

We encourage CMS to follow through on its efforts to ensure accurate sponsor cost data and to provide documentation to establish how it has addressed each of the recommendations we specified. We continue to monitor CMS's progress.

Primary OIG Report

2009 SEP *Medicare Part D Reconciliation Payments for 2006 and 2007.*
OEI-02-08-00460. [Full Text.](#)

See Also

- 2011 NOV *Review of the Centers for Medicare & Medicaid Services' Audits of Part D Sponsors' Financial Records.* A-03-10-00007. [Full Text.](#)
- 2011 AUG *Review of Aetna, Inc., Pharmacy Audit Recoveries for Medicare Part D Drugs Dispensed in Calendar Year 2008.* A-03-11-00001. [Full Text.](#)
- 2011 MAR *Concerns With Rebates in the Medicare Part D Program.* OEI-02-08-00050. [Full Text.](#)
- 2010 NOV *Medicare Part D Pharmacy Discounts for 2008.* OEI-02-10-00120. [Full Text.](#)
- 2010 JUN *Medicare Part D – Prescription Drug Event Reconciliation Process.* A-18-08-30102. [Full Text.](#)
- 2010 JUN *Review of Coventry Health Care, Inc.'s 2007 Prescription Drug Event Data Elements Related to Yearend Reconciliation.* A-03-09-00020. [Full Text.](#)
- 2010 MAR *OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, "Oversight Challenges in the Medicare Prescription Drug Program."* [Testimony.](#)
- 2008 NOV *Centers for Medicare & Medicaid Services Audits of Medicare Part D Bids.* OEI-05-07-00560. [Full Text.](#)
- 2007 OCT *Medicare Part D Sponsors – Estimated Reconciliation Amounts for 2006.* OEI-02-07-00460. [Full Text.](#)

Medicare Part D > Accuracy of Payments > Part D Manufacturer Rebates

Sponsor Data—Ensure the Accuracy of Sponsors’ Rebate Estimates in Part D Bids (New)

Recommendations To Be Implemented

We recommend that CMS

- ensure that sponsors more accurately include their expected rebates in their bids,
- require sponsors to use methods CMS deems reasonable to allocate rebates across plans,
- ensure that sponsors have sufficient audit rights and access to rebate information, and
- ensure that sponsors appropriately report the fees that pharmacy benefit managers (PBM) collect from manufacturers.

Savings probable but not estimated.

The recommendations would result in more accurate sponsor estimates of remunerations from rebates in their Part D bids, thus ensuring more appropriate levels of Medicare and beneficiary spending for Part D prescription drugs during the plan year. The recommendations would also help ensure more accurate yearend reconciliation of payments with actual costs.

A March 2011 OIG report revealed that Part D sponsors underestimated rebate remunerations in 69 percent of their bids for plan year 2008. The report noted that it is possible that some sponsors deliberately underestimate their rebates to increase profits. The March 2011 OIG report explained that when sponsors underestimate expected rebates in their bids, both the Government and beneficiaries pay too much to Part D sponsors during the plan year. In reconciliation, the Government recoups some, but not all, of its excessive prepayments. However, beneficiaries do not recoup any of the money they pay in excessive premiums.

The March 2011 report also found issues concerning how sponsors allocate rebates across plans, sponsors’ lack of authority over and access to rebate information, and reporting of fees that PBMs receive from manufacturers. (See “Progress” section for new reporting requirements.)

Additional Background >

An independent audit issued by OIG in June 2010 described a vulnerability concerning calculations of actual costs in reconciliations. Actual costs for reconciliation as those actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration. (42 CFR § 423.308.) If sponsors understate remuneration (such as from rebates) in yearend reconciliation—and CMS’s controls fail to detect the understatements—plan sponsors could receive larger yearend payments from CMS than they are entitled to. The report found that plan sponsors are not required to update the estimated remuneration information they submitted to CMS once actual amounts are known.

Therefore, CMS does not receive the final remuneration data from plan sponsors (or other sources) that it needs to accurately reconcile costs and payments.

Federal regulations define “direct or indirect remuneration” for reconciliation purposes as including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor for the drug. (42 CFR § 423.308.)

Progress of Implementation

In responding to our review, CMS said it will consider adding to its bid reviews a comparison of the rebates sponsors actually receive to the expected rebates they include in their bids; that it has already provided plan sponsors with sufficiently detailed guidance on how they should monitor PBM rebate information; and that it has a process in place to ensure that sponsors appropriately report the fees that PBMs collect from manufacturers. CMS agreed to evaluate whether additional clarification is needed about when fees to PBMs should be reported as rebates.

In April 2012, CMS published a final rule that included changes to the Medicare prescription drug benefit program. Pursuant to the Affordable Care Act, § 6005, the rule requires PBMs to report to sponsors and sponsors to report to CMS several data points including the aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees as defined in § 423.501) that the PBM negotiates that are attributable to patient utilization under the plan. It also requires reporting of the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor and the total number of prescriptions dispensed. (77 Fed. Reg. 22171 (April 12, 2012), 42 CFR § 423.514.)

We note that CMS’s existing processes and guidance did not prevent our finding that Part D sponsors underestimated rebate remunerations in 69 percent of their bids for plan year 2008. We encourage CMS to follow through on its corrective actions and in the process to implement the recommendations we specified. We continue to monitor CMS’s progress.

Primary OIG Report

2011 MAR *Concerns With Rebates in the Medicare Part D Program*. OEI-02-08-00050. [Full Text](#).

See Also

2010 NOV *Medicare Part D Pharmacy Discounts for 2008*. OEI-02-10-00120. [Full Text](#).

2010 JUN *Medicare Part D – Prescription Drug Event Reconciliation Process*. A-18-08-30102. (Direct and Indirect Remuneration (DIR), section 3., pp. 13-15.) [Full Text](#).

❖ Beneficiary Cost Sharing

Most Part D drug plans charge a monthly premium fee that varies by plan. The Part D premium is in addition to the Part B premium. The annual deductible is the amount a beneficiary must pay each year for prescriptions before the plan begins to pay its share of the covered drugs. Deductibles vary between plans. No plan may have a deductible more than \$320 in 2012. Some plans don't have a deductible. The copayment, or coinsurance, is the amount a beneficiary pays for each prescription after the deductible, if any, has been met. Some plans have different levels, or "tiers," of coinsurance or copayments, with different costs for different types of drugs.

Most Medicare drug plans have a coverage gap (also called the "donut hole"). This means there is a temporary limit on what the plan will cover for drugs. Not everyone will enter the coverage gap. The coverage gap begins after the beneficiary and the drug plan have spent a certain amount for covered drugs. Once beneficiaries get out of the coverage gap, they automatically get "catastrophic coverage," which ensures that they pay only a small coinsurance amount, or copayment, for covered drugs for the rest of the year. ([Medicare.gov](http://www.Medicare.gov))

Coverage Gap Savings—Pursuant to the Affordable Care Act, § 3301, cost-sharing in the coverage gap will decrease each year until beneficiaries are required to pay only 25 percent of the costs of covered Part D drugs in 2020 and beyond.

Medicare Part D > Beneficiary Cost Sharing > Costs in Coverage Gap

Coverage Gap—Support Outreach and Education for Beneficiaries Before They Enter the Coverage Gap

Recommendations To Be Implemented

We recommend that CMS

- support outreach and education targeted at beneficiaries who make more prescription drug purchases before entering the coverage gap and
- target low-income subsidy outreach to beneficiaries who entered the coverage gap in previous years without financial assistance.

Savings for beneficiaries probable but not estimated.

The recommendations would help beneficiaries manage the effect of the statutory coverage gap on their prescription drug utilization and costs. Beneficiaries may receive financial assistance for drug costs during the coverage gap from several sources (such as from low-income subsidies or third-party payers), but some do not.

A March 2009 OIG report revealed that 7 percent of Part D beneficiaries entered the coverage gap and did not receive financial assistance with prescription drug costs in 2006. During the coverage

gap, drug-purchasing behavior changed for 98 percent of the beneficiaries, with 69 percent reducing the average number of drugs they purchased during the gap. The greater the average number of drugs per month that they purchased before the coverage gap, the more they reduced the average number of drugs purchased during the gap.

We found that beneficiaries who purchased an average of at least nine drugs per month had the largest decrease at 18 percent. When surveyed, beneficiaries identified specific changes in the way they purchased or used drugs during the coverage gap, including 38 percent who reported seeking at least one less-costly alternative to purchasing drugs and one-third who compromised their drug regimens.

Additional Background >

Although the Affordable Care Act reduced beneficiary liability in the coverage gap and the gap will close in 2020, several years remain in which beneficiaries in the gap would benefit from outreach and counseling.

Progress of Implementation

In its initial response to our review, CMS said that it would not be feasible to provide additional personalized outreach to individual beneficiaries who used a large number of drugs each month according to the prior year's PDE data. CMS said that it would continue to emphasize the value of the low-income subsidy to attract beneficiaries with significant drug utilization who might benefit from the subsidy.

In its update for 2011, CMS said it continues to refine outreach methods and will use research findings to shape future outreach strategies, including how to communicate the value of the low-income subsidy program to those with high drug utilization.

In its 2012 update, CMS said the Affordable Care Act provides for a 50-percent discount on covered brand-name drugs and some coverage for generic drugs for beneficiaries who reach the coverage gap.

While the Affordable Care Act reduced beneficiary liability in the coverage gap and the gap will close in 2020, there are several more years in which beneficiaries could fall into the gap and experience high drug costs. We maintain that outreach and education would help high-utilization beneficiaries identify cost-saving strategies.

Primary OIG Report

2009 MAR *Effect of the Part D Coverage Gap on Medicare Beneficiaries Without Financial Assistance in 2006*. OEI-05-07-00610. [Full Text](#).

Medicare Part D > Beneficiary Cost Sharing > TrOOP costs

Coverage Gap—Track Beneficiaries’ True Out-of-Pocket Costs

Recommendations To Be Implemented

We recommend that CMS

- ensure that Part D plans collect, process, and submit all the data that are required to track enrollees’ true out-of-pocket (TrOOP) costs in a timely manner,
- consider options for increasing the number of data-sharing agreements and for seeking to expand its authority to collect data under those agreements, and
- begin or complete implementation of oversight activities regarding tracking TrOOP costs.

Savings to beneficiaries probable but not estimated.

The recommendations would protect beneficiaries’ cost-sharing interests by ensuring that TrOOP cost data are accurately tracked. TrOOP costs also affect Medicare Part D payments to plans. TrOOP costs are the prescription drug expenditures that count toward the annual out-of-pocket threshold that beneficiaries must reach before catastrophic drug coverage begins.

A December 2007 OIG report revealed that information on Part D plan enrollees’ other prescription drug coverage was not consistently submitted in 2006. Nearly two-thirds of Part D plans cited problems with transferring TrOOP balances when enrollees changed plans. More than one-third of Part D plans failed to submit data to CMS in accordance with CMS requirements. CMS has conducted only limited oversight of Part D plans’ tracking of TrOOP costs.

Additional Background >

Tracking TrOOP costs involves coordination and communication among CMS; contractors, such as coordination of benefits contractors; Part D plans; and other payers of prescription drug benefits.

Under section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA), all group health plans are required to report coverage information related to hospital and medical benefits that are primary to Medicare. Although MMSEA does not specifically mandate the reporting of private prescription drug coverage, this reporting option is being offered to all entities required to report under the section 111 reporting processes. As a result, CMS expects to receive a significant number of reports of prescription drug data via the section 111 process.

Progress of Implementation

In its initial response to our review, CMS agreed that more work is needed to ensure that Part D plans are calculating TrOOP costs correctly. CMS said that it had taken or will take steps to respond to each of our recommendations.

In its March 2009 status update to OIG, CMS said that it had implemented an automated TrOOP balance transfer process among Part D plans and between Point-of-Sale Facilitated Enrollment (POS FE) Contractors and Part D plans, which went into effect on January 1, 2009. CMS said that it would monitor performance via standard and exception reporting.

In its December 2011 status update, CMS indicated that it issued 67 TrOOP-related compliance actions. CMS also indicated that it has implemented an automated process for transferring TrOOP information and continues to monitor sponsor performance.

CMS should submit to OIG additional information about the activities described so we can determine whether the recommendations we specified have been addressed. We continue to monitor CMS's implementation of oversight activities related to the tracking of TrOOP costs.

Primary OIG Report

2007 DEC *Tracking Beneficiaries' True Out-of-Pocket Costs for the Part D Prescription Drug Benefit.* OEI-03-06-00360. [Full Text](#).

See Also

2012 MAY *WellPoint, Inc., Did Not Always Calculate Enrollees' True-Out-Of-Pocket Costs in Accordance with Federal Requirements.* A-05-11-00018. [Full Text](#).

❖ Sponsor Compliance With Conditions for Payment

Medicare Part D > Conditions for Payment > Prescription Drugs > Provider Identifiers

Claims Processing—Ensure the Validity of Prescriber Identifiers on Claims

Recommendations To Be Implemented

We recommend that CMS

- conduct periodic reviews to ensure the validity of prescriber identifiers used on prescription drug event (PDE) records and
- require Part D plans to institute procedures to identify invalid identifiers in the prescriber identifier field on Part D drug claims and flag for review Part D drug claims that contain invalid identifiers in the prescriber identifier field.
- For Schedule II drugs, we recommend that CMS
- issue specific guidance requiring sponsors to include a valid Drug Enforcement Administration (DEA) number on both standard and nonstandard format PDE records and
- implement an edit to reject PDE records for Schedule II drugs when the prescriber identifier field contains an invalid prescriber identifier number.

Savings probable but not estimated.

The recommendations would help verify that the prescribers of the claimed drugs were eligible to order the drugs for beneficiaries. All Part D plans must submit data and information necessary for CMS to carry out Part D payment provisions. The recommendations would also reduce instances of fraud and abuse in Part D.

A June 2010 OIG report revealed that \$1.2 billion in Medicare Part D prescription drug claims contained invalid prescriber identifiers in 2007. Invalid identifiers were used on more than 18 million prescription drug claims. These identifiers either were not listed in the pertinent registry databases or had been deactivated or retired before January 1, 2006.

A February 2011 OIG report described the results of our review of PDE records for the validity of prescriber identifiers for Schedule II drugs. Schedule II drugs (controlled substances) have a high potential for abuse, have an accepted medical use with severe restrictions, and may cause severe psychological or physical dependence if abused. We found that \$20.6 million in Medicare Part D prescription drug claims contained invalid prescriber identifiers in 2007 for Schedule II Drugs.

Additional Background >

Part D Plans submit an electronic record to CMS for each covered prescription filled for their enrollees. This electronic record, called a PDE record, contains drug cost and payment data fields that enable CMS to make payments to plans and oversee the Part D benefit.

The Affordable Care Act, § 6402, required the Secretary to issue a regulation by January 1, 2011, mandating that all Medicare and Medicaid providers include their NPI on all claims and enrollment applications.

Progress of Implementation

In responding to our review, CMS said that although invalid prescriber identifiers can hinder program oversight efforts for monitoring prescribing practices, invalid prescriber identifiers are not an automatic indication of invalid prescriptions or pharmacy claims.

- In its update for 2011, CMS said that to the extent that it implements a requirement for the use of a single prescriber identifier, it also expects to implement a process for verifying the accuracy of the number.
- In light of OIG's June 2010 report on invalid provider identifiers, CMS announced in its April 4, 2011, "[CY 2012 Call Letter](#)" that it was considering a regulatory change in the Part D program that would limit acceptable prescriber identifiers on claims and PDE records in 2013 to only the individual NPI. (Call Letter, p. 113.) The Call Letter also announced the imposition of additional requirements on plan sponsors with regard to Part D claims for all controlled substances. (Call letter p. 112.)
- In October 2011, CMS published a proposed rule that included Part-D-related NPI provisions. ([76 Fed. Reg. 63018](#) (October 11, 2011).) (See [p. 63061](#).) A final rule with comment period, which is applicable January 1, 2013, was published on April 12, 2012. ([77 Fed. Reg. 22072](#).) (See [p. 22143](#).) The rule requires Part D plan sponsors to submit to CMS only PDE records that contain an active and valid individual prescriber NPI. (42 CFR § 423.120(c).)
- An April 17, 2012, notice proposed to amend 45 CFR Part 162 to specify the circumstances under which an organization-covered health care provider must require certain noncovered individual health care providers who are prescribers to obtain and disclose an NPI. ([77 Fed. Reg. 22950](#).) The proposal would virtually ensure the availability of NPIs for Part D reimbursement. See the discussion beginning on p. [22965](#), "III. Proposed Addition to the National Provider Identifier Requirements." The final rule was published at 77 Fed. Reg. 54664 (September 5, 2012).

We encourage CMS to follow through on improving the use of NPIs on PDE records and to address each of the recommendations we specified. We continue to monitor CMS's progress.

Primary OIG Reports

- 2010 JUN *Invalid Prescriber Identifiers on Medicare Part D Drug Claims.* OEI-03-09-00140. [Full Text.](#)
- 2011 FEB *Oversight of the Prescriber Identifier Field in Prescription Drug Event Data for Schedule II Drugs.* A-14-09-00302. [Full Text.](#)

Medicare Part D > Conditions for Payment > Atypical Antipsychotic Drugs in Nursing Homes

Atypical Antipsychotic Drugs—Ensure That Part D Sponsors Have Information Needed To Make Accurate Coverage and Reimbursement Determinations (New)

Recommendations To Be Implemented

We recommend that CMS

- facilitate Part D sponsors' access to information necessary to ensure accurate coverage and reimbursement determinations for prescription drugs for nursing home residents,
- determine whether survey and certification processes offer adequate safeguards against unnecessary atypical antipsychotic drug use in nursing homes,
- explore alternative methods beyond survey and certification processes to promote compliance with Federal standards regarding unnecessary drug use in nursing homes, and
- take appropriate action regarding the claims associated with erroneous payments identified in our sample.

Savings probable but not estimated. Implementation would increase beneficiary safety and quality of care.

The recommendations would help ensure that Medicare pays only for drugs that are used for medically accepted indications approved by FDA (or are supported by specified drug compendia) and that elderly and disabled nursing home residents are free from unnecessary drugs (an issue of patient safety and quality of care).

A May 2011 OIG report revealed that 14 percent of 2.1 million elderly nursing home residents had at least 1 claim for atypical antipsychotic drugs. We determined through medical record review that 22 percent of such drugs were not administered in accordance with CMS standards for unnecessary drug use in nursing homes and 83 percent of claims for atypical antipsychotic drugs were associated with off-label conditions (diagnoses). For atypical antipsychotic drugs, "off label" conditions would be those other than schizophrenia and/or bipolar disorder.

We found that 88 percent of claims were associated with a diagnosis of dementia, the condition specified by the FDA boxed warning. An "FDA boxed warning" is an alert placed on a drug's packaging to warn prescribers and consumers of severe or life-threatening risks. There is an increased risk of mortality when atypical antipsychotic drugs are used for to treat behavioral disorders in elderly patients with dementia.

Physicians are not prohibited from prescribing drugs for off-label conditions or in the presence of conditions specified in an FDA boxed warning. However, Medicare will pay only for drugs that are

used for medically accepted indications approved by FDA or supported by specified drug compendia.

Unless diagnosis information is required and included on a Part D claim, determining whether a drug was provided for a medically accepted indication is not possible using claims data alone. It is not standard practice for prescribers to provide the diagnosis with the prescription. Hence, absent a medical review, CMS and Part D sponsors are unable to determine whether Part D claims lacking such data meet payment requirements.

Progress of Implementation

In responding to our analysis, CMS said it does not have statutory authority to require physicians to include necessary diagnosis information on prescriptions (which are generally governed by State law) and it cannot distribute compendia information (another type of necessary information) because they are commercially licensed products with licensing agreements. Given that all Part D drugs are affected by these data deficiencies, we encourage CMS to implement the recommendations we specified.

In an October 11, 2011 Medicare Part-D-related proposed rule, CMS announced that it was considering changes to the Conditions of Participation for Long-Term-Care (LTC) Facilities. Citing our May 2011 report, the proposed rule outlined measures to increase beneficiary protections. (76 Fed. Reg. 63018). In the April 12, 2012, final rule with comment period, CMS provided additional information related to Part D drug utilization in long-term-care (LTC) settings. (77 Fed. Reg. 22072.) See provision II.B.5, "Independence of LTC Consultant Pharmacists," p. 22100, column 3, and provision II.E.9., "Medication Therapy Management Comprehensive Medication Reviews and Beneficiaries in LTC Settings," p. 22140.

We encourage CMS to follow through on implementing appropriate protections and address each of our recommendations. We continue to monitor CMS's progress.

Primary OIG Report

2011 MAY *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents.* OEI-07-08-00150. May 2011. [Full Text](#).

See Also

2012 JUL *Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs.* OEI-07-08-00151. [Full text](#).

2011 NOV *Ensuring That Medicare Part D Reimbursement Is Limited to Drugs Provided for Medically Accepted Indications.* OEI-07-08-00152. [Full Text](#).

2001 NOV *Psychotropic Drug Use in Nursing Homes.* OEI-02-00-00490. [Full Text](#).

2001 NOV *Psychotropic Drug Use in Nursing Homes. Supplemental Information – Ten Case Studies.* OEI-02-00-00491. [Full Text](#).

Medicare Cross-Cutting Initiatives

❖ Medicare Parts A, B, C, and D

Medicare Part A/B > Other Management and Systems Issues > Language Access Services

Language Access Services—Increase Medicare Providers’ and Plans’ Implementation of Standards for Culturally and Linguistically Appropriate Services

Recommendations To Be Implemented

We recommend that CMS

- improve Medicare providers’ awareness and implementation of Culturally and Linguistically Appropriate Services in Health Care (CLAS) standards and help providers offer language access services and
- improve Medicare plans’ awareness and implementation of CLAS standards.

We recommend that the HHS Office of Minority Health (OMH)

- collaborate with CMS to inform Medicare plans that they should notify limited-English-proficient (LEP) persons both verbally and in writing of their right to receive language access services,
- increase outreach to providers to familiarize them with CLAS standards, and
- offer model translated written materials and signs to providers.

Implementation would increase beneficiary safety and quality of care.

The recommendations would ensure that language access services are sufficient to promote effective communication between LEP persons and non-LEP persons with regard to CMS programs. Language access services can include oral interpretation, written translation, and other provisions that enhance communication, such as translated signs. Office for Civil Rights (OCR) guidance and OMH’s CLAS standards address the provision of language access services.

Two July 2010 OIG reports revealed the findings of companion reviews (one on Medicare providers and another on Medicare plans) to examine the extent to which they conducted a four-factor assessment recommended by OCR; offered language access services consistent with OMH’s CLAS standards; and reported benefits and encountered obstacles in providing such services.

In our review of Medicare providers, 69 percent of providers conducted the recommended assessment when determining what language access services to offer. However, only 33 percent of providers offered services consistent with all standards for language access services.

In our review of Medicare plans, 88 percent of plans conducted the recommended assessment when determining what language access services to offer. However, a lower percentage (67 percent) of plans offered services consistent with the standards for language access services, largely because Medicare plans did not verbally inform LEP persons of their right to language access services.

Progress of Implementation

For the report on Medicare providers, OCR and OMH concurred with our recommendations, and CMS indicated that it did not have any substantive comments. OMH said that it will develop specific marketing strategies to inform providers of the CLAS standards and will disseminate information through existing CMS communication channels (e.g., listservs, Web sites, and provider partner organizations). OMH has outline a number of steps it is taking to implement our recommendations, and we are in communication with OMH about what specifically remains to be done.

For Medicare plans, CMS and OMH collaboratively drafted a memorandum that was sent to all Medicare Part C and D organizations on December 9, 2010, describing the OMH CLAS standards and indicating how they apply to Part C and Part D organizations. However, the memorandum did not address OIG's specific recommendation to provide both verbal and written notices.

In its December 2011 update, CMS indicated it is developing a script that interpreters will read to non-English speaking callers to Part C and Part D call centers. CMS anticipates this will be in effect during the 2013 enrollment season (fall 2012). CMS also required Medicare Part C and Part D sponsors to include written notifications on their 2012 marketing materials that informed beneficiaries that translations were available for free. CMS's actions are likely to address the pertinent recommendations when fully implemented.

We continue to monitor CMS's and OMH's implementation of the recommendations we specified.

Primary OIG Reports

2010 JULY *Guidance and Standards on Language Access Services – Medicare Providers.*
OEI-05-10-00050. [Full Text.](#)

2010 JULY *Guidance and Standards on Language Access Services – Medicare Plans.*
OEI-05-10-00051. [Full Text.](#)

Medicaid Program

❖ Avoid Wasteful Spending

Wasteful spending occurs when Medicaid's laws, policies, and methodologies fail to ensure that program costs are reasonable and appropriate in the health care marketplace and fail to reflect Medicaid's role as a high-volume, prudent insurer/payer. The Office of Inspector General (OIG) designated avoiding waste in health care pricing methodologies as one of the top management and performance challenges facing the Department of Health and Human Services (HHS) in FY 2012. The recommendations in this section would help curb wasteful spending by modifying current laws, policies, methodologies, systems, and oversight.

OIG's audits and evaluations do not routinely project the annual cost savings that could be realized at program level from implementing the recommendations. However, reports are indicative of the extent to which policies and methodologies may be less than effective and in need of corrective action.

Acronyms and Abbreviations for Selected Terms Used in This Section

AAC—Actual acquisition costs	FFS—fee-for-service
AMP—average manufacturer price	MDRP—Medicaid drug rebate program
DRA—Deficit Reduction Act of 2005	NDC—National Drug Code
FDA—Food and Drug Administration	RAC—Recovery Audit Contractor

Medicaid >Wasteful Spending > Prescription Drugs > Pharmacy Reimbursements

Prescription Drugs—Develop National Pharmacy Acquisition Cost Data as a Benchmark for Reimbursing Prescription Drugs (New)

Recommendations To Be Implemented

We recommend that the Centers for Medicare & Medicaid Services (CMS)

- develop a national benchmark that accurately reflects actual acquisition costs and encourage States to consider it when determining Medicaid reimbursement for prescription drugs and
- enable States to develop different reimbursement benchmarks for single-source drugs, brand-name multiple-source drugs, and generic multiple-source drugs.

Savings probable but not estimated.

The recommendations would reduce wasteful Federal spending by streamlining Medicaid reimbursement systems; providing a transparent basis for payment; and, if appropriately applied, significantly reducing Medicaid payment amounts for prescription drugs.

- A July 2011 OIG report revealed that most Medicaid State agencies (44 of 51) said they would prefer a single national prescription drug benchmark to use in setting their Medicaid reimbursement rates. Twenty-four States specifically wanted a benchmark based on pharmacies' actual acquisition costs.
- An October 2011 OIG report concluded that States could better approximate pharmacies' actual acquisition costs of drugs by developing different reimbursements for single-source drugs, brand-name multiple-source drugs, and generic multiple-source drugs.
- The conclusion mirrors a September 2002 OIG report in which we demonstrated that Medicaid could achieve more accurate alignments between reimbursements and pharmacy acquisition costs by separately evaluating reimbursement levels for multiple tiers of brand-name and generic drugs. OIG issued reports in August 2001 and March 2002 concluding that States could better control costs for drugs if they would develop reimbursement methodologies that were more in line with actual acquisition costs.

Optimally, CMS would make actual acquisition cost data available at the national level for various drug categories that States could use in their drug reimbursement methodologies.

Progress of Implementation

In a February 2012 proposed rule CMS stated: "... in light of the OIG reports concerning published prices (OIG Audit reports A-06-00-00023, A-06-01-00053, A-06-02-00041), we believe it is necessary for States to have a more accurate reference price to base reimbursement for prescription drugs. Therefore, we propose to replace the term, "estimated acquisition cost" with "actual acquisition cost" (AAC)." ([77 Fed. Reg. 5318, 5320](#), column 3, (February 2, 2012).)

As a supporting initiative, CMS's [Survey of Retail Prices](#) will provide State Medicaid agencies with an array of covered outpatient drug prices that are based on acquisition costs and consumer purchase prices that they can use to compare their own pricing methodologies and payments to those derived from the surveys. The Survey of Retail Prices has two parts:

- Part I – Retail Community Pharmacy Consumer Prices. These data will result in National Average Retail Prices (NARP) for Medicaid-covered outpatient drugs.
- Part II – Survey Of Drug Acquisition Costs Paid By Retail Community Pharmacies. These data will result in National Drug Acquisition Costs (NDAC) that may be used as reference prices for States to consider when setting their reimbursement methodologies. The NDACs will reflect data for multiple drug categories, consistent with OIG's recommendations.

We encourage CMS to follow through on the steps it is taking. When the proposed rule is finalized and new reference prices are established and are available to States, we will determine whether our recommendations have been effectively implemented.

Primary OIG Report

2011 July *Replacing Average Wholesale Price: Medicaid Drug Payment Policy.* OEI-03-11-00060. [Full Text](#).

2011 OCT *Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices.* A-06-11-00002. [Full Text](#).

See Also

- 2005 JUN *Variation in State Medicaid Drug Prices*. OEI-05-02-00681. [Full Text](#).
- 2005 JUN *Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices*. OEI-03-05-00110. [Full Text](#).
- 2004 DEC *OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations*. "Medicaid is Paying Too Much for Prescription Drugs." [Testimony](#).
- 2002 SEP *Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products*. A-06-02-00041. [Full Text](#).
- 2002 MAR *Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products*. A-06-01-00053. [Full Text](#).
- 2001 AUG *Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products*. A-06-00-00023. [Full Text](#).
- 2001 JUL *Cost Containment of Medicaid HIV/AIDS Drug Expenditures*. OEI-05-99-00611. [Full Text](#).

Medicaid Wasteful Spending > Prescription Drugs > Monitoring FDA Approval of Drugs

Prescription Drugs—Require Manufacturers To List All Approved Products With the Food and Drug Administration as a Requirement of Medicaid Eligibility

Recommendations To Be Implemented

We recommend that

- the Food and Drug Administration (FDA) work CMS and Congress to compel manufacturers to list all approved products with FDA before the products become eligible for Medicaid payment and
- CMS work with FDA to identify any potentially problematic Medicaid payments for drugs that have not been approved by FDA.

Savings probable but not estimated. We estimated \$20 million quarterly on the basis of an analysis of 2007 fourth-quarter Medicaid expenditures.

The recommendations would help curb the wasteful Medicaid spending that occurs when CMS and States cannot determine from FDA's listings whether drugs are eligible for payment under Medicaid.

With certain exceptions, covered outpatient drugs must be approved by FDA for safety and effectiveness to qualify for Federal payments, including Medicaid.

A November 2010 OIG report highlighted the fact that the National Drug Code (NDC) Directory cannot reliably be used to verify the approval and listing status of drugs paid for under the Medicaid drug rebate program. The report revealed that 38 percent of drugs paid for by Medicaid in 2008, accounting for about 25 percent of total Medicaid expenditures for prescription drugs in 2008, either did not have an approved application number listed with FDA (12 percent) or were not in the FDA's NDC Directory at all (26 percent).

According to FDA, one reason that the NDC Directory is neither fully accurate nor complete is that drug manufacturers do not always submit the required information. Also, the presence of an NDC in the NDC Directory does not always denote approval by FDA.

A July 2009 OIG report revealed that in a manual review of 75 high-expenditure nonmatching NDCs, we identified a potential problem involving unapproved drugs. Medicaid paid \$20 million in the fourth quarter of 2007 for 32 drugs that were not approved by FDA, and Medicaid may have continued to inappropriately pay for the ineligible products beyond that quarter. FDA noted that many health care providers may be prescribing unapproved drugs because they are unaware of the drugs' approval status.

Progress of Implementation

In CMS's 2012 update, it said that it is continuing to work with FDA to identify potentially problematic Medicaid payments for drugs that do not meet the definition of a covered outpatient drug for the purposes of the Medicaid drug rebate program. CMS said that FDA provides it with information on unapproved drugs that may be ineligible for coverage and that CMS reviews the information to determine whether action should be taken to remove these drugs from the list of covered drugs.

The *HHS Budget in Brief* documents for FY 2012 and FY 2013 proposed to require drugs to be properly listed with the FDA in order to receive Medicaid coverage. This proposal aligns Medicaid coverage requirements with Medicare requirements. (Savings were not estimated.)

In February 2012, CMS released a proposed rule revising Medicaid requirements for covered outpatient drugs pursuant to the Affordable Care Act and other authorities. If finalized, the proposed rule would require all drugs to have an NDC and to be electronically listed with FDA before the drugs can be treated as covered outpatient drugs under Medicaid. It would further require that manufacturers submit any relevant, approved FDA application numbers. Such numbers would help CMS obtain information from FDA as to whether a drug has been approved. (77 Fed. Reg. 5318 (February 2, 2012). See p. 5322, column 3.)

We are monitoring CMS's and FDA's progress in implementing the recommendations we specified and CMS's progress in finalizing the proposed rule.

Primary OIG Reports

2010 NOV *FDA's Approval Status of Drugs Paid for by Medicaid*. OEI-03-08-00500. [Full Text](#).

2009 JUL *Accuracy of Drug Categorizations for Medicaid Rebates*. OEI-03-08-00300. [Full Text](#).

See Also

2006 AUG *The Food and Drug Administration's National Drug Code Directory*. OEI-06-05-00060. [Full Text](#).

Medicaid Wasteful Spending > Prescription Drugs > Average Manufacturer Price Issues

Prescriptions Drugs—Clarify and Improve Program Guidance to Drug Manufacturers on Average Manufacturer Price Issues

Recommendations To Be Implemented

We recommend that CMS

- clarify specified terms and the treatment of certain aspects of determining average manufacturer prices (AMP) that we identified,
- address the various industry group concerns about AMP that we reported, and
- encourage States to analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies.

Savings probable but not estimated.

The recommendations would help curb the wasteful Medicaid spending that occurred because guidelines for determining AMPs were not clear and comprehensive and manufacturers' methods for calculating such prices were inconsistent. We continue to monitor this area in light of the progress that is being made.

AMPs are one of the prices are used in calculating manufacturer rebates on drugs purchased through Medicaid. Broadly, AMPs are the average prices paid directly to pharmaceutical manufacturers in the United States by certain purchasers of Medicaid-covered drug products. AMPs are also used in determining the Federal upper limit for reimbursement of generic drugs.

A May 2006 OIG report revealed that the manufacturers we reviewed interpreted AMP requirements differently, ultimately impacting Medicaid rebates. Our findings demonstrated the need to clarify aspects of the definition of AMP and the treatment of pharmacy benefit manager rebates and Medicaid sales in AMP calculations. Industry groups also emphasized the need to clarify certain AMP requirements and raised additional issues related to the implementation of provisions of the Deficit Reduction Act of 2005 (DRA) that made changes to AMP provisions. In addition, the uses of AMP by CMS and other agencies highlighted the need to ensure the timeliness and accuracy of manufacturers reporting AMPs. Our Medicaid reviews in prior years also found issues related to AMPs.

Additional Background >

The May 2006 OIG report was mandated by the DRA, § 6001(c)(3). The DRA also required the Secretary to clarify the requirements for and the manner in which AMPs are determined by promulgating a regulation no later than July 1, 2007, taking into consideration our recommendations.

Many reports of OIG's AMP-related reviews contain proprietary information and are therefore not published on OIG's Web site. A link to the May 2006 report is provided at the end of this section.

Progress of Implementation

Several actions in recent years pertain to the issues we raised in our May 2006 report:

- In July 2007, pursuant to the AMP-related provisions of the DRA of 2005, CMS promulgated a final rule that in part established upper limits for multiple-source drugs and revised the definition of AMP. ([72 Fed. Reg. 39142](#) (July 17, 2007)). However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing it. Subsequently, CMS published a final rule to withdraw those parts of the 2007 final rule that revised the definition of AMP and that established upper limits for multiple-source drugs. ([75 Fed. Reg. 69591](#) (November 15, 2010).)
- The Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), [§ 2503](#), revised the definition of AMP effective October 1, 2010, eliminating a key term that was subject to inconsistent interpretations. It specified the entities that drug manufacturers are to include and exclude from the determination of AMP and clarified the treatment of discounts and other incentives. It also established the use of monthly AMP data in determining Federal upper limits for reimbursing multiple-source drugs.
- In 2010 and 2011, CMS issued three [Medicaid Drug Rebate Program releases](#) for participating drug manufacturers: Release No. 83 to provide guidance on the AMP process for calculating monthly AMP, Release No. 81 to remind manufacturers that they are required to report pricing information to CMS on a timely basis, and Release No. 80 to provide guidance on AMP and best-price recalculations.
- In February 2012, CMS published a proposed rule revising regulations for Medicaid requirements for covered outpatient drugs. The rule includes the Affordable Care Act changes involving the definition of AMP and addresses retail community pharmacies; base date AMP recalculations; AMP smoothing; and other AMP-related policies, including enforcement of manufacturers' monthly reporting of AMPs. ([77 Fed. Reg. 5318](#) (February 2, 2012).)

The recommendations and concerns described in our May 2006 report remain open pending CMS's implementation of legislative and regulatory clarifications and changes and whether manufacturers implement consistent methods to calculate AMPs.

Primary OIG Reports

2006 MAY *Determining Average Manufacturers Prices for Prescription Drugs Under the Deficit Reduction Act of 2005*. A-06-06-00063. [Full Text](#).

See Also

2010 SEP *Drug Manufacturers' Noncompliance With Average Manufacturer Price Reporting Requirements*. OEI-03-09-00060. [Full Text](#).

2010 SEP *Special Advisory Bulletin—Average Manufacturer Price and Average Sales Price Reporting Requirements*. [Full Text](#).

Medicaid Wasteful Spending > Prescription Drugs > Drug Payments and Rebates

Prescription Drugs—Establish a Connection Between the Calculations of Medicaid Drug Reimbursements and Rebates

Recommendations To Be Implemented

We recommend that CMS

- seek legislation that would require Medicaid drug rebates and reimbursements to be developed using the same basis or
- review viable alternatives to the current program.

Savings probable but not estimated.

The recommendations would help curb the wasteful Medicaid spending that occurs because of an inconsistency between the key values used for calculating reimbursements and rebates. When a State increases its reimbursements for a drug, it does not receive a correspondingly higher rebate on that drug purchase because there is no connection between the reimbursement and rebate calculations.

A May 1998 OIG report noted that legislation was needed to establish the connection. Medicaid requires that rebates be based on a specifically designated value, AMP, while, at the same time, allowing reimbursements to be calculated using other, estimated values (historically, a discounted average wholesale price (AWP)). This creates a situation whereby fluctuations in reimbursements do not result in a corresponding adjustment in the associated rebates. The inconsistency between the key values used for calculating rebates and reimbursements causes wasteful spending for drugs.

The 1998 report analyzed a scenario using AWP in calculating both reimbursements and rebates (i.e., AWP/AWP), and the principle applies to other matching alignments as well. For example, given that AWP is no longer the preferred basis for States' drug reimbursements, another combination could be established, e.g., AMP/AMP.

Progress of Implementation

The Deficit Reduction Act of 2005 (DRA), § 6001, amended the Social Security Act to require that CMS provide States with AMP data that would have provided States with a new pricing source for establishing acquisition costs. CMS promulgated a corresponding final rule. However, a Federal injunction prohibited its implementation. Subsequent changes in law and regulations have not established the necessary connection between rebates and payments.

The Affordable Care Act, § 2503(b), modified the DRA requirement in a way that may limit the availability of AMP information for establishing an AMP/AMP connection.

We remain concerned that until all States use the same basis in their rebate and reimbursement formulas, fluctuations in reimbursements will not result in corresponding adjustments to the associated rebates. We continue to monitor this issue.

Primary OIG Report

1998 MAY *Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs.* A-06-97-00052. [Full Text](#).

See Also

2006 MAY *Determining Average Manufacturers Prices for Prescription Drugs Under the Deficit Reduction Act of 2005.* A-06-06-00063. [Full Text](#).

2004 DEC OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations – “Medicaid is Paying Too Much for Prescription Drugs.” [Testimony](#).

Medicaid > Wasteful Spending > Prescription Drugs > Physician Administered Drugs

Prescription Drugs—Ensure That States Are Accurately Identifying and Collecting Rebates on Physician-Administered Drugs (New)

Recommendations To Be Implemented

We recommend that CMS

- ensure that all States are accurately identifying and collecting rebates owed by manufacturers for these drugs,
- work with States to develop guidance for implementing system edits that increase the efficiency of physician-administered drug claim reviews,
- work with States to administer guidance to providers and Medicare contractors about the physician-administered drug rebate requirements,
- ensure that the crosswalk file (a CMS data file that links two types of commonly used drug codes) is complete and accurate and identifies rebateable physician-administered drugs, and
- take action against States that do not meet statutory requirements to collect rebates on physician-administered drugs.

Savings probable but not estimated.

The recommendations would reduce the wasteful Medicaid spending that occurs when States do not collect manufacturer rebates on physician-administered drugs. Federal law requires that for Federal matching funds to be available for certain physician-administered drugs, States must collect manufacturer rebates for the drugs.

A June 2011 OIG report revealed that 73 percent of 49 responding states self-reported that they met or exceeded Federal requirements to collect rebates for certain physician-administered drugs; however, 29 states reported difficulties with manufacturer nonpayment of rebates for the drugs. The States attributed the difficulty mainly to inaccuracies in the drug code information that providers entered on claims. Because of incomplete and potentially inaccurate data provided by States, we were unable to calculate the total rebate dollars all States collected for physician-administered drugs and, therefore, could not determine the impact that collecting such rebates had on reducing prescription drug expenditures.

CMS creates a quarterly crosswalk file that links drugs' Healthcare Common Procedure Coding System (HCPCS) codes to their applicable National Drug Codes (NDC). Unlike the NDC, the HCPCS code does not identify the manufacturer responsible for paying a rebate. States that described issues with the crosswalk file used the file either to identify the NDC or to validate the NDC information on the claim. The States expressed concern with the accuracy and completeness of the data, as well as the file's usefulness for identifying and crosswalking rebateable physician-administered drugs. The States mentioned that an official crosswalk that contains accurate and up-to-date information for physician-administered drugs would make rebate collections more efficient and timely.

Additional Background >

An April 2001 OIG report found that only 17 States collected rebates from manufacturers for physician-administered drugs in 2001. Partly on the basis of this work, the DRA required that States collect rebates on all claims for certain physician-administered drugs for matching Federal funds to be available. The DRA also mandated that claims for physician-administered drugs include NDCs, a type of code that identifies a drug's manufacturer, thereby enabling States to invoice manufacturers responsible for paying rebates.

Progress of Implementation

In responding to our review, CMS said it would reiterate the DRA rebate requirements in a release to States, as well as provide technical assistance. CMS said that if a State does not meet these rebate requirements, it may consider withholding Federal matching funds in the future, although CMS anticipates its additional assistance will make such actions unnecessary.

CMS generally considers direct provider communication to be within the States' purview. Therefore, CMS has left this responsibility to the States. CMS maintains that Medicare contractors are aware of these requirements and have established procedures to accept NDCs on crossover claims. CMS also said that the DRA's NDC requirements render this file unnecessary. However, our findings show that the crosswalk file is still being relied upon by certain States. Therefore, we continue to recommend that CMS ensure that States have access to a reliable crosswalk file.

In its 2012 update, CMS indicated it will continue to monitor and meet with States to encourage accurate identification and collection of rebates for physician-administered drugs.

In February 2012, CMS released a proposed rule revising Medicaid requirements for covered outpatient drugs. The proposed rule states that no Federal financial participation (FFP) is available for physician-administered drugs for which a State has not required the submission of claims using

codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates. ([77 Fed. Reg. 5318](#) (February 2, 2012. See p. [5367](#), column 2.)

We encourage CMS to address each recommendation we specified and finalize its rule withholding FFP for insufficiently documented claims. We continue to monitor CMS's progress.

Primary OIG Report

2011 JUN *States' Collection of Medicaid Rebates for Physician-Administered Drugs.* OEI-03-09-00410. [Full Text](#).

See Also

2011 AUG *Nationwide Rollup Report for Medicaid Drug Rebate Collections.* A-06-10-00011. [Full Text](#).

2004 APRIL *Medicaid Rebates for Physician-Administered Drugs.* OEI-03-02-00660. [Full Text](#).

2005 JUL *Multistate Review of Medicaid Drug Rebate Programs.* A-06-03-00048. [Full Text](#).

Medicaid Wasteful Spending > Prescription Drugs > Generic Drugs > Additional Rebates

Prescriptions Drug Rebates—Extend the Additional Rebate Payment Provisions for Brand-Name Drugs to Generic Drugs

Recommendation To Be Implemented

- We recommend that CMS seek legislative authority to extend the additional rebate provisions for brand-name drugs to generic drugs.

Savings probable but not estimated. An August 2011 OIG report estimated that rebates reduced Medicaid's expenditures for selected generic drugs by only 3 percent in 2009 (\$13.5 million out of \$449 million) compared to 45 percent for selected brand-name drugs.

The recommendation would help curb the potentially wasteful Medicaid spending that occurs because additional rebates available for brand-name drugs do not similarly apply to generic drugs.

Rebates for brand-name drugs (those still under patent or those once covered by patents) have two components: a basic rebate and an additional rebate. Manufacturers pay an additional rebate when the AMP for a brand-name drug increases more than a specified inflation factor. (Social Security Act, § 1927(c)(2).) Generally, the amount of the additional rebate is based on the amount that the drug's reported AMP exceeds its inflation-adjusted baseline AMP. Manufacturers pay the additional rebate for each unit of the drug reimbursed by Medicaid.

An October 2007 OIG report estimated that by applying the statutory method for calculating additional rebates for brand-name drugs to generic drugs, the Medicaid program would have received \$966 million in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004.

Additional Background >

OIG subsequently collected data in a review of rebates in 2009. An August 2011 OIG report of the review revealed that 55 percent of the total Medicaid rebates owed for 100 selected brand-name drugs in 2009 were owed because manufacturers paid the additional inflation-based rebates along with basic rebates. Total rebates reduced Medicaid's expenditures for the 100 selected brand-name drugs by 45 percent (\$2.9 billion out of \$6.4 billion). Rebates reduced Medicaid's expenditures for selected generic drugs by only 3 percent in 2009 (\$13.5 million out of \$449 million).

Progress of Implementation

In responding to our review, CMS said that it considers all improvements to the Medicaid drug rebate program, including seeking legislative change when CMS believes it is appropriate.

CMS noted that the Affordable Care Act, [§ 2501](#), increased the rebate amounts and formulas for brand-name and generic drugs effective January 1, 2010.

We continue to recommend that CMS align rebate policies for generic drugs with rebate policies for brand-name drugs.

Primary OIG Report

2007 OCT *Review of Generic Drug Price Increases*. A-06-07-00042. [Full Text](#).

See Also

2011 AUG *Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D*. OEI-03-10-00320. [Full Text](#).

Medicaid > Wasteful Spending > Prescription Drugs > 340B Discount Drug Program

Prescription Drugs—Improve the Policies and Information Available for State Medicaid Agencies To Oversee Reimbursements for 340B-Purchased Drugs (New)

Recommendations To Be Implemented

We recommend

- that CMS direct State Medicaid Agencies to create written policies for how covered entities are to bill Medicaid for the drugs they purchased at a discount pursuant to the Public Health Service Act, § 340B, prescription drug discount program (340B program);
- that CMS inform States about tools they can use to identify claims for 340B-purchased drugs; and
- that the Health Resources and Services Administration (HRSA) share 340B ceiling prices with States.

Savings probable but not estimated.

The recommendations would reduce the wasteful spending that occurs when State Medicaid agencies overpay for drugs purchased pursuant to the 340B program because States lack definitive billing policies for covered entities, cannot effectively identify 340B-related claims, lack access to 340B ceiling prices, and therefore cannot establish necessary prepayment system edits.

The 340B program requires drug manufacturers to provide covered outpatient drugs to certain eligible health care entities (safety-net entities) at or below statutorily defined discount prices. Such entities include eligible community health centers, critical access hospitals, and children's hospitals. The entities bill Medicaid for reimbursement of the drugs they provide to Medicaid patients.

A June 2011 OIG report revealed that HRSA's guidance directs covered entities to follow States' 340B policies, but about half of the State Medicaid agencies (25 of 51) did not have written policies for how 340B-covered entities are to bill Medicaid for reimbursement. Without written policies, covered entities may not know how States expect them to bill Medicaid.

We also found that States did not effectively identify claims by covered entities that dispense 340B-purchased drugs to Medicaid patients. States need to identify 340B claims so they do not subject drug manufacturers to duplicate discounts by including 340B claims in utilization data submitted for Medicaid rebates. Conversely, States may inappropriately forgo rebates they are owed by manufacturers if the incorrectly exclude non-340B claims from their utilization data. CMS should inform States of various options for identifying 340B-purchased drugs.

We found that State Medicaid agencies do not have the 340B pricing information they need to create prepayment edits to prevent overpaying 340B-purchased drugs. They do not have 340B ceiling prices because the prices are calculated using AMP, to which States historically have not had access. Without prepay edits, States reimburse 340B-purchased drugs at the amounts that covered entities bill—which may be above 340B prices. HRSA should provide ceiling prices to State Medicaid agencies.

Additional Background >

- The Affordable Care Act, [§ 7102](#), requires the Secretary to improve covered entities' compliance with 340B by developing more detailed guidance describing methodologies and options available to covered entities for billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts. However, it did not require the development of State-specific policies for billing of 340B-purchased drugs. HRSA's directive that covered entities follow State policies is still in effect.
- Section [7102](#) also provides for covered entities to access the applicable ceiling prices for covered drugs. However, it did not provide for State Medicaid agencies to access such data.

Progress of Implementation

In responding to our review, CMS concurred with our recommendations and outlined steps it will take to implement them. However, we have not received documentation that the actions were taken.

In a December 2011 update, HRSA indicated that because of statutory limitations, it is not able to implement the recommendation to share 304B ceiling prices with States. It did not indicate whether it intends to seek the authority it needs.

We continue to monitor CMS's and HRSA's implementation of the recommendations we specified.

Primary OIG Report

2011 JUN *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs.*
OEI-05-09-00321. [Full Text](#).

See Also

2005 DEC OIG Testimony Before the House Committee on Energy and Commerce,
Subcommittee on Oversight and Investigations: "340B Program." [Testimony](#)

Medicaid Wasteful Spending > Enhanced Payments to Public Providers

Payments to Public Providers—Limit Medicaid Payments to Costs and Require That Payments Returned by Public Providers Be Used To Offset the Federal Share

Recommendations To Be Implemented

We recommend that CMS

- issue definitive guidance for calculating enhanced payment limits, which should include using facility-specific limits that are based on actual cost report data (with the effect of limiting enhanced payments to cost) and
- require that returns of Medicaid payments by a county or local government to the State be declared refunds of those payments and thus be used to offset the Federal share generated by the original payments.

Savings – A January 2007 proposed rule that effectively addressed our concerns was estimated to result in \$120 million in savings during the first year and \$3.87 billion in savings over five years; however the final rule was vacated and withdrawn. A May 2012 OIG report of a review of 15 State-owned facilities revealed that \$700 million in Federal savings could have been achieved in State fiscal year 2009 had the State used actual costs as the starting point in its rate methodology for those facilities.

The recommendations would help curb the wasteful Federal spending that occurs when States claim Federal reimbursement for Medicaid payments to public providers and such payments are not used in accordance with their intended purpose or do not comply with the Federal requirement that that payments be consistent with economy and efficiency.

A September 2001 OIG report revealed that for seven enhanced payment programs in six States, the enhanced payments to local government-owned providers were not based on the actual cost of providing services to Medicaid beneficiaries. Enhanced payments are in addition to the basic payment rates for Medicaid providers. We did not find a direct relationship in the use of these funds to increase the quality of care provided by the public facilities.

Medicaid permits States to provide enhanced payments, which qualify for Federal reimbursement, to non-State-owned government providers, such as county or local publically owned nursing facilities and hospitals. All Medicaid payments for care and services are required to be consistent with efficiency, economy, and quality of care. Essentially, funds are to be used to pay for daily needs of Medicaid beneficiaries in nursing facilities for medical services and room and board expenses for food and for personnel salaries, etc.

We found that some or most of the funds were transferred back to the States for other uses. Some of the funds transferred back to the State governments were earmarked for use in health-care-related service areas but not necessarily for Medicaid-covered services approved in the State plans.

For the portion of the enhanced payments that was returned to the States, it appeared that the States did not incur a health care expenditure for which Federal matching funds were claimed. This condition calls into question whether the amounts returned to the State agencies constitute a refund required to be reported as other collections and consequently to be offset against expenditures reported to CMS. As is, State agencies have developed mechanisms to obtain Federal Medicaid funds without committing the States' share of required matching funds.

Such practices limit the ability of Congress, HHS, and State and local governments to manage, account for, and assess the public benefits of Medicaid dollars.

Additional Background >

OIG reports issued in 2004 and 2005 revealed that substantial portions of enhanced payments directed to local-government-owned nursing facilities were returned to the States, leaving the facilities underfunded. All the nursing facilities we reviewed had been identified by State survey and certification reviewers as having serious deficiencies in patient care. For more detail on enhanced payments and related vulnerabilities, see [OIG testimony](#), June 2005, and the reports listed under "See Also" at the end of this section.

A May 2012 OIG report of a review in one State (New York) revealed misalignments of costs and payments with regard to State-operated Intermediate Care Facilities (ICF) for individuals with intellectual and developmental disabilities (developmental centers). The Federal Government might have saved over \$700 million in reimbursements in State FY (SFY) 2009 for the 15 selected State-operated developmental centers had the State used prior year actual costs as the starting point in its rate methodology instead of its current method in calculating the daily rate. We concluded that New York may not have met the Federal requirement that payments be consistent with economy and efficiency. The daily rate for Medicaid beneficiaries to reside in the selected developmental centers grew from \$195 per day in SFY 1985 to \$4,116 per day in SFY 2009, which is the equivalent of \$1.5 million per year for one Medicaid beneficiary. The developmental center rate was more than nine times the average rate for all other State-operated and privately operated ICFs in New York in SFY 2009.

Progress of Implementation

Several actions in recent years pertain to the issues we raised in our September 2001 report:

- On January 18, 2007, CMS published a proposed rule at [72 Fed. Reg. 2236](#) that proposed to "clarify the documentation required to support a certified public expenditure; limit reimbursement for health care providers that are operated by units of government to an amount that does not exceed the provider's cost; [and] require providers to receive and retain the full amount of total computable payments for services furnished under the approved State plan" Savings were estimated to result in \$120 million during the first year and \$3.87 billion over five years ([p. 2244](#)).
- However, effective May 25, 2007, the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, § 7002, prohibited implementation of CMS's proposed rule for 1 year following the date of the law's enactment.
- On May 29, 2007, CMS published a Final Rule With Comment Period at [72 Fed. Reg. 29748](#) that modified Medicaid reimbursement consistent with our recommendations.

- However, on May 23, 2008, the U.S. District Court for the District of Columbia found that the Department of Health and Human Services (HHS) had violated the Congressional moratorium on finalization of the regulation, vacated the rule, and remanded the matter to HHS.
- The American Recovery and Reinvestment Act of 2009 (Recovery Act), § 5003(d)(1), provided that it was the sense of Congress that the Secretary of HHS should not promulgate the regulation.
- Accordingly, CMS formally withdrew the final rule. (75 Fed. Reg 73972 (November 30, 2010).)
- CMS informed OIG that in 2010 it initiated enhanced reporting capability within the Form CMS-64 report to require quarterly reporting of supplemental payments.
- The HHS *Budget in Brief* documents for FY 2012 and FY 2013 proposed to prevent States from using Federal funds to pay the State share of Medicaid or CHIP unless specifically authorized under law to match Medicaid or CHIP funds (savings not estimated). (p. 63.)

In its 2012 update, CMS said that through the State plan amendment review process, CMS asks States to identify the funding source of the non-Federal share and to indicate whether providers retain their payments.

We continue to monitor CMS's progress toward limiting payments to public providers to cost and requiring that Medicaid payments returned by public providers be used to offset the Federal share.

Primary OIG Report

2001 SEP *Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers.* A-03-00-00216. [Full Text](#).

See Also

2012 SEP Office of Inspector General Testimony Before the House Committee on Oversight and Government Reform. *Examining the Administration's Failure To Prevent and End Medicaid Overpayments.* [Testimony](#).

2012 MAY *Medicaid Rates for New York State-Operated Developmental Centers May Be Excessive.* A-02-11-01029. [Full Text](#).

2005 JUN Office of Inspector General Testimony Before the Senate Committee on Finance. *Financing Mechanisms To Shift the Cost of Medicaid to the Federal Government Contrary to Federal and State Sharing Formulas.* [Testimony](#).

2005 APR *Adequacy of New York State's Medicaid Payments to A. Holly Patterson Extended Care Facility.* A-02-03-01004. [Full Text](#).

2005 MAR *Adequacy of Washington State's Payments to Newport Community Hospital, Long Term Care Unit.* A-10-04-00001. [Full Text](#).

2005 MAR *Adequacy of Tennessee's Medicaid Payments to Nashville Metropolitan Bordeaux Hospital, Long-Term Care Unit.* A-04-03-03023. [Full Text](#).

2004 JUN *Adequacy of Medicaid Payments to Albany County Nursing Home.* A-02-02-01020. [Full Text](#).

More > *North Carolina.* [A-04-00-00140](#). *Alabama.* [A-04-00-02169](#). *Illinois.* [A-05-00-00056](#).

Washington State. [A-10-00-00011](#). Pennsylvania. [A-03-00-00203](#). Nebraska. [A-07-00-02076](#). Alabama. [A-04-00-02165](#).

Medicaid Wasteful Spending > Uncollected Refunds > System Support for Monitoring Credit Balances

Uncollected Refunds—Establish a National Medicaid Credit Balance Reporting Mechanism To Monitor Refundable Amounts in Providers' Patient Accounts

Recommendations To Be Implemented

We recommend that CMS

- establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A and
- require its regional offices to actively monitor the reporting mechanism that is established.

Savings probable but not estimated.

The recommendations would help curb the wasteful Medicaid spending that occurs because CMS does not require States to routinely monitor providers' efforts to identify and refund credit balances in Medicaid patient accounts.

Credit balances generally occur when the reimbursement that a provider receives for services provided to a Medicaid beneficiary exceeds the charges billed, such as when a provider receives a duplicate payment for the same service from the Medicaid program or a third-party payer, such as Medicare. Medicaid is generally the payer of last resort. Credit balances could indicate that the some or all of the payments a State made to the provider on behalf of a Medicaid patient should be refunded to the State.

OIG reports issued in March 1993 and May 1995 revealed that significant outstanding Medicaid credit balances existed nationwide. We reported that many State agencies' efforts were inadequate to ensure that providers were identifying the majority of credit balances in Medicaid patient accounts and determining any amounts that should be refunded to the State in a timely manner.

Progress of Implementation

CMS decided not to establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A, citing uncertain or minimal savings potential, the Administration's commitment to enhancing States' flexibility, and avoiding the imposition of an unfunded mandate.

In 2010, CMS described actions it had taken to update and issue its financial management review guide addressing Medicaid provider overpayments, to develop an annual work plan for reviewing high-risk financial management areas, and to establish overpayment reporting mechanisms in the

CMS-64 quarterly expenditure reports. CMS also stated that Medicaid Integrity Contractors (MIC) and Recovery Audit Contractors (RAC) for Medicaid are charged with identifying and recovering Medicaid overpayments to providers.

We continue to recommend that CMS establish a national Medicaid credit balance reporting mechanism and require its regional offices to monitor reporting. We are pursuing audit work in the Medicaid credit balance area to update our work.

Primary OIG Reports

1995 MAY *Quarterly Credit Balance Reporting Requirements for Medicaid.* A-05-93-00107. [Full Text.](#)

1993 MAR *Nationwide Audit of Medicaid Credit Balances.* A-04-92-01023. [Full Text.](#)

See Also

Reviews of Medicaid Credit Balances at Various Providers:

2011 SEP A-04-10-04007. [Full Text.](#)

2011 JUN A-09-11-02000. [Full Text.](#)

2010 JUL A-09-09-00106. [Full Text.](#)

2010 MAY A-06-09-00102. [Full Text.](#)

2010 APR A-09-09-00107. [Full Text.](#)

2009 NOV A-09-09-00090. [Full Text.](#)

2009 NOV A-09-09-00078. [Full Text.](#)

2009 AUG A-09-09-00077. [Full Text.](#)

2009 AUG A-09-09-00073. [Full Text.](#)

2009 AUG A-09-09-00072. [Full Text.](#)

2009 JUL A-07-09-02756. [Full Text.](#)

2009 JUL A-07-09-02755. [Full Text.](#)

2009 JUL A-07-09-02751. [Full Text.](#)

2009 JUN A-09-09-00079. [Full Text.](#)

Medicaid > Wasteful Spending > Third-Party Liability for Payment

Third-Party Liability—Ensure That States Collect From Noncustodial Parents With the Ability To Contribute Toward Their Children’s Medicaid or Children’s Health Insurance Program (CHIP) Costs

Recommendations To Be Implemented

We recommend that CMS

- clarify third-party liability regulations to help State Medicaid agencies coordinate with States’ child support enforcement programs to collect Medicaid costs from noncustodial parents with the ability to contribute medical support;
- seek legislation that would allow States to accumulate medical support payments to offset Medicaid fee-for-service (FFS) costs for a reasonable period;
- determine whether more Federal funds are needed to help States interface their databases;
- implement a process to collect program costs from noncustodial parents; and
- as appropriate, provide funds for this purpose.

Savings probable but not estimated. On the basis of two 8-State reviews, we estimated \$99 million for Medicaid and \$14 million for CHIP for the selected States over 2 years.

The recommendations would help curb the wasteful Medicaid spending that occurs because State child support enforcement (CSE) agencies fail to collect Medicaid costs from noncustodial parents who have the financial ability to pay.

Medicaid regulations do not address how State Medicaid agencies should coordinate with CSE agencies or how the States should establish and administer Medicaid FFS recoveries.

Two OIG reports issued in May and June 2005 summarized reviews of the ability of noncustodial parents to contribute toward the medical costs of their Medicaid-eligible children. Using the most recent data available from each State in 2001 or 2002, we estimated that Title IV-D children who were enrolled in Medicaid had noncustodial parents who were financially able to contribute \$99 million. Children who received CHIP benefits had noncustodial parents who could potentially contribute \$14 million toward the CHIP premiums.

Additional Background >

- Unless the custodial parent and children already have satisfactory health insurance other than Medicaid, Federal regulations require State agencies operating child support enforcement programs pursuant to Title IV-D of the Social Security Act to petition the court or administrative authority to include health insurance that is available to the noncustodial parent at reasonable cost in new or modified orders for support.

- Title XXI of the Social Security Act, which authorizes CHIP, is silent with regard to collecting CHIP costs from noncustodial parents. Although some States have taken steps to collect CHIP costs from noncustodial parents, others have questioned their authority to do so or expressed concern about the costs that would be incurred.

Progress of Implementation

CMS agreed to work toward drafting legislation to allow States to accumulate medical support payments because Federal laws and regulations prohibit States from accumulating additional medical support payments. The *HHS Budget in Brief for FY 2013* proposed to allow States to collect medical child support where health insurance is available from a noncustodial parent. CMS's responses to the recommendations included the following.

- CMS agreed to alert States to their option to pursue the Federal and State shares of these costs.
- Subsequently, CMS told us that it had provided guidance to States on the collection of Medicaid costs from available employer-sponsored health care coverage of noncustodial parents and on their authority under Federal law to collect CHIP costs from noncustodial parents.

CMS noted that States had the authority to fund the administrative costs of building an infrastructure with the State child support enforcement agency under their 10-percent administrative CHIP cap and recognized that there is no mechanism in CHIP to provide States with more funding if they spend funds up to the cap.

We encourage CMS to follow through on its efforts to ensure that States appropriately collect from noncustodial parents for the health care costs of Medicaid- and CHIP-eligible children. We continue to recommend that CMS consider alternatives to ensure that States receive adequate funds, especially if States are at or near their 10-percent administrative cap.

Primary OIG Reports

- 2005 JUN *Eight-State Review of the Ability of Noncustodial Parents To Contribute Toward the Medical Costs of Title IV-D Children That Were Paid Under the Medicaid Program.* A-01-03-02501. [Full Text.](#)
- 2005 MAY *Eight-State Review of the Ability of Noncustodial Parents To Contribute Toward the Medical Costs of Title IV-D Children Under the State Children's Health Insurance Program.* A-01-03-02502. [Full Text.](#)

Medicaid > Wasteful Spending > Hospitals > Inpatient Outlier Payments

Hospital Payments—Encourage States To Update Hospital Outlier Payment Methodologies (New)

Recommendations To Be Implemented

We recommend that CMS encourage all States that make Medicaid outlier payments to

- use the most recent cost-to-charge ratios to calculate Medicaid outlier payments,
- reconcile Medicaid outlier payments upon cost report settlement or use an alternative method to ensure that outlier payments are more closely aligned with actual costs, and
- amend their State plans accordingly.

Savings probable but not estimated.

The recommendations would reduce the wasteful Medicaid spending that occurs when States miscalculate outlier payments. To protect hospitals against large financial losses from extraordinarily high-cost cases, State agencies may supplement base payments with an additional “outlier” payment.

A July 2011 OIG report revealed that eight State agencies we reviewed did not calculate Medicaid inpatient hospital cost outlier payments in a way that would effectively limit such payments to extraordinarily high-cost cases. Medicaid outlier payments are calculated using formulas that vary by State. The States we reviewed used outdated cost-to-charge ratios and did not reconcile Medicaid outlier payments upon settlement of cost reports. We estimated that if the eight States had used the most recent cost reports to calculate the cost-to-charge ratios, they could have, between FYs 2004 and 2006, more effectively limited the payments to extraordinarily high-cost cases, thereby reducing Medicaid outlier payments by \$320 million.

The review is a followup to similar audits we conducted in 2004.

Medicaid outlier payments increased from approximately \$913 million in FY 2004 to approximately \$1.2 billion in FY 2006. During this period, Medicaid outlier payments increased substantially faster than Medicaid diagnosis review group base payments and Medicare outlier payments.

Progress of Implementation

CMS agreed that reconciliation would better align outlier payments to the costs incurred by hospitals but added that “... it is more appropriate to defer to States and let them determine what changes, if any, are appropriate.” CMS also stated that two of the audited states, Pennsylvania and Illinois, have proposed to revise outlier payment methodologies. Illinois’ proposed State plan amendment would increase the threshold for designating a case as an outlier. Pennsylvania’s

proposed State plan amendment would make adjustments to the way the State calculates its outlier payments. Both States report a decrease in expenditures related to these proposed amendments.

CMS intends to issue informational guidance to all States that outlines the findings and encourages States to review existing outlier payment methodologies. This guidance may also include options for States interested in revising their outlier payment methodologies.

We encourage CMS to follow through on its plan to issue guidance to States. We will continue to monitor the progress of implementation.

Primary OIG Report

2011 JUL *Medicaid Hospital Outlier Payment Followup for Fiscal Years 2004 Through 2006.*
A-07-10-04160. [Full Text.](#))

Medicaid Wasteful Spending > Adult Day Health Services

Adult Day Health Settings—Ensure That Services Provided Qualify for Medicaid Reimbursement (New)

Recommendations To Be Implemented

We recommend that CMS

- specify what minimum services are required to qualify for Medicaid reimbursement of adult day health services,
- direct States to enforce supervision requirements for staff who provide therapy services in Medicaid adult day health centers, and
- take appropriate action with regard to the adult day health centers that did not respond to repeated data requests.

Savings probable but not estimated.

The first recommendation would help curb the wasteful Medicaid spending that occurs when CMS lacks clear standards and information to determine whether services billed by adult day health providers are eligible for Federal reimbursement under Medicaid.

The second recommendation would help reduce the patient safety and quality-of-care vulnerabilities that occur when therapy services provided in an adult day health setting do not meet the States' supervision and qualifications requirements.

Adult day health centers provide outpatient health, therapeutic, and social services and activities. Within broad Federal Medicaid requirements, individual States establish the specific requirements that must be met for Medicaid reimbursement of adult day health services.

Federal and State reviews have identified questionable billings and vulnerabilities in the reimbursement systems, which vary between States. CMS and State Medicaid agencies often do not receive information from providers about the individual services being provided.

A July 2011 OIG report summarized a review of 12 State Medicaid programs that allow nursing- and therapy-focused adult day health services as a State plan benefit. For the last 6 months of 2007, we found that on 40 percent of service days paid for by Medicaid, beneficiaries received no documented health services. (We defined health services as nursing or therapy services.) However, most States do not require that beneficiaries receive a health service each day in an adult day health setting. On 86 percent of the Medicaid-paid service days on which there were no documented health services, meals and/or snacks were the only documented services provided.

CMS does not have any standard definition or guidance as to what constitutes a health service for adult day care. Clear delineation as to what services are required for Medicaid reimbursement of adult day health services would ensure that CMS pays a Federal share only for the services necessary to deliver quality care to beneficiaries.

Also, OIG found that approximately 43 percent of the therapy services we reviewed were provided by staff members who lacked the supervision required under the States' laws or regulations. Therapy services on sampled service dates sometimes lacked documentation about who actually provided the services. Insufficiently supervised therapy services could undermine quality of care.

Additional Background >

- In general, adult day health services must be ordered or requested by a physician or other medical practitioner, correspond with the patient assessment and plan of care, be rendered by staff whose qualifications and/or supervision meet State licensing requirements, and be supported by appropriate documentation. In addition to providing health services, adult day health centers also generally provide meals, assistance with activities of daily living, social and recreational activities, and transportation to and from the center.
- Eligibility may be for a limited period to address a rehabilitative goal or for many years to address a chronic health issue.
- Although States have established requirements for services (such as adult day health) that are covered under the rehabilitative benefit, there are no explicit Federal requirements concerning the types of services that are eligible for Medicaid reimbursement. CMS issued a proposed rule on Medicaid coverage for rehabilitative services on August 13, 2007, but withdrew it in November 2009. ([72 Fed. Reg. 45201](#) (August 13, 2007).)

Progress of Implementation

In its [response](#) to our review, CMS outlined several steps it planned to take to implement our recommendations. We encourage CMS to follow through on its planned actions and provide evidence of such actions to OIG. We continue to monitor CMS's progress on implementing the recommendations we specified.

Primary OIG Report

2011 JUL *Medicaid Services Provided in an Adult Day Health Setting.* OEI-09-07-00500.
[Full Text.](#)

❖ Identify and Reduce Improper Payments

Medicaid improper payments are commonly associated with claims-based or claims-processing-based deficiencies. Improper payments, which cost Federal programs billions of dollars annually, are payments that should not have been made or that were made in incorrect amounts and include overpayments and underpayments.

The Federal Government reimburses States on the basis of the State's Medicaid expenditures and other approved costs. However, States do not always effectively identify and reduce erroneous and inappropriate billing by providers and suppliers prior to submitting the amounts to CMS for Federal reimbursement. For claims deemed to be inappropriate, the items or services reflected on bills are not supported by the documentation in the providers' medical files, are not medically necessary, may have administrative or policy errors, or do not meet other Federal and State requirements.

OIG's audits and evaluations do not routinely project the annual cost savings that could be realized at program level from implementing the recommendations. However, reports are indicative of the extent to which policies and methodologies may be less than effective and in need of corrective action.

Acronyms and Abbreviations for Selected Terms Used in This Section

CMS—Centers for Medicare & Medicaid Services

PPS—prospective payment system

DOJ—Department of Justice

PCS—personal care services

IDEA—Individuals With Disabilities Education Act

Medicaid Improper Payments > School-Based Health Services

School-Based Health Services—Ensure Compliance With Medicaid Requirements

Recommendations To Be Implemented

We recommend that CMS ensure that States

- disseminate CMS guidance and other information to the local education agencies in a timely manner,
- monitor local education agencies to ensure compliance with Federal and State requirements, and
- help local education agencies develop written policies and procedures that require service providers to document all pertinent health services and retain those records for review.

Savings probable but not estimated.

The recommendations would help prevent the improper Federal Medicaid payments that occur when States claim reimbursement for school-based services that were not provided or failed to comply with Federal and State standards.

In a number of reviews conducted from 2001 through 2011, we identified Medicaid overpayments for school-based health services; the Federal share of the overpayments was estimated at more than \$1 billion. Many of the services claimed lacked a referral by appropriate medical professionals or were not provided by or under the direction of qualified providers. These unallowable claims occurred generally because States did not provide sufficient guidance and oversight of local education agencies and rates were not developed in accordance with applicable Federal cost allocation requirements or CMS program guidelines.

Additional Background >

Medicaid pays for school-based health services when they are included in an individualized education plan or individualized family service plan established pursuant to the Individuals With Disabilities Education Act (IDEA).

Progress of Implementation

According to our findings, CMS has taken recovery actions on improper claims and/or the claims have been settled by the Department of Justice (DOJ). We have noted through our continuing work in this area that CMS has also initiated efforts to bring State plans into compliance with Federal law, regulations, and policy in the coverage areas that pertain to Medicaid services delivered in school settings.

- In December 2007, CMS issued a final rule specifying that Federal financial participation under the Medicaid program will not be available for school-based administrative and certain transportation costs. The rule addressed long-standing concerns about improper billing by school districts as determined by both HHS's Inspector General and the Government Accountability Office.
- A moratorium issued in the Medicare, Medicaid, and SCHIP Extension Act Of 2007 prevented implementation of the final rule through June 30, 2008.
- In May 2010, CMS issued a school-based services financial management review guide for use by its staff, titled *Claims for IDEA-Related School Based Services*.
- CMS said it continues to provide guidance to States regarding claiming for services provided in schools in conjunction with the State plan amendment process. CMS said it routinely provides States with copies of approved State plan amendments, cost reports, and cost report instruction for use as templates. Central and regional office staff meet with State staff prior to and after an amendment is submitted to ensure that the State is aware of all CMS requirements. Requirements for reimbursement are detailed in the internal CMS manual that helps ensure consistent application of reimbursement policies for school-based services throughout the regions.

Although CMS developed a review guide for its staff to use in reviewing school-based claims, it has not yet taken steps to provide guidance for dissemination by States to local education agencies in an effort to reduce unallowable claims. Our reviews that continue to identify unallowable claims point to the need for such guidance at the local level. We continue to monitor CMS's efforts to ensure that States comply with our recommendations.

Primary OIG Reports

- 2012 APR Review of Colorado Direct Medical Service and Specialized Transportation Costs for the Medicaid School Health Services Program for State Fiscal Year 2008. A-07-11-04185. [Full Text](#).
- 2012 JAN *Review of Medicaid Payments for School-Based Health Services Made to Manchester, New Hampshire*. A-01-10-00014. [Full Text](#).

See Also

- 2011 *West Virginia*. A-03-05-00203.
- 2010 *New Jersey*. A-02-07-01052 and A-02-07-01051. *Arizona*. A-09-07-00051.
- 2009 *West Virginia*. A-03-06-00201.
- 2008 *New Jersey*. A-02-04-01017.
- 2007 *Utah*. A-07-06-04069. *Maryland*. A-03-05-00206.
- 2006 *Nevada*. A-09-05-00054. *Minnesota*. A-05-05-00040. *Kansas*. A-07-05-01018. *Kansas*. A-07-06-01030. *Kansas*. A-07-03-00155. *New Jersey*. A-02-03-01003. *Texas*. A-06-02-00051.
- 2005 *Texas*. A-06-02-00047. *New York City*. A-02-03-01023. *New York City*. A-02-02-01029. *Illinois*. A-05-02-00050. *Kansas*. A-07-03-00154. *Vermont*. A-01-03-00004. *Maine*. A-01-04-00004.
- 2004 *Massachusetts*. A-01-02-00016. *New York State*. A-02-03-01008. *New York State*. A-02-02-01030. *North Carolina*. A-04-01-00005. *Iowa*. A-07-02-02099. *Rhode Island*. A-01-02-00014. *Texas*. A-06-02-00037.
- 2003 *Illinois*. A-05-02-00049. *Washington State*. A-10-02-00008. *Massachusetts*. A-01-02-00009. *Connecticut*. A-01-02-00006. *New Jersey*. A-02-02-01022. *Oklahoma*. A-06-01-00083. *Maryland*. A-03-01-00224. *Wisconsin*. A-05-02-00023.
- 2002 *New York City*. A-02-02-01018. *Oklahoma*. A-06-01-00077. *Oregon*. A-10-01-00006. *Connecticut*. A-01-01-00006. *Washington State*. A-10-01-00011.
- 2001 *North Carolina*. A-04-00-02161.

Medicaid Improper Payments > Home Health Services

Home Health—Prevent Duplicate Medicaid and Medicare Payments

Recommendation To Be Implemented

- We recommend that CMS ensure that Medicaid does not pay home health providers for nonroutine medical supplies and therapeutic services paid by Medicare.

Savings probable but not estimated.

The recommendation would help prevent the improper Medicaid payments that occur when States claim reimbursement for home health services that are paid for by Medicare. When Medicaid and Medicare cover particular supplies and services, Medicaid is the payer of last resort and Medicare should pay first for services provided to individuals who meet dual-eligibility requirements.

A May 2008 OIG report revealed that each of the five States we examined had established payment system edits to compare claims for home health services to Medicare eligibility information; however, incomplete eligibility information and payment system edit overrides resulted in inappropriate payments. States do not have direct access to Medicare prospective payment system (PPS) data that would provide information about whether and when a beneficiary is receiving Medicare-paid services. The order of claims submission dates and dates of payment indicated that some home health providers were submitting Medicaid claims for medical supplies and therapeutic services when they had already received Medicare payments.

Additional Background >

Home health services are intended to restore health and minimize the effects of illness and disability, enabling beneficiaries to live in community settings and avoid institutionalization. Medicaid and Medicare pay home health providers for services specified in the plans of care for beneficiaries; however, both programs should not pay for the same supplies or services for the same beneficiaries. The May 2008 report revealed that four States inappropriately paid home health providers a combined \$1 million for claims for nonroutine medical supplies (e.g., catheters, dressings, syringes, and needles) and therapeutic services that were also paid by Medicare. This represented about 1 percent of the \$113 million that the four States spent on home health nonroutine medical supplies and therapeutic services. In two States, Medicaid paid \$6.6 million for routine medical supplies (e.g., cotton balls, gloves, and incontinence items) on the same dates that Medicare covered home health services, but the Medicaid claims data did not include enough information to determine whether the supplies qualified for Medicare payment.

Progress of Implementation

In responding to our review, CMS said that it recognized the importance of preventing duplicate Medicaid and Medicare billings. CMS's 2012 update of its response to this recommendation said that since our report was issued, many States have been able to obtain Medicare crossover claims data. In addition, CMS said it is working with States to refine and improve the integration of

Medicare claims information into States' Medicaid claims processing systems by using additional data elements to correctly adjudicate duplicate Medicaid and Medicare claims for home health services. Furthermore, CMS said it will conduct a special study in collaboration with a selected State to identify suspected duplicate payments and payment aberrancies.

We continue to monitor the implementation of CMS's actions to ensure that Medicaid does not pay home health providers for nonroutine medical supplies and therapeutic services already covered under the Medicare benefit.

Primary OIG Report

2008 MAY *Duplicate Medicaid and Medicare Home Health Payments – Medical Supplies and Therapeutic Services*. OEI-07-06-00640. May 2008. [Full Text](#).

See Also

2009 FEB *Memorandum Report – Medicaid and Medicare Home Health Payments for Skilled Nursing and Home Health Aide Services*. OEI-07-06-00641. [Full Text](#).

Medicaid Improper Payments > Personal Care Services

Personal Care Services—Enforce Policies Prohibiting Payments for Personal Care Services for Institutionalized Beneficiaries

Recommendations To Be Implemented

We recommend that CMS

- enforce Federal Medicaid payment policies that prohibit Medicaid reimbursement for personal care services (PCS) provided over a range of dates if the range includes dates on which the beneficiary was institutionalized and
- work with States to reduce erroneous Medicaid payments for PCS provided during institutional stays.

Savings probable but not estimated.

The recommendations would help prevent the improper Federal Medicaid payments that occur when States claim Federal reimbursement for PCS provided during institutional care stays.

An August 2008 OIG report revealed that although five States we reviewed reported having Medicaid controls to prevent payments for PCS provided during institutional stays, the controls did not fully prevent erroneous payments. In three States, we estimated nearly \$11 million in a single quarter may have been paid in error.

Additional Background >

PCS provide the elderly, people with disabilities, and individuals with chronic or temporary conditions with the assistance they need to remain in their homes or communities. PCS are currently offered as either a State Plan optional benefit or through various demonstrations and waivers in 50 States. State Medicaid programs may reimburse the cost of PCS for individuals who are not inpatients or residents of certain institutions but should not separately reimburse for PCS furnished during institutional stays.

Progress of Implementation

CMS's 2012 update indicated that it is continuing to work with its regional offices and with the States on a solution for disseminating information to ensure that Medicaid does not pay for Medicare-paid services. In addition, CMS indicated that it has begun collecting information from States on prepayment review procedures to detect PCS provided during institutional stays and plans to publish States' best practices. CMS also indicated that it is preparing guidance to assist States in educating providers regarding the prohibition against billing for PCS during institutional stays.

We continue to monitor CMS's progress in enforcing policies to reduce erroneous Medicaid payments for PCS during institutional stays.

Primary OIG Report

2008 AUG *Payments Made in Error for Personal Care Services During Institutional Stays.* OEI-07-06-00620. [Full Text.](#)

See Also

Selected Audits of Other PCS-Related Issues:

2012 JUN *West Virginia Complied With Certain Federal Requirements for Most of the Personal Care Services Claimed for Its Aged and Disabled Waiver Program.* A-03-11-00205. [Full Text.](#)

2012 JAN *Review of Medicaid Personal Care Claims Submitted by Providers in New Jersey.* A-02-09-01002. [Full Text.](#)

2011 NOV *Review of Personal Care Services Claimed Under Maryland's Medicaid State Plan.* A-03-11-00200. [Full Text.](#)

2011 JUL *Nebraska Medicaid Payments for Personal Care Services.* A-07-10-03152. [Full Text.](#)

2011 JUN *Review of Medicaid Personal Care Services Claimed by Washington State.* A-09-09-00030. [Full Text.](#)

2011 JUN *Review of Medicaid Personal Care Services Claims Submitted by Providers in North Carolina.* A-04-10-04003. [Full Text.](#)

2009 JUN *Review of Medicaid Personal Care Services Claims Made by Providers in New York City.* A-02-07-01054. [Full Text.](#)

2008 NOV *Partnership Review of Medicaid Claims Processed by Cerebral Palsy and Stavros for Personal Care Attendant Services Provided to Beneficiaries During Inpatient Stays.* A-01-08-00001. [Full Text.](#)

2008 OCT *Medicaid-Funded Personal Care Services in Excess of 24 Hours per Day.*
OEI-07-06-00621. [Full Text.](#)

Medicaid > Improper Payments > Personal Care Services

Personal Care Services—Ensure that Medicaid Claims Provided by Attendants With Undocumented Qualifications Are Not Paid (New)

Recommendations To Be Implemented

We recommend that CMS work with States to

- ensure that Medicaid claims for PCS provided by attendants with undocumented qualifications are not paid and
- take action regarding the inappropriately paid claims identified in our review.

Savings probable but not estimated.

The recommendations would encourage provider and supplier compliance with Federal and State documentation requirements. Insufficiently documented claims are improper and should not be paid.

A December 2010 OIG report of a 10-State review revealed that Medicaid paid about \$724 million for PCS claims that we determined were inappropriate because PCS attendants' qualifications were undocumented. These claims represented 18 percent of Medicaid PSC claims in the 10 States. The qualifications most often undocumented were background checks, age, and education.

We also estimated that Medicaid paid an additional 2 percent of claims inappropriately because the respondents had no record of providing services to the beneficiaries. Respondents were agencies or individuals that State Medicaid agency officials indicated we should contact to request documentation to support attendants' qualifications. We reviewed claims paid from September 1, 2006, through August 31, 2007.

Additional Background >

PCS provide the elderly, people with disabilities, and individuals with chronic or temporary conditions with the assistance they need to remain in their homes or communities. PCS are currently offered as either a State Plan optional benefit or through various demonstrations and waivers in 50 States. Combined State and Federal Medicaid expenditures for PCS totaled \$9.9 billion in 2006, an increase of 20 percent from 2004. Although there are no Federal requirements for PCS attendant qualifications, States are required to institute provider safeguards to protect the health, welfare, and safety of Medicaid beneficiaries receiving PCS. Examples of safeguards include the establishment of attendant qualifications, such as requiring criminal background checks and establishing minimum age, health status, education, and training requirements.

Progress of Implementation

CMS's 2012 update described plans to work with States to ensure that Medicaid claims for PCS provided by attendants who do not meet States' qualifications are not paid. CMS said it will work through the State plan amendment and waiver review process and other educational and communication opportunities to address this recommendation. CMS said it will review the information regarding the inappropriate claims we identified and take action based on that review.

We encourage CMS to follow through on its plans for implementing our specific recommendations. We continue to monitor CMS's progress.

Primary OIG Report

2010 DEC *Inappropriate Claims for Medicaid Personal Care Services*. OEI-07-08-00430. [Full Text](#).

See Also

2012 JUN *Review of New Mexico Medicaid Personal Care Services Provided by Clovis Homecare, Inc.* A-06-09-00117. [Full Text](#).

2011 OIG's [Spotlight on Medicaid Personal Care Services](#), available on our Web site.

2006 DEC *States' Requirements for Medicaid-Funded Personal Care Service Attendants*. OEI-07-05-00250. [Full Text](#).

❖ Protect the Health of Medicaid Children

According to CMS, over [42 million children](#) were enrolled in Medicaid and/or the Children's Health Insurance programs for part or all of FY 2010, representing 5.4-percent growth over the previous year. Over 34 million children were enrolled in Medicaid alone in FY 2010. The Early and Periodic Screening, Diagnostic, and Treatment ([EPSDT](#)) benefit provides comprehensive and preventive health care services for children under age 21 who are enrolled in Medicaid. EPSDT is key to ensuring that children and adolescents receive appropriate preventive, dental, mental health, developmental, and specialty services.

Medicaid > Children's Health > Preventive Screening Services

Improve Medicaid Children's Utilization of Preventive Screening Services

Recommendations To Be Implemented

We recommend that CMS

- require States to report beneficiaries' vision and hearing screenings,
- collaborate with States and providers to develop effective strategies to encourage beneficiary participation in Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) screenings,
- collaborate with States and providers to develop education and incentives for providers to encourage complete medical screenings, and
- identify and disseminate promising State practices for increasing children's participation in EPSDT screenings and providers' delivery of complete medical screenings.

The recommendations would help reduce the risks to children's health that arise from inadequate screening and treatment programs. Services provided under EPSDT benefits are intended to screen, diagnose, and treat children eligible for EPSDT services at early, regular intervals to avoid or minimize childhood illness. The EPSDT services cover four health-related areas—medical, vision, hearing, and dental.

A May 2010 OIG report revealed that Medicaid-covered children were not fully benefiting from Medicaid's EPSDT comprehensive screening services. Appropriate laboratory tests were the most often missing component. Seventy-six percent of children (2.7 million children) in nine selected States did not receive all the required medical, vision, and hearing screenings.

Additional Background >

Officials from all nine selected States identified strategies to improve participation in the EPSDT and the completeness of medical screenings. The disconnect between States' efforts to improve the EPSDT program and the low number of children receiving required screenings is difficult to account for, but indicates that additional efforts are required. Forty-one percent of children did not receive any of the required medical screenings. More than half of children did not receive any required vision or hearing screenings. Of the 55 percent of children in the nine States who received a medical screening during the review period, 59 percent lacked at least one component of a complete medical screening.

Progress of Implementation

In responding to our review, CMS said that it is undertaking efforts in conjunction with States and national experts to improve the provision of EPSDT services. CMS also said that a National EPSDT Improvement Workgroup had been formed and was tasked with making recommendations on improving EPSDT data collection opportunities. CMS plans to encourage individual States to submit promising practices for increasing participation in EPSDT screening and said it would post these on its Web site.

We continue to monitor CMS's implementation of our recommendations.

Primary OIG Report

2010 MAY *Most Medicaid Children in Nine States Are Not Receiving All Required Preventive Screening Services.* OEI-05-08-00520. [Full Text.](#)

See Also

2005 JUL *Children's Use of Health Services While in Foster Care – Common Themes.* OEI-07-00-00645. [Full Text.](#)

2005 JUN *Children's Use of Health Services While in Foster Care – New York.* OEI-02-00-00362. [Full Text.](#)

2005 JAN *Children's Use of Health Services While in Foster Care – Georgia.* OEI-07-00-00644. [Full Text.](#)

2004 AUG *Children's Use of Health Services While in Foster Care – North Dakota.* OEI-07-00-00643. [Full Text.](#)

2004 JUN *Foster Care Children's Use of Medicaid Services in Oregon.* OEI-02-00-00363. [Full Text.](#)

2004 FEB *Children's Use of Health Services While in Foster Care – Texas.* OEI-07-00-00641. [Full Text.](#)

2004 FEB *Children's Use of Health Services While in Foster Care – Illinois.* OEI-07-00-00642. [Full Text.](#)

2003 AUG *Children's Use of Health Services While in Foster Care – Kansas.* OEI-07-00-00640. [Full Text.](#)

2003 JUL *Foster Care Children's Use of Medicaid Services in New Jersey.* OEI-02-00-00360. [Full Text.](#)

❖ Ensure the Adequacy of Data for Oversight

The Department and OIG rely heavily on the availability and completeness of data to ensure that the over 300 departmental programs are operating as intended and to help identify instances of fraud, waste, and abuse. The Department's programs compile an enormous amount of data on beneficiaries, providers, drugs, equipment and supplies, the delivery of services, and the quality of care. When these data are unavailable, are incomplete, or contain inaccuracies, program oversight and monitoring activities are hindered. OIG identified the availability and quality of data for effective oversight as one of the top challenges facing HHS in FY 2012.

OIG work has shown challenges in the Medicaid Statistical Information System (MSIS) in that the data are not current, available, complete, and accurate. The MSIS is the only national database of Medicaid claims and beneficiary eligibility information. CMS does not always enforce certain MSIS data requirements, such as the submission of managed care encounter data. To conduct necessary Medicaid oversight, OIG, CMS, and others conducting Medicaid research must sometimes request data directly from each State.

Medicaid Oversight Data > Managed Care > Encounter Data

Managed Care—Enforce Federal Requirements for Submitting Medicaid Managed Care Encounter Data

Recommendation To Be Implemented

- We recommend that CMS enforce Federal requirements that States include managed care encounter data in Medicaid Statistical Information System (MSIS) submissions.

The recommendation would ensure that MSIS has accurate and complete data necessary for oversight of Medicaid managed care.

A May 2009 OIG report revealed that the usefulness of the MSIS was limited because CMS did not enforce encounter data requirements for all States. Encounter data are the primary records of Medicaid services provided to beneficiaries enrolled in capitated Medicaid managed care. CMS could develop system edits to ensure that States comply with MSIS requirements and that the data are complete and meet quality expectations. The Affordable Care Act, [§ 6402\(c\)](#) authorizes the Secretary to withhold the Federal matching payments for States that fail to report enrollee encounter data in the MSIS.

The Balanced Budget Act of 1997 (BBA) requires that Medicaid claims submitted to CMS “on or after January 1, 1999, provide for electronic transmission of claims data in the format specified by the Secretary of HHS and consistent with the MSIS.” As the only national database of Medicaid claims and beneficiary eligibility information, the MSIS is used by CMS to manage, analyze, and

disseminate data regarding Medicaid beneficiaries, services, and payments and is widely used for research and policy analysis and for detecting fraud, waste, and abuse.

Progress of Implementation

CMS concurred with the recommendation. CMS's 2011 update of its response to our recommendation said that it intends to increase efforts to consistently enforce the Federal reporting requirements for encounter data and that it will review statutory and regulatory authorities to determine areas in which it can strengthen the reporting of these data. We continue to monitor CMS's efforts to ensure that all States enter timely, accurate encounter data into the MSIS.

Primary OIG Reports

2009 MAY *Medicaid Managed Care Encounter Data – Collection and Use*. OEI-07-06-00540.
[Full Text](#).

2009 AUG *MSIS Data Usefulness for Detecting Fraud, Waste, and Abuse*. OEI-04-07-00240.
[Full Text](#).

Public Health Agencies

Public health activities and programs represent the country's primary defense against acute and chronic diseases and disabilities and provide the foundation for the Nation's efforts to promote and enhance the health of the American people.

❖ Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) operates a health surveillance system to monitor and prevent disease outbreaks, including bioterrorism; implements disease prevention strategies; and maintains national health statistics.

Public Health > Centers for Disease Control and Prevention > Public Health Emergencies > Pandemics

Public Health Crises—Improve States' and Localities' Medical Surge Preparedness for Pandemics

Recommendation To Be Implemented

- We recommend that the Assistant Secretary for Preparedness and Response (ASPR), in collaboration with the Centers for Disease Control and Prevention (CDC), work with States and localities to improve their efforts within each of the five components of medical surge that we reviewed.

The recommendation would help reduce the large-scale threats to public health that would occur under pandemic conditions, such as widespread influenza.

A September 2009 OIG report revealed that all of the 10 localities that we reviewed had established partnerships to prepare for a medical surge; however, the degree to which coordination occurred varied. Fewer than half of the localities had started to recruit medical volunteers, and none of the five States that we reviewed had implemented an electronic system to manage volunteers. Similarly, the 10 localities had acquired limited medical equipment for a pandemic, but only 3 of the 5 States had electronic systems to track available beds and equipment.

As of late summer 2008, most of the localities were in the early stages of planning for alternate care sites, and most had not identified guidelines for altering triage, admission, and patient care during a pandemic. Although the localities conducted medical surge exercises, none consistently documented the lessons learned.

Additional Background >

A pandemic would affect much of the country at the same time, so medical resources—such as hospital beds, medical equipment, and personnel—likely would be scarce. The ability to rapidly respond to an increased demand for medical resources is often referred to as a “medical surge.” The

public health emergency caused by an outbreak of human cases of H1N1 influenza has highlighted the need for States and localities to be prepared for a medical surge.

The five components of medical surge that we reviewed were: coordinating with and involving a wide array of stakeholders in medical surge and pandemic planning; recruiting, registering, and training medical volunteers for use in a pandemic; managing medical equipment being stockpiled for a public health emergency, such as a pandemic; planning for alternate care sites for use during a pandemic; and identifying and adopting guidelines for altering triage, admission, and patient care during a pandemic.

Progress of Implementation

ASPR indicated that it was taking steps toward implementation.

- In October 2009, ASPR said that it had updated its *Medical Surge Capacity and Capability Handbook* and added hospital reporting requirements to aid State health care system planning.
- In December 2010, ASPR said that it was engaging with other agencies and Departments administering health-related preparedness grants as a primary partner in a “grant alignment” project designed to streamline all Federal grant mechanisms and to maximize the efficiency of grant management processes to improve preparedness and response outcomes.

We encourage ASPR to follow through on its efforts. We continue to monitor ASPR’s progress in implementing our recommendation.

Primary OIG Report

2009 SEP *State and Local Pandemic Influenza Preparedness – Medical Surge.*
OEI-02-08-00210. [Full Text](#)

See Also

2012 JUN *Medicaid Vaccines for Children Program: Vaccine Storage and Management.*
OEI-04-10-00430. [Full Text](#).

❖ Food and Drug Administration

The Food and Drug Administration (FDA) is responsible for ensuring the safety of the Nation's food, drugs, medical devices, biologics, cosmetics, and animal food and drugs.

Public Health > Food and Drug Administration > Ethics Oversight

Ethics Oversight—Ensure That Clinical Investigators Disclose All Financial Interests

Recommendations To Be Implemented

We recommend that FDA

- require that sponsors submit financial information as part of the pretrial application process,
- ensure that sponsors submit complete financial information for all their clinical investigators, and
- ensure that FDA reviewers consistently review financial information and take action in response to disclosed financial interests by using a review template and providing guidance and training to reviewers.

The recommendations would improve FDA's ability to identify financial interests between clinical investigators and drug sponsors that could create a potential for bias and compromise the safety of human subjects and the integrity of research data.

Sponsors (often pharmaceutical or device companies) are responsible for developing and testing investigational products in clinical trials. Sponsors are required to disclose all clinical investigators' financial interests to FDA in the marketing application.

A January 2009 OIG report revealed that in FY 2007, FDA could not determine whether sponsors had submitted financial information for all clinical investigators because it did not have a complete list of the clinical investigators. We found that FDA approved 42 percent of marketing applications in FY 2007 that were missing financial information. In almost one-third of marketing applications, FDA reviewers did not document a review of financial interest information, and neither FDA nor sponsors took action on 20 percent of marketing applications with disclosed financial interests. When FDA did act, it did not consistently take action in response to disclosed financial interests.

Additional Background >

Although sponsors must collect financial information from clinical investigators before the trials, sponsors submit financial information to FDA only when they submit their marketing applications after the clinical trials end. For each clinical investigator, sponsors submit a financial form either

certifying that the investigator does not have a financial interest regarding the outcome of the trial or disclosing such a financial interest.

Progress of Implementation

In responding to our review and with regard to requiring sponsors to submit financial information for clinical investigators during the pretrial application process, FDA emphasized that collecting financial information before clinical trials is the sponsors' responsibility.

- As of February 2009, FDA required entities submitting marketing applications to include a complete list of clinical investigators and either certify to the absence of reportable financial arrangements or disclose the nature of the financial arrangements.
- In May 2011 FDA issued [draft guidance](#), *Guidance for Clinical Investigators, Industry, and FDA Staff – Financial Disclosure by Clinical Investigators*. (76 Fed. Reg. 30175, May 24, 2011.) FDA also updated the *Compliance Program Guidance Manual* chapter entitled "Clinical Investigator Inspections."

We continue to recommend that sponsors submit financial information as part of the pretrial application process and will monitor FDA's progress in implementing this recommendation. The proposed revisions are aimed at strengthening FDA's oversight and review of clinical investigators' financial disclosures. Once FDA's guidance is finalized, OIG will consider the recommendations about clinical investigators' information and FDA's reviewers to be closed.

Primary OIG Report

2009 JAN *The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information*. OEI-05-07-00730. [Full Text](#)

See Also

2007 SEP *The Food and Drug Administration's Oversight of Clinical Trials*. OEI-01-06-00160. [Full Text](#).

2000 JUN *FDA Oversight of Clinical Investigators*. OEI-05-99-00350. [Full Text](#).

Public Health > Food and Drug Administration > Safety of Medical Devices

Safety of Medical Devices—Use Adverse Event Reports To Detect and Address Safety Concerns

Recommendations To Be Implemented

We recommend that FDA

- develop a clear protocol for reviewing adverse event reports that specifically addresses following up with manufacturers who routinely submit reports late or with incomplete information and enhancing outreach strategies to reduce user facility underreporting and
- seek legislative authority to eliminate the regulation for user facilities to submit redundant annual reports.

The recommendations would reduce the public safety risks that arise when manufacturers and facilities that use medical devices delay reporting or fail to report to FDA adverse events associated with medical devices.

Adverse events include deaths, serious injuries, malfunctions, and events that require remedial action to prevent an unreasonable risk of substantial harm to the public. FDA's adverse event reporting system provides FDA and manufacturers with a means to identify and monitor significant adverse events involving medical devices. Regulations require that manufacturers of medical devices and facilities that use these devices (user facilities) submit reports to FDA within specific timeframes ranging from 5 days to 1 year following the occurrence of an adverse event.

An October 2009 OIG report revealed that FDA has not documented followup on adverse events, nor does it consistently perform its first-time reading of adverse event reports in a timely manner. In addition, FDA rarely acts when manufacturers and user facilities submit reports late. The inability to obtain complete and usable information in adverse event reports hinders analysts' review of the reports, and FDA makes limited use of annual reports. Overall, FDA received twice as many adverse event reports for medical devices in 2007 as in 2003; however, the number of some types of reports, such as 5-day reports, decreased. Although manufacturers submitted most adverse event reports on time, many 5-day manufacturer reports and 5-day user facility reports were late.

Additional Background >

A clear protocol is needed to ensure that all responsible parties report and take appropriate action in response to adverse events associated with medical devices. We recommended that FDA seek legislative authority to eliminate the requirement for user facilities to submit annual reports because, other than a count of total adverse event reports, all the information in the annual reports is redundant to the originally submitted reports. Eliminating this requirement (21 U.S.C. § 360i(b)(c)) would decrease the regulatory burden on user facilities, as well as the review burden

on FDA. Instead, FDA should emphasize the importance of timely and appropriate reporting of all injuries and deaths by user facilities.

Progress of Implementation

In its comments on our review, FDA said that it would develop a clear review protocol that addresses the needs that our report identified. FDA said it is implementing a new database, FDA Adverse Event Reporting System (FAERS), which should allow for more extensive documentation and followup on adverse events and permit FDA to more readily identify late and incomplete reports.

The database is designed to support FDA's postmarketing safety surveillance program for drug and therapeutic biologic products. If a manufacturer receives an adverse event report, it is required to send the report to FDA as specified by regulations. The reports received directly and the reports from manufacturers are entered into FAERS.

Although the new FAERS database provides more data for analysis and oversight, FDA has not demonstrated that it addresses our recommendation about establishing a protocol to ensure followup with late-reporting manufacturers and to reduce underreporting.

We continue to monitor FDA's progress in implementing the recommendations we specified, including seeking statutory authority to eliminate redundant annual reporting that poses a burden to manufacturers.

Primary OIG Report

2009 OCT *Adverse Event Reporting for Medical Devices*. OEI-01-08-00110. [Full Text](#)

Public Health > Food and Drug Administration > Food Safety

Food Safety—Improve and Strengthen Food Facilities' Compliance With Records Requirements for Traceability of Food Products

Recommendations To Be Implemented

We recommend that FDA

- seek statutory authority to ensure that facilities are complying with record requirements,
- work with the food industry to develop additional guidance to strengthen traceability,
- address issues related to mixing raw food products from a large number of farms, and
- conduct education and outreach to inform the food industry about its records requirements.

The recommendations would facilitate effective traceability of food products when FDA has reasonable belief that a product is adulterated and presents a serious threat to public health.

Traceability is the ability to follow the movement of food products through the stages of production, processing, and distribution. FDA is not authorized to request facilities' records regarding traceability during routine inspections. Traceability is often needed in product recalls and seizures to identify the sources of contamination and the recipients of the contaminated food.

A March 2009 OIG report noted that we were able to trace only 5 of 40 selected products through each stage of the food supply chain. For most products, we were able to identify facilities that likely handled the products. Several factors prevented us from tracing products through the food supply chain, including that facilities did not always maintain lot-specific information; products were not labeled with required information; and raw products from multiple farms were comingled. Fifty-nine percent of the facilities we reviewed did not meet FDA's record requirements about sources, recipients, and transporters, and one quarter of the food facilities were not aware of FDA's records requirements. We could estimate only a range of deliveries (from one or more facilities) that may have included the products we purchased.

Additional Background >

Beginning in 2005, FDA required certain food facilities to maintain records identifying the sources, recipients, and transporters of food products. These records enable FDA to trace articles of food through each stage of the supply chain—from retail outlets back to farms—if FDA has a reasonable belief that a food product is adulterated and presents a serious health threat.

Progress of Implementation

In responding to our review, FDA said it would consider seeking statutory authority to ensure that facilities are complying with record requirements and described its efforts to work with the food industry to conduct education and outreach.

- FDA's February 2011 update noted that it has taken several steps to improve recordkeeping and food tracing. For example, FDA completed a pilot study on tracing in the tomato industry and is planning several other pilot studies to assess the feasibility of different tracing systems and technologies. FDA described its efforts to work with the food industry to conduct education and outreach.
- FDA's December 2011 update that it and USDA held public meetings in December 2009 on whole chain traceability. The public comment period associated with these meetings closed March 10, 2010 and FDA indicated it was still reviewing the comments received.

We acknowledge the efforts FDA has taken and continue to monitor its progress in implementing our recommendations. Two of the report's six original recommendations have been resolved. We encourage FDA to address the remaining four recommendations and emphasize seeking statutory authority to ensure that facilities are complying with the record requirements related to food traceability.

Primary OIG Report

2009 MAR *Traceability in the Food Supply Chain*. OEI-02-06-00210. [Full Text](#)

See Also

2009 MAR OIG Testimony Before the House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies. "Traceability in the Food Supply Chain." [Testimony](#)

Public Health > Food and Drug Administration > Food Safety

Food Safety—Ensure That Food Facility Registry Provides Complete and Accurate Information

Recommendations To Be Implemented

We recommend that FDA

- consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that either fail to register or fail to provide accurate information for the registry and
- work with the food industry to conduct additional education and outreach activities to inform food facilities about the registry requirements.

The recommendations would help reduce the risk that FDA would not be able to quickly locate facilities during an outbreak of foodborne illness.

Section 305(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires certain food facilities to register with FDA. The purpose of this registration is to provide FDA with sufficient and reliable information about food facilities so that it can locate the facilities for inspection.

A December 2009 OIG report raised questions about the accuracy and utility of the food facility registry. We found that 52 percent of the facility managers at the selected facilities reported that they were unaware of FDA's registry requirements. Seven percent either failed to register or failed to cancel their registrations with FDA, as required. Additionally, 48 percent of selected facilities either failed to provide accurate information when they first registered or failed to provide accurate information after changes in the facility's information, as required. For each of these facilities, FDA was missing information or had inaccurate information, which could hinder FDA's ability to identify food facilities that may be linked to an outbreak of foodborne illness.

As of December 2003, FDA began requiring food facilities that manufacture, process, pack, or hold food for consumption in the United States to register their facilities with FDA. In many cases, because providing certain information in the registry is optional, facilities failed to provide information that may be useful to FDA in an emergency.

Progress of Implementation

In responding to our review, FDA noted that the study confirmed problems that the agency has encountered as well as the need for additional statutory authority.

Regarding the first recommendation to seek statutory authority to impose civil penalties, the food safety bill passed by the House of Representatives in the 111th Congress (H.R. 2749, the Food Safety Enhancement Act) would have authorized (in section 135) civil penalties for food-related violations of section 301 (prohibited acts) of the Federal Food, Drug, and Cosmetic Act. However, this civil penalty authority was not included in the FDA Food Safety Modernization Act (FSMA, P.L. 111-353) that was ultimately enacted. FDA indicated that it does not currently plan to pursue this authority; however, it remains supportive of this and will look for opportunities to pursue this in the longer term.

In its January 2011 update, FDA indicated that it continues activities to inform food facilities about the registry requirements. An outreach strategy will be developed and the necessary documents will be created or updated accordingly.

We continue to monitor FDA's progress in addressing the recommendations we specified. Although the FDA Food Safety Modernization Act implemented one of the report's recommendations (that facilities be required to reregister on a routine basis), we continue to emphasize the need for FDA to have additional authority to penalize noncompliant facilities.

Primary OIG Report

2009 DEC *FDA's Food Facility Registry*. OEI-02-08-00060. [Full Text](#)

Public Health > Food and Drug Administration > Food Safety

Food Safety—Strengthen Inspections of Domestic Food Facilities To Ensure Safety and Compliance

Recommendations To Be Implemented

We recommend that FDA

- provide additional guidance about when it is appropriate to lower official-action-indicated (OAI) classifications;
- take appropriate actions against facilities with OAI classifications, particularly those that have histories of violations;
- ensure that violations are corrected for all facilities that receive OAI classifications; and
- consider seeking statutory authority that would allow FDA to impose civil penalties through administrative proceedings.

The recommendations would reduce the risks to public health that arise when FDA does not regularly inspect food facilities' compliance with Federal requirements, does not take or follow up on corrective actions in a timely manner, and does not implement enforcement mechanisms.

An April 2010 OIG report revealed that many food facilities went 5 years or longer without an FDA inspection. There was a large decline in the number of food facility inspections conducted by FDA over a 5-year period, as well as a decline in the number of violations identified by FDA inspectors. Further, when violations were identified, FDA did not routinely take swift and effective action to ensure that these violations were remedied. Specifically, for 36 percent of the facilities that received OAI classifications, FDA took no additional steps to ensure that the violations were corrected.

Additional Background >

FDA inspects food facilities to ensure food safety and compliance with regulations. According to FDA guidance, when FDA identifies violations that are significant enough to warrant an OAI classification, some type of regulatory action should be recommended. This action could include issuing a warning letter; holding a regulatory meeting; or initiating an enforcement action, such as a seizure or an injunction.

Progress of Implementation

In responding to our review, FDA agreed with our recommendation to provide additional guidance about when it is appropriate to lower OAI classifications.

In its December 2011 update, FDA noted that it had made progress on the two recommendations designed to improve FDA's method of handling OAI classifications. Specifically, FDA initiated the OAI Follow-up Inspection Improvement Project, which ensures that FDA takes appropriate actions against facilities with OAI classifications and ensures that violations are corrected.

Notably, FDA recommended a 6-month timeframe for followup inspections of food facilities with OAI classifications. FDA has not provided documentation of the full implementation of this initiative.

Regarding the recommendation to seek statutory authority to impose civil penalties, the food safety bill passed by the House of Representatives in the 111th Congress (H.R. 2749, the Food Safety Enhancement Act) would have authorized (in section 135) civil penalties for food-related violations of section 301 (prohibited acts) of the Federal Food, Drug, and Cosmetic Act. However, this civil penalty authority was not included in the FDA Food Safety Modernization Act (FSMA) that was ultimately enacted. FDA indicated that it does not currently plan to pursue this authority; however, it remains supportive of this and will look for opportunities to pursue this in the longer term.

We will continue to monitor FDA's implementation of the recommendations we specified.

Primary OIG Report

2010 APR *FDA Inspections of Domestic Food Facilities*. OEI-02-08-00080. [Full Text](#)

See Also

2011 DEC *Vulnerabilities in FDA's Oversight of State Food Facility Inspections*. OEI-02-09-00430. [Full Text.](#))

Public Health > Food and Drug Administration > Food Safety

Food Safety—Ensure That Food Facility Inspections Conducted by State Agencies Are Complete, Properly Documented, and Appropriately Paid For (New)

Recommendations To Be Implemented

We recommend that FDA

- ensure that all contract inspections are completed, properly documented, and appropriately paid for;
- ensure that contract inspections are properly classified in accordance with FDA guidance;
- ensure that all inspection violations are remedied by routinely tracking all actions taken to correct violations;
- ensure that the minimum audit rate is met in all States; and
- address any systemic problems identified by audits.

The recommendations would help ensure the quality and effectiveness of food facility inspections and audits conducted by State agencies under contract with FDA.

FDA is responsible for safeguarding the Nation's food supply and for routinely inspecting food facilities. In addition to conducting its own inspections, FDA relies on State agencies to conduct inspections on its behalf. A December 2011 OIG report revealed that although FDA has increasingly relied on States to inspect food facilities, we identified significant weaknesses in FDA's oversight of these inspections.

We found that in eight States, FDA failed to ensure that the required number of inspections was completed. Moreover, FDA paid for many inspections that were incomplete. In addition, FDA did not ensure that all inspections were properly classified or that all inspection violations were remedied. We found that FDA officials were often unclear about how to properly classify contract inspections. Also, FDA officials reported that when States are responsible for correcting violations, FDA was not always informed about actions taken by the States. As a result, FDA was unable to ensure that all inspection violations were remedied. Finally, FDA failed to complete the required number of audits in one-third of the States with inspection contracts.

Additional Background >

FDA often enters into contracts with State agencies responsible for ensuring food safety. Each contract includes the number of food facility inspections the State will conduct for FDA and the amount the State will be paid for each inspection. During an inspection, State inspectors may identify potential violations of food safety laws and regulations. These violations are recorded in the inspection report. On the basis of the inspection report, FDA generally assigns one of three

classifications: official action indicated (OAI), voluntary action indicated (VAI), or no action indicated (NAI).

Progress of Implementation

Since the issuance of this report, two State agencies have informed OIG of discrepancies between the number of inspections reported in FDA data systems and that in State records. As a result of this new information, FDA said it is implementing new processes and quality checks to ensure that future contract inspections are received, accounted for, and accurately entered into FDA data systems in a timely manner.

We will continue to monitor FDA's progress in implementing our recommendations.

Primary OIG Report

2011 DEC *Vulnerabilities in FDA's Oversight of State Food Facility Inspections.*
OEI-02-09-00430. [Full Text](#).

❖ Health Resources and Services Administration

The Health Resources and Services Administration (HRSA) maintains a safety net of health services for people who are low income or uninsured or who live in rural areas or urban neighborhoods where health care is scarce.

Public Health > Health Resources and Services Administration > Patient Safety

Patient Safety—Increase Reporting of Medical Malpractice Cases to the National Practitioner Data Bank

Recommendations To Be Implemented

- We recommend that Health Resources and Services Administration (HRSA) and the National Institutes of Health (NIH) each
 - implement corrective action to address unreported cases and
 - improve internal controls involving file management.
- HRSA should also assign staff members to assume responsibility for addressing practitioner questions/complaints and data entry of reports into the National Practitioner Data Bank (NPDB).

The recommendations would help ensure the completeness and usefulness of the NPDB. Pursuant to an HHS policy directive issued on October 15, 1990, all settled or adjudicated medical malpractice cases involving HHS must be reported to the NPDB.

An October 2005 OIG report revealed that as of October 2004, HHS agencies had failed to report as many as 474 medical malpractice cases to the NPDB. Individual agency underreporting was as follows:

- IHS, 290 cases
- HRSA, 179 cases
- NIH, 5 cases

This underreporting was caused by a number of factors, including lost medical malpractice files; incomplete information in medical malpractice files; a decision by the HHS peer review entity, the Medical Claims Review Panel, not to identify practitioners who met the standard of care (a decision that was inconsistent with policy); and the failure to replace a key Program Support Center claims official or to reassign the person's reporting duties.

Progress of Implementation

Before we issued our October 2005 report, IHS started reporting cases in which standards of care were not met. HRSA also started reporting such cases soon thereafter. HRSA's Administrator indicated that HHS was developing a policy on reporting cases in which standards of care were not met.

- As of April 2008, HRSA had submitted 297 reports to NPDB. As of April 2008, NIH had not submitted any reports. In March 2009, HRSA informed OIG that it had submitted 17 medical malpractice payment reports between January 1 and December 31, 2008.
- In December 2010, HRSA said that it submitted 22 medical malpractice payment reports to NPDB in FY 2010. In December 2011, HRSA stated that it worked with IHS to draft a new Medical Claims Review Panel charter to increase NPDB reporting. That same month, NIH said that it will not submit reports to NPDB until a revised departmental policy is issued. We have not been informed as to the status of finalizing the charter.

We continue to monitor the implementation of our recommendations to HRSA and NIH, including the development of departmental policy by HRSA and NIH's reporting to NPDB.

Primary OIG Report

2005 OCT *HHS Agencies' Compliance With the National Practitioner Data Bank Malpractice Reporting Policy*. OEI-12-04-00310. [Full Text](#)

Public Health > Health Resources and Services Administration > Wasteful Spending > 340B Drug Program

Wasteful Spending—Eliminate Excessive Costs in the 340B Drug Pricing Program

Recommendations To Be Implemented

We recommend that HRSA

- establish detailed standards for the calculation of 340B ceiling prices,
- ensure that entities are charged at or below the 340B ceiling price, and
- provide participating entities with secure access to certain pricing data to help approximate the 340B ceiling prices.

Savings – We estimated savings based on \$3.9 million in overpayments by 340B entities in 1 month in 2005, multiplied by 12 to calculate savings for 1 year. Indirect savings to HHS are likely but have not been estimated.

The recommendations would help reduce the wasteful spending by certain federally supported entities for prescription drugs that occurs because of deficiencies in the Government's management and oversight of the 340B Drug Pricing program.

Section 340B of the Public Health Service Act created the 340B Drug Discount Program to lower drug prices for more than 15,000 safety-net entities, such as community health centers, critical access hospitals, and children's hospitals.

An October 2005 OIG report revealed that because of systemic problems with the accuracy and reliability of the Government's record of 340B ceiling prices, HRSA could not adequately oversee the 340B Drug Pricing Program. HRSA lacks the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price. Participating entities cannot independently verify that they receive the correct 340B discount due to confidentiality provisions.

Additional Background >

A July 2006 followup report revealed that 14 percent of purchases made by 340B entities exceeded the 340B ceiling price, resulting in \$3.9 million in projected overpayments for a single month, June 2005.

Progress of Implementation

HRSA has taken some positive steps toward implementing our recommendations as follows.

- In April 2007, HRSA said that it had implemented a 1-year 340B Drug Pricing Program pilot project requesting manufacturers to voluntarily submit their prices for comparison with the ceiling price.

- In September 2009, HRSA reported that its pilot project revealed that apparent discrepancies between the manufacturer's price and the 340B ceiling price were primarily because of differences in the package sizes that were being compared.
- In 2010, the Patient Protection and Affordable Care Act (Affordable Care Act), § 7102, directed the Secretary of HHS to improve manufacturer compliance with 340B reporting rules, including verifying the accuracy of ceiling prices, establishing a system for manufacturers to refund overcharges, and providing 340B participating entities with access to ceiling prices.

We continue to monitor HRSA's implementation the recommendations we specified.

Primary OIG Reports

2005 OCT *Deficiencies in the Oversight of the 340B Drug Pricing Program.*
OEI-05-02-00072. [Full Text](#).

See Also

2011 JUN *State Medicaid Policies and Oversight Activities Related to 340b-Purchased Drugs.*
OEI-05-09-00321. [Full Text](#).

2006 JUL *Review of 340B Prices.* OEI-05-02-00073. [Full Text](#).

2005 DEC Testimony of Stuart Wright, Deputy Inspector General of Evaluation and Inspections, before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations on the "340B Program." [Testimony](#).

❖ Indian Health Service

The Indian Health Service (IHS) provides or funds health care services for American Indians and Alaska Natives.

Public Health > Indian Health Service > Wasteful Spending > Contract Health Services

Wasteful Spending—Reduce Overpayments for Contract Health Services Hospital Claims and Cap Payments for Nonhospital Services at Medicare Rates

Recommendations To Be Implemented

- We recommend that IHS seek legislative authority to cap payments for Contract Health Services (CHS) nonhospital services at the Medicare rate for those services.

Savings– We estimated that if IHS and tribal payments for nonhospital claims were capped at the Medicare rate, IHS and tribes could have saved as much as \$13 million in one calendar quarter: January – March 2008.

The recommendation would reduce the wasteful spending that occurs because historically IHS and tribes have had difficulty negotiating rates similar to Medicare rates for CHS because of the relatively small number of American Indians and Alaska Natives and because there are few private providers in rural areas.

IHS contracts with private providers, such as hospitals and physicians, to deliver emergency or specialty services to eligible Indians when an IHS or a tribal facility is unable to provide the necessary care. The passage of an MMA provision helped ensure lower rates for hospital services. A separate provision may be necessary to ensure lower rates for nonhospital services.

A September 2009 OIG report revealed that IHS and tribes paid above the Medicare rate for 22 percent of hospital claims. As a result, IHS and tribes overpaid \$1 million for hospital claims between January and March 2008. We also determined that if IHS and tribal payments for nonhospital claims were capped at the Medicare rate, IHS and tribes could have saved as much as \$13 million between January and March 2008. Savings from claims over the Medicare rate could have paid for about 41,000 more nonhospital claims between January and March 2008 that might otherwise have been deferred or denied. Moreover, IHS and tribes paid above Medicare rates for 71 percent of nonhospital claims, most of which were for physician services.

Additional Background >

Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and its implementing regulations, all Medicare-participating hospitals must accept reimbursement no greater than the Medicare rate as payment in full for patients eligible for CHS contracts. Nonhospital providers, including physicians, are not covered by the MMA provision. We reviewed the extent to which IHS and tribes paid above the Medicare rate for CHS hospital claims.

Whatever method IHS uses to cap payments reasonably and accurately should be determined after careful determination of the impact of the new rates on the provider community, as well as other potential barriers to implementing the new rates.

Progress of Implementation

In its responding to our review, IHS said that it will continue to meet with tribes and tribal organizations to develop a plan to cap payments for CHS nonhospital services.

We encourage IHS to follow through on its efforts. We continue to monitor IHS's implementation of our recommendation.

Primary OIG Report

2009 SEP *IHS Contract Health Services Program – Overpayments and Potential Savings.*
OEI-05-08-00410. [Full Text](#)

Public Health > Indian Health Service > Quality of Care > Mental Health and Dialysis Services

Quality of Care—Improve Access to Mental Health and Dialysis Services at IHS and Tribal Facilities (New)

Recommendations To Be Implemented

The Indian Health Service (IHS) should provide guidance and technical assistance to

- help tribes explore potential partnerships with non-American-Indian-and-Alaska-Native (AI/AN) providers of community mental and behavioral health services,
- help IHS and tribal facilities offer alternative treatments for dialysis services,
- continue to expand its telemedicine capabilities for mental health services,
- develop a plan and provide expertise to assist tribes in expanding dialysis services, and
- create a database of all IHS and tribal health care facilities.

The recommendations would reduce the risks to quality of care that occur when IHS guidance to tribes is insufficient to ensure optimal use of available external resources, alternative treatments, telemedicine capabilities, and other expansions of care. The last recommendation would improve the quality of data needed formulate a comprehensive approach to Indian health care reform” and provide planning information relative to the distribution of health services for AI/ANs throughout the country.

Compared to other populations in the United States, AI/ANs experience a disproportionately high rate of mental and behavioral health challenges and a high incidence of end stage renal disease. IHS is responsible for providing Federal health services to AI/ANs. IHS operates from 12 Area Offices across the country to oversee the delivery of health services to members of federally recognized tribes eligible for IHS health care.

We conducted two evaluations of AI/ANs' access to mental health and kidney dialysis services at IHS and tribal health facilities. Two September 2011 OIG reports presented the results of these evaluations.

- **Mental Health Services.** Of the 630 IHS and tribal facilities, 514 provide some type of mental health service. Facilities that do not provide mental health services refer clients to other providers either outside the AI/AN community or on the reservation. Staffing issues and shortages of highly skilled providers limit AI/ANs' access to mental health services. Physical, personal/social, and economic challenges of AI/ANs may affect access to mental health services.
- **Kidney Dialysis Services.** Only 20 of 506 IHS and tribal facilities reported that kidney dialysis services are provided at their facilities; most AI/ANs receive dialysis services at non-IHS/nontribal dialysis facilities. Of the facilities that did not provide dialysis services, 56 percent reported that they assist in referring their patients to other facilities, both IHS/tribal and non-IHS/nontribal. The remoteness of dialysis facilities can affect the availability of services and create hardships for AI/ANs. Most IHS and tribal facilities do not provide kidney dialysis services because of a lack of resources and small patient populations. Finally, many IHS and tribal facilities assist tribal members in accessing dialysis services by providing transportation and expanding access to specialists.

Progress of Implementation

In its response to our review, IHS outlined actions it intends to take to implement our recommendations.

Regarding the mental health report, IHS said that it will collaborate with the Substance Abuse and Mental Health Services Administration (SAMHSA) to develop written guidance that addresses mental and behavioral health service gaps and lack of coordination between States, IHS, tribal facilities, and non-AI/AN providers. IHS also said that it will provide technical assistance to tribes regarding Federal reimbursement policies for eligible AI/ANs and that it will assist tribes in collaborating with SAMHSA, States, and non-AI/AN providers to address the challenges of obtaining culturally sensitive services for AI/AN patients.

Regarding the dialysis report, IHS said that it will conduct a tribal consultation process to determine whether tribes need increased centralized IHS assistance in expanding dialysis services and offering alternative treatments for dialysis services.

We continue to monitor IHS's progress toward implementing the recommendations we specified.

Primary OIG Reports

SEP 2011 *Access to Mental Health Services at Indian Health Service and Tribal Facilities.*
OEI-09-08-00580. [Full Text.](#)

SEP 2011 *Access to Kidney Dialysis Services at Indian Health Service and Tribal Facilities.*
OEI-09-08-00581. [Full Text.](#)

❖ National Institutes of Health

The National Institutes of Health (NIH) supports medical and scientific research examining the causes of and treatments for diseases, such as cancer, human immunodeficiency virus (HIV), and acquired immunodeficiency syndrome (AIDS).

Public Health > National Institutes of Health > Ethics Oversight

Ethics Oversight—Increase Oversight of Grantees’ Management of Financial Conflicts of Interest in Research

Recommendations To Be Implemented

We recommend that NIH increase oversight to ensure that grantee institutions

- maintain proper financial interest documentation,
- take appropriate actions against researchers who do not follow institutions' policies and procedures, and
- provide adequate oversight of subgrantee compliance.

NIH should also develop and disseminate guidance on methods to verify researchers' financial interests.

The recommendations would improve NIH's ability to identify financial interests that could create a potential for bias and compromise the safety of human subjects and the integrity of research data.

Federal regulations establish standards to ensure that the design, conduct, or reporting of research funded under Public Health Service (PHS) grants is not biased by any conflicting financial interest of an investigator.

- A January 2008 OIG report examined the extent to which NIH oversees grantee institutions' financial conflicts of interest for FY 2004 through FY 2006. We found that NIH's primary method of oversight was to rely on grantees' assurances that financial conflict-of-interest regulations were being followed.
- A November 2009 OIG report examined the nature of financial conflicts of interest reported to NIH in FY 2006 and the ways in which grantee institutions managed, reduced, or eliminated these conflicts. We found a number of vulnerabilities.

Additional Background >

Federal regulations require each institution that receives NIH funds to have a written policy for identifying investigators' financial conflicts of interest and ensuring that such conflicts are managed, reduced, or eliminated. Of NIH's 27 Institutes and Centers, 24 have grant-making authority and are responsible for managing and overseeing grants. Grantees must inform their respective funding

institutes of any financial conflicts of interest before spending any NIH grant funds. Conflicts identified during the grant period must be reported to the institutes within 60 days.

Progress of Implementation

In August 2011, NIH published a final rule revising regulations covering financial conflicts of interest on the part of investigators. ([76 Fed. Reg. 53256](#) (August 25, 2011).) The final rule addressed prior OIG recommendations to require grantee institutions to provide details regarding the nature of financial conflicts of interest and the ways in which they are managed, reduced, or eliminated.

We continue to monitor NIH's progress in ensuring that grantees are complying with the new requirements outlined in the regulation.

Primary OIG Reports

- 2009 NOV *Review of How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health.* OEI-03-07-00700. [Full Text](#)
- 2008 JAN *National Institutes of Health – Conflicts of Interest in Extramural Research.* OEI-03-06-00460. [Full Text](#)

Public Health > National Institutes of Health > Ethics Oversight > Institutional Conflicts Of Interest

Ethics Oversight—Require NIH Grantee Institutions To Identify, Report, and Address Institutional Financial Conflicts of Interest (New)

Recommendations To Be Implemented

- We recommend that the National Institutes of Health (NIH) promulgate regulations that address institutional conflicts of interest.

The recommendation would help ensure that grantee institutions identify, report, and manage actual or potential institutional financial conflicts of interest.

An institutional conflict may arise when a grantee institution's own financial interests (e.g., royalties, equity, stockholdings, and gifts) or those of its senior officials pose risks of undue influence on decisions involving the grantee institution's research. There are no Federal requirements that grantee institutions identify, report, and manage actual or potential institutional financial conflicts of interest. We surveyed 250 grantee institutions to determine whether they have developed any policies and procedures regarding institutionally held financial interests and conflicts related to NIH grants awarded in fiscal year 2008.

A January 2011 OIG report revealed that although there are no requirements, of the 156 responding NIH grantee institutions, 70 had policies addressing institutional financial interests and 69 had policies addressing conflicts of such interests. Grantee institutions that had written policies and

procedures were more likely to identify a conflict (15 of 69 grantee institutions) compared to those that did not have written policies and procedures (3 of 87 grantee institutions). Eighteen grantee institutions identified at least 38 institutional conflicts related to NIH research grants in FY 2008.

Progress of Implementation

When we issued our report in January 2011, NIH was reviewing public comments to finalize regulations regarding researchers' financial conflicts of interest. On August 25, 2011, NIH published a final rule revising regulations covering financial conflicts of interest for researchers. However, the final rule does not address our recommendation regarding institutional conflicts of interest. Instead, in the final rule, NIH states that "[w]e continue to believe that further careful consideration is necessary before PHS regulations could be formulated that would address the subject of institutional conflict of interest"

We continue to recommend that NIH promulgate regulations to address institutional financial conflicts of interest. Until regulations are promulgated, NIH should encourage grantee institutions to develop policies and procedures regarding institutional financial interests and conflicts.

Primary OIG Report

2011 JAN *Institutional Conflicts of Interest at NIH Grantees*. OEI-03-09-00480.
[Full Text](#).

Human Services Agencies

❖ Administration for Children and Families

The Administration for Children and Families (ACF) operates over 30 programs that promote the economic and social well-being of children, families, and communities, including Temporary Assistance for Needy Families (TANF); the national child support enforcement (CSE) system; the Head Start program for preschool children; and assistance for child care, foster care, and adoption services.

Human Services > Administration for Children and Families > Refugee Assistance > Quality of Services to Children

Quality of Services to Children—Delineate Roles and Enforce Unaccompanied Children's Services Requirements

Recommendation To Be Implemented

- We recommend that the Administration for Children and Families (ACF) establish a memorandum of understanding (MOU) between HHS and the Department of Homeland Security (DHS) to clearly delineate the roles and responsibilities of each Department with regard to unaccompanied alien children.

An MOU between HHS and DHS with regard to unaccompanied alien children would reduce the risks that such children may be in unsafe conditions and sponsors may not be in compliance with their agreements with the Government.

An unaccompanied alien child is a child under the age of 18 who has no lawful immigration status in the United States and who has no parent or legal guardian in the United States available to provide care and physical custody. When an unaccompanied alien child is found, DHS apprehends and detains the child and contacts the ACF Office of Refugee Resettlement (ORR), which coordinates placement and care of the child. Pursuant to the Homeland Security Act of 2002, the Director of ORR is responsible for the care and custody of unaccompanied alien children and DHS is responsible for immigration benefits and enforcement.

In our case file reviews of unaccompanied children apprehended by DHS who were in facilities overseen by ORR between April 1 and September 30, 2006, we found that most children were placed in and released from such facilities in accordance with Federal standards. However, we determined from our file reviews and facility visits that improvements were needed in case file documentation, program oversight, and the delineation of responsibilities between DHS and HHS.

At a minimum, the MOU should address the following.

Delineate each entity's specific responsibilities for gathering and exchanging information when a child comes into Federal custody and is placed into a facility overseen by ORR.

Delineate each entity's specific responsibilities for gathering and exchanging information about children who have been reunified with a sponsor to ensure that children are safe and that sponsors are adhering to agreements.

Progress of Implementation

In July 2011, ACF said that ORR was drafting a *Joint Operations Manual* (JOM) with DHS, with the ultimate goal of drafting an MOU. The revised JOM will conform to the new statutory requirements in the Trafficking Victims Protection Reauthorization Act of 2008.

We requested that ACF provide OIG a copy of the JOM when it is finalized. We will continue to monitor ACF's development and finalization of an MOU.

Primary OIG Report

2008 MAR *Division of Unaccompanied Children's Services: Efforts To Serve Children.* OEI-07-06-00290. [Full Text](#)

See Also

- 2005 SEP Department of Homeland Security, OIG. OIG 05-45. *A Review of DHS' Responsibilities for Juvenile Aliens.* [Full Text.](#)
- 2004 MAR Department of Justice, OIG. *Open Inspector General Recommendations Concerning the Former Immigration and Naturalization Service from 'Unaccompanied Juveniles in INS Custody.'* OIG-04-18. [Full Text.](#)
- 2001 SEP Department of Justice, OIG. *Unaccompanied Juveniles in INS Custody.* I-2001-009. [Linked Contents.](#)

Administration for Children and Families > Services to Children > Safety and Quality

Quality of Services to Children—Early Head Start Program Should Ensure That All Teachers Have the Required Credentials (New)

Recommendation To Be Implemented

- We recommended that ACF provide guidance to programs about training teachers.

The recommendation would help ensure that Early Head Start programs have the support they need from ACF to hire and train teachers.

Early Head Start provides comprehensive services to low-income pregnant mothers and infants and toddlers from birth to age 3. Head Start programs reported challenges to employing only teachers with the required credentials and to training teachers. Programs most commonly reported finding substitutes and managing work schedules as challenges to providing training. Other challenges to training teachers appeared to be more prevalent in rural areas. Despite the challenges expressed,

81 percent of Early Head Start teachers had the required credentials that met or exceeded a CDA. Nearly all Early Head Start programs reported requiring teachers to complete training.

Additional Background >

In 2007, Congress reauthorized the Head Start Act and created the first law governing the credentialing and training of center-based Early Head Start teachers. The Head Start Act requires that by September 30, 2010, all center-based Early Head Start teachers have a minimum of a child development associate (CDA) credential and have been trained (or have equivalent coursework) in early childhood development. It also requires that all Early Head Start teachers have training (or have completed equivalent coursework) in early childhood development with a focus on infant and toddler development by September 30, 2012.

Progress of Implementation

In its response to our review, ACF said that it could provide guidance about teacher training, but that it could not require a certain number of training hours without a regulatory change. However, in a subsequent update, ACF provided examples of training opportunities that were made available for EHS staff. To implement this recommendation, ACF could update guidance documents to reflect the EHS program's current strategies to provide training, paying particular attention to rural programs and the challenges identified in our report.

We continue to monitor ACF's progress with regard to supporting grantees in hiring and training teachers.

Primary OIG Report

2011 AUG *Most Early Head Start Teachers Have the Required Credentials, But Challenges Exist.*
OEI-05-10-00240. [Full Text](#).

❖ Administration for Community Living

The Administration for Community Living (ACL) includes the Administration on Aging (AoA), the Administration on Intellectual and Developmental Disabilities (AIDD), the Center for Disability and Aging Policy (CDAP), and an administrative component. It provides national leadership and direction to plan, manage, develop, and raise awareness of coordinated systems of long-term services and supports that enable older Americans and individuals with disabilities, including intellectual, developmental, and physical disabilities, to maintain their health and independence in their homes and communities. (*Statement of Organization, Functions, and Delegations of Authority*. 77 Fed. Reg. 23250, April 18, 2012.)

Human Services > Administration for Community Living > Administration on Aging > Grants Management

AoA Grants Management—Use Voluntary Contributions To Expand Services for the Elderly

Recommendations To Be Implemented

We recommend that AoA revise its regulations in accordance with the Older Americans Act of 1965 (OAA), as amended, to make it clear that

- recipients' voluntary contributions and related interest earned are to be treated as program income that must be used only to expand the services for which the contributions were given and
- recipients' voluntary contributions are not to be used to meet Federal matching requirements.

Savings probable but not estimated. On the basis of information in financial status reports for all States, the District of Columbia, and Puerto Rico, we estimated that \$90.8 million could have been saved in FY 1996 if AoA had made it clear to States that recipients' contributions were not to be used as matching funds.

The recommendation would curb States' noncompliance with the OAA that occurs when States misuse the voluntary contributions made by recipients of OAA-funded services for purposes not authorized by the OAA.

A February 2001 OIG report revealed that instead of using OAA recipients' voluntary contributions to expand specific OAA services, States improperly diverted the recipients' contributions to meet Federal matching requirements. (OAA, § 315(b).²) The diversion occurred because AoA's related

² The February 2001 OIG report from which the recommendations are derived states that the use of voluntary contributions to meet cost-sharing or matching requirements as permitted by these regulations is contrary to

regulations did not make the OAA requirement clear and allowed a matching alternative that is not authorized by the OAA. (45 CFR 1321.67(b).) In its January 8, 2001 [response](#) to OIG's review, AoA agreed that its regulation was inconsistent with the OAA and said it would submit revised regulations. However, as of 2012, AoA had yet to revise its regulations.

Our 2001 report revealed that 28 States and the District of Columbia misused \$90.8 million in recipients' voluntary contributions in FY 1996 to meet the matching requirements of their grant agreements.

Additional Background >

The OAA authorizes grants for programs that provide meals and various supportive services to help vulnerable older persons remain in their own homes. Services provided under the grants include congregate and home delivered meals, transportation, and in-home support. Pursuant to the OAA, § 315(b), grantees may solicit noncoersive contributions from recipients and encourage contributions from individuals whose self-declared income is at or above a designated percent of the poverty line. Contribution levels are to be based on the actual cost of services. All collected contributions must be safeguarded and accounted for and be used to expand the service for which each contribution was given. The 2006 reauthorization amendments clarified that contributions are to supplement (not supplant) Federal funds received under the OAA. (OAA, § 315(b)(4)(E).)

In April 2012, the Secretary incorporated AoA into the new Administration for Community Living. AoA supports programs that provide services such as meals, transportation, and caregiver support to older Americans at home and in the community through the nationwide network of services for the aging.

Progress of Implementation

AoA concurred with this recommendation. The OAA is being reauthorized. As part of this activity, AoA conducted an open process for soliciting input throughout the country and received recommendations related to voluntary contributions as well as other proposals for improving provisions in the OAA. Also, in July 2012, AOA distributed to its Regional Offices and States a document summarizing the various types of consumer contributions that may be collected by OAA services providers. This document states that "All funds received from voluntary contributions must be used to expand the service for which the payment or contribution was given and may not be used to supplant other funding." Following a reauthorized statute, AoA will determine whether regulatory changes are needed.

We continue to monitor AoA's progress in revising its regulations.

Primary OIG Report

2001 FEB *States' Use of Voluntary Contributions Under Title III of the Older Americans Act.*
A-12-00-00002. [Full Text](#)

§ 307(a)(13)(C)(ii) of the Older Americans Act (Act) and that the section requires that voluntary contributions be used to increase the services." The current OAA reference for the requirement is § 315(b).

Human Services > Administration for Community Living > Administration on Aging > Grants Management

AoA Grants Management—Ensure That States’ Cost-Sharing Practices Comply With Requirements and Improve Data Quality

Recommendations To Be Implemented

We recommend that AoA

- ensure that States’ recipient cost-sharing practices comply with OAA requirements,
- provide more guidance to States about recipient cost sharing, and
- improve the quality of its data so that any effects of recipient cost sharing can be determined.

The recommendations would ensure that States that implement recipient cost sharing pursuant to the OAA comply with all the OAA’s pertinent requirements.

Historically, the OAA has allowed States to solicit and collect voluntary contributions from recipients of OAA services. The OAA Amendments of 2000 added an option to implement recipient cost sharing for certain OAA services. Under cost sharing, fees may be charged to recipients pursuant to OAA rules. OAA requirements include that each collected cost-sharing payment be used to expand the service for which such payment was given. It also provides that services for which funds are received under the OAA not be denied for an older individual because of the income of such individual or such individual’s failure to make a cost-sharing payment. (OAA, § 315(a)(5).)

A September 2006 OIG report revealed that of the 12 States that had implemented cost sharing in 2005, not all had followed the OAA’s requirements. As of 2005, AoA had provided only limited guidance to States about implementing cost sharing.

Additional Background >

The OAA includes a number of requirements for States that are intended to ensure that low-income older individuals can obtain services. Pursuant to the OAA Amendments of 2000, the Assistant Secretary of AoA is to annually conduct a comprehensive evaluation of practices for cost sharing to determine its impact on participation rates (with particular attention to low-income older individuals, including low-income minority older individuals, older individuals with limited English proficiency, and older individuals residing in rural areas). If the Assistant Secretary finds that there is a disparate impact upon low-income or minority older individuals or older individuals residing in rural areas in any State or region within the State regarding the provision of services, the Assistant Secretary shall take corrective action to ensure that such services are provided to all older individuals without regard to the cost-sharing criteria. (OAA, § 315(d).)

AoA collects participation data for many OAA services through the NAPIS/SPR. States report data in the NAPIS/SPR differently, and the demographic data in the NAPIS/SPR are incomplete. As a result, data in the NAPIS/SPR do not present a complete picture of participation and, therefore, cannot be

used to measure any impact that cost sharing might have on overall participation or on participation of low-income individuals and other subgroups specified in the OAA. We recommended that AoA improve the quality of its data so that the effects of recipient cost sharing can be determined.

Note: In April 2012, the Secretary incorporated AoA into the new Administration for Community Living. (77 Fed. Reg. 23250, April 18, 2012.)

Progress of Implementation

In its response to our review, AoA indicated that it had taken several actions, including holding senior agency staff meetings with regional administrators to review OAA cost-sharing requirements and establishing technical assistance and developing guidance for State Units on Aging. Regarding the recommendation to improve the quality of data, AoA noted that it had made several improvements, such as developing a software reporting structure and training manual.

We encourage AoA to follow through on its oversight of States' implementation of cost sharing and request that AoA provide OIG with documentation if it believes any of the recommendations we specified above have been fully implemented. New reauthorization legislation has been introduced. We continue to monitor AoA's progress.

Primary OIG Report

2006 SEP *Cost Sharing for Older Americans Act Services*. OEI-02-04-00290. [Full Text](#)

See Also

1996 MAY *Cost Sharing Under the Older Americans Act*. OEI-05-95-00170. [Full Text](#).

1990 OCT *Cost Sharing for Older Americans*. OEI-02-90-01010. [Full Text](#).

Other HHS-Related Issues

Other HHS-Related Issues > Financial Management

Financial Management—Improve Financial Analysis and Reporting Processes

Recommendations To Be Implemented

We recommend that HHS

- continue to develop and refine its financial management systems and processes to improve its accounting, analysis, and oversight of financial management activity and
- continue to focus on remediating the remaining financial management system deficiencies.

The recommendations would help ensure the continuous improvement of HHS's ability to produce reliable consolidated information from its reporting systems.

The Government Management Reform Act of 1994 (GMRA) requires that many Federal agencies, including HHS, prepare annual financial statements. The FY 2011 financial statement audit noted significant improvement in the internal control weaknesses in HHS financial management systems and financial analyses and oversight reported in previous fiscal years. HHS implemented automated tools to address issues regarding the segregation of duties and implemented a new Consolidated Financial Reporting Systems (CFRS). HHS used CFRS to automatically and consistently consolidate financial information from the three financial systems: the Unified Financial Management System, the National Institutes of Health Business System, and the Healthcare Integrated General Ledger Accounting Systems.

Despite the improvements detailed above, the FY 2011 financial statement audit still noted general control issues related to the design and operation of key controls related to security management, access controls, configuration management, and contingency planning. In addition, weaknesses were noted in general controls, business process controls, interface controls, and data management system controls for specific financial applications.

The FY 2011 financial statement audit also noted certain reconciliations and account analyses were not adequately or promptly performed to ensure that differences were identified and resolved. HHS's financial management systems still did not substantially comply with Federal financial management systems requirements.

Additional Background >

The Government Accountability Office's (GAO) *Government Auditing Standards* and the Office of Management and Budget's (OMB) Bulletin 07-04, *Audit Requirements for Federal Financial Statements*, provide auditors with guidance about how to audit and report on the Federal financial statements. OMB Bulletin A-127, *Financial Management Systems*, requires that financial statements

be the culmination of a systemic accounting process. The statements are to result from an accounting system that is an integral part of a total financial management system containing sufficient structure, effective internal control, and reliable data.

Progress of Implementation

In the *FY 2011 Agency Financial Report*, issued in November 2011, HHS generally concurred with the findings in the audit report. HHS will prepare corrective action plans to address the findings.

We continue to monitor HHS's progress in improving its financial analysis and report processes and related controls as part of the annual audit of the HHS's financial statements.

Primary OIG Report

2011 NOV *Department of Health and Human Services Fiscal Year 2011 Agency Financial Report*. Section II. Daniel R. Levinson, Inspector General, *Report on the Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2011*. A-17-11-00001. (pp. II-5, II-45.)

Other HHS-Related Issues > Safety and Quality of Care > Persons With Disabilities

Safety and Quality of Care—Strengthen State Protections for Persons With Disabilities in Residential Settings

Recommendations To Be Implemented

We recommend that the pertinent HHS agencies work cooperatively to

- provide information and technical assistance to States to improve the reporting of potential abuse or neglect of persons with disabilities across all residential settings,
- strengthen investigation and resolution processes,
- assist in analyzing incident data to identify trends that indicate systemic problems, and
- identify the nature and causes of incidents to prevent future abuse.

Several HHS operating divisions fund programs or services that play a role in protecting persons with disabilities from abuse or neglect.

A May 2001 OIG report revealed that between 1999 and 2000, about 90 percent of persons with disabilities in residential facilities were in facilities that are not subject to oversight by the Centers for Medicare & Medicaid Services (CMS) and relied solely on protections offered by State systems to identify, investigate, and resolve reports of abuse or neglect, including the misuse of restraints and seclusion. The levels of protection provided by State systems vary widely. Limited Federal standards, partly because of HHS's limited statutory authority to set requirements for many

facilities and homes, have left persons with disabilities more vulnerable in residential facilities in which State systems are not well developed. Also, HHS was at a disadvantage in identifying systemic problems because it received limited information on occurrences of abuse or neglect.

Additional Background >

For facilities receiving Medicare or Medicaid funds—including nursing homes, psychiatric facilities, and intermediate care facilities for individuals with intellectual disabilities, CMS has established Conditions of Participation (CoP) requiring that residents and patients be protected from abuse or neglect. ACF and the Substance Abuse and Mental Health Services Administration (SAMHSA) provide States with grants to establish protection and advocacy systems for investigating allegations of abuse or neglect. Also, FDA oversees the regulation of medical devices, including physical restraints, and receives information on deaths that occur during the use of restraints.

Progress of Implementation

CMS, ACF, SAMHSA, and FDA concurred with working cooperatively to provide information and technical assistance to States. Each agency detailed actions that it was taking or planned to take to improve safeguards.

The SAMHSA grant program to support implementation of effective alternatives to restraint and seclusion was initiated in FY 2001 and concluded in FY 2010. SAMHSA has established a national technical assistance center for seclusion and restraint and trauma-informed care. A number of Technical Assistance (TA) events have been provided to an array of audiences and a National Summit was held November 14 - 15, 2011, to formally launch the new TA initiative.

In FY 2010, ACF added tasks related to the investigation of abuse and neglect in home and community-based settings to the technical assistance contract for protection and advocacy agencies.

In FY 2011, the Training and Advocacy Support Center (TASC), funded through an interagency agreement between the ACF Administration on Developmental Disabilities (ADD), SAMHSA, and Department of Education's Rehabilitation Services Administration (RSA), conducted a community monitoring project to track the quality of life and outcomes of individuals coming out of large institutions to live in the community. Findings and information from the project are being disseminated to the State Protection and Advocacy Systems (P&A) network. ACF/ADD has been leading cross-agency meetings (monthly) of the Federal agencies that fund the P&A system, including SAMHSA, RSA, HRSA, and the Social Security Administration, to discuss ways of strengthening the system. Some of the discussions across the Federal agencies have focused on improving reporting requirements and processes for the P&A systems.

We continue to monitor the progress made on the recommendations we specified.

Primary OIG Report

2001 MAY *Reporting Abuses of Persons with Disabilities*. A-01-00-02502. [Full Text](#)

Other HHS-Related Issues > Ethics Oversight > Waivers

Ethics Oversight—Require That HHS’s Conflict-of-Interest Waivers Be Documented as Recommended (New)

Recommendations To Be Implemented

We recommend that the Office of the General Counsel (OGC)

- require HHS operating divisions (OPDIV) and staff divisions (STAFFDIV) to document conflict-of-interest waivers as recommended in Governmentwide Federal ethics regulations and the Secretary’s instructions,
- develop additional guidance and training to assist OPDIVs and STAFFDIVs in documenting conflict-of-interest waivers as recommended in Governmentwide Federal ethics regulations and the Secretary’s instructions,
- take action to revise the conflict-of-interest waivers in our review that were not documented as recommended in Governmentwide Federal ethics regulations and the Secretary’s instructions if the waivers are still in effect,
- expand the review of conflict-of-interest waivers for special Government employees (SGE) on committees, and
- require all employees to sign and date their conflict-of-interest waivers or otherwise document that they received and acknowledged them.

The recommendations would help ensure that HHS operating divisions comply with Federal documentation requirements for conflict-of-interest waivers.

HHS employees, including SGEs serving as subject-matter experts on Federal advisory committees (committees), play an influential role in the Federal Government’s public health policies. HHS employees are prohibited from participating in certain official Government matters affecting their personal financial interests. These interests may include outside employment, grants, and stock ownership.

An August 2011 OIG report revealed that most (56 percent) of HHS conflict-of-interest waivers in our review were not documented as recommended in provisions of selected Governmentwide Federal ethics regulations and the January 2009 instructions of the Secretary of HHS (Secretary). In addition, although signatures and dates were not required, 18 percent of waivers were signed and dated by the HHS employees receiving them. Most of the waivers (27 of 28) were granted to SGEs on committees.

Additional Background >

The Office of Government Ethics (OGE) promulgates Governmentwide Federal ethics regulations for all executive branch employees and oversees all Federal agencies’ ethics programs. With oversight

and guidance from OGC, an HHS OPDIV or STAFFDIV may grant conflict-of-interest waivers to HHS employees if the OPDIV or STAFFDIV determines that the conflicts are not likely to affect the integrity of the employees' services to the Government or if the need for the employees' services outweighs the potential for conflicts. Waivers permit employees who have conflicts of interest to act in an official Government capacity on matters in which they would otherwise be prohibited from participating.

OGE said that as a general matter, the recommendations support good documentation practices that it strongly recommends

According to selected regulations and the Secretary's instructions, a waiver should describe, among other things, the employee's specific financial interest that poses the conflict; the particular matter(s) in which the employee is permitted to participate; and the particular matter(s), if any, in which the employee is prohibited from participating. In addition, although it is not a Federal requirement for employees to sign and date their waivers, OGC's sample waivers have a signature line. Signatures and dates show that employees received, acknowledged, and may be held accountable for complying with their waivers.

Progress of Implementation

We encourage OGC to address each of the recommendations we specified and provide documentation on how they have been implemented. We continue to monitor the progress of HHS's implementation of the recommendations.

Primary OIG Report

2011 AUG *Conflict-of-Interest Waivers Granted to HHS Employees in 2009*. OEI-04-10-00010.
[Full Text](#).

<https://oig.hhs.gov>