



Department of Health & Human Services

Office of  
Inspector  
General

# Compendium of Unimplemented Recommendations

March 2011 Edition

OIG

# Introductory Message From the Office of Inspector General

## Background

**T**HE DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS) Office of Inspector General (OIG) *Compendium of Unimplemented Recommendations* (Compendium) summarizes significant<sup>1</sup> monetary and nonmonetary recommendations that, when implemented, will result in cost savings and/or improvements in program efficiency and effectiveness. Compendium recommendations result from audits and evaluations that are performed pursuant to the Inspector General Act of 1978, as amended. Implementation generally requires one or more of three types of actions: legislative, regulatory, or administrative. Some issues involve more than one type of action.

Each narrative in the Compendium contains a background summary, findings, recommendation(s), management response summary, status, and report titles, numbers, and issue dates. In the case of monetary recommendations, there is also an estimate of the savings that may be achieved by implementing the recommendations. The estimated value of each monetary recommendation is based on the specifics of each review and is not projected beyond the scope of the original review. The estimates provide indicators of potential savings, but the actual savings to be achieved depend on the scope of the legislative, regulatory, or administrative implementing actions.

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 recommendations that were included in the preceding edition of the Compendium and in reports that were issued during the closed fiscal year. The March edition of the Compendium updates the status of recommendations that were not fully implemented as of September 30, 2010 and represent significant opportunities for action in FY 2011.

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<sup>1</sup> 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.

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.

## **HHS Organization and Programs**

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 Departmentwide 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 (AoA) 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.

- Departmentwide and cross-cutting issues. Departmentwide 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.

## **Priority Recommendations**

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, which are a mix of monetary and nonmonetary improvements, are presented in the order in which they are found in the Compendium.

### **Compendium Part I**

#### **Medicare Part A and Part B (Traditional Medicare)**

- Hospitals—Modify Policy To Reduce or Eliminate Medicare Payments for Hospital Bad Debts. Estimated savings \$340 million.
- Hospices—Ensure That Hospice Claims for Beneficiaries in Nursing Facilities Comply With Medicare Coverage Requirements. Nonmonetary.
- Practitioners—Adjust Eye Global Surgery Fees To Reflect the Number of Evaluation and Management Services Actually Being Provided by Physicians. Estimated savings \$97.6 million.
- Medical Equipment and Supplies—Ensure Medical Equipment Suppliers’ Compliance With Medicare Enrollment Standards. Estimated savings to be determined (TBD).
- Medical Equipment and Supplies—Reduce the Rental Period for Medicare Home Oxygen Equipment. Estimated savings \$3.2 billion.
- Medical Equipment and Supplies—Eliminate Medicare’s Vulnerability to Fraudulent or Excessive Inhalation Drug Claims. Estimated savings TBD.

- Medical Equipment and Supplies—Ensure That Medicare Power Wheelchair Suppliers Meet Documentation Requirements.

## **Compendium Part II**

### **Medicare Part C (Medicare Advantage)**

- Modify Payments to Medicare Advantage Organizations. Estimated savings \$1.97 billion.
- Review Vulnerabilities Within Sales Agents' Marketing of Medicare Advantage Plans. Nonmonetary. (New)

### **Medicare Part D (Prescription Drug Benefit)**

- Ensure Accuracy of Prescription Drug Plan Sponsors' Bids and Prospective Payments. Estimated savings TBD.
- Implement Safeguards To Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans. Nonmonetary.
- Ensure the Validity of Prescriber Identifiers on Medicare Part D Drug Claims.

## **Compendium Part III**

### **Medicaid Reviews**

- Medicaid Federal and State Partnership—Limit Enhanced Payments to Costs and Require That Medicaid Payments Returned by Public Providers Be Used To Offset the Federal Share. Estimated savings \$120 million.
- Medicaid Prescription Drugs—Ensure That Medicaid Reimbursement for Brand-Name Drugs Accurately Reflects Pharmacy Acquisition Costs. Estimated savings \$1.08 billion for brand-name drugs.
- Medicaid Prescription Drugs—Establish Connection Between the Calculation of Medicaid Drug Rebates and Drug Reimbursement. Estimated savings \$1 billion.
- Medicaid Prescription Drugs—Extend Additional Rebate Payment Provisions to Generic Drugs. Estimated savings \$966 million.

- Children’s Health— Improve Medicaid Children’s Access to Required Preventive Screening Services.

## Compendium Part IV

### Public Health Reviews

- Centers for Disease Control and Prevention—Improve State and Localities’ Medical Surgical Preparedness for Pandemics. Nonmonetary.
- Food and Drug Administration—Improve and Strengthen Food Facilities’ Compliance With Records Requirements for Traceability of Food Products. Nonmonetary.
- Food and Drug Administration and National Institutes of Health—Ensure That Clinical Investigators Disclose All Financial Interests. Nonmonetary.
- National Institutes of Health—Increase Oversight of Grantee Institutions To Ensure Compliance With Federal Financial Conflict-of-Interest Regulations. Nonmonetary.
- Indian Health Service—Reduce Overpayments for Contract Health Services Hospital Claims and Cap Payments for Nonhospital Services at the Medicare Rate for Those Services

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

OIG’s Compendium and other key publications are available on our Web site at:

<http://www.oig.hhs.gov/publications.asp>

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# Part I:

# Medicare Part A and Part B

# Part I:

## Medicare Part A and Part B

### Home Health Agencies

Medicare Part A and Part B > Home Health Agencies > Deficiencies and Sanctions

#### Consider Intermediate Sanctions for Deficiency History in Medicare Recertifications of Home Health Agencies

**Background:** The Social Security Act, § 1891(c)(2)(A), requires that the Centers for Medicare & Medicaid Services (CMS) survey the quality of care and services furnished by home health agencies (HHA) at least every 36 months. HHAs participating in the Medicare program must comply with 15 Medicare Conditions of Participation (CoP) and 69 standards. CMS contracts with State agencies to conduct initial HHA certification and recertification surveys to determine CoP compliance. State agencies annually survey a 5-percent targeted sample of at-risk HHAs. Noncompliance with one or more CoP is cause for termination of participation. Termination is the only sanction available to CMS in response to HHA noncompliance.

**Findings:** We found that 15 percent of HHAs repeated the same deficiency citation on three consecutive surveys. In HHAs with repeat citations, the most frequently repeated deficiency citation related to patient plans of care. On the three most recent surveys, these HHAs received, on average, twice as many deficiency citations per survey compared with HHAs without repeated citations. Most HHAs with repeat citations are located in six States and tend to be concentrated in highly populated areas. We also found that CMS does not use all of the available deficiency history information in its oversight of HHAs; deficiency history beyond the most recent survey can be an important indicator of performance on the next survey and can improve CMS's identification of at-risk HHAs. For HHAs with one or more condition-level deficiency, CMS has no sanction other than initiating a termination.

**Recommendations:** CMS should (1) use existing survey data to identify patterns of deficiency citations and at-risk HHAs by (a) requiring surveyors to review all of the available survey data before each survey and (b) including multiple survey results in its algorithm to identify HHAs at risk of providing poor quality of care,

and (2) implement intermediate sanctions as directed by the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987).

**Management Response Summary:** In response to our 2008 draft report, CMS partially concurred with our recommendations and said that during the preceding several years, it had taken steps to improve oversight of HHAs, many of which address the issue of repeated deficiencies. CMS concurred, in part, with the recommendation that the State survey agency use all survey data to identify patterns of deficiency citations and at-risk HHAs before conducting each survey. CMS did not concur with the recommendation to include multiple survey results in its algorithm to identify a targeted sample of HHAs that are at risk of providing poor quality of care. CMS explained that including an algorithm of three standard surveys would result in HHAs, particularly newer ones, not being considered in the targeting process because these HHAs lack historical survey data. 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 stated that it had drafted an alternative sanction that was under review. However, in 2010 CMS developed a new proposed rule, anticipated to be published in the fall of 2011, that would require unannounced and extended surveys of HHAs, and the imposition of sanctions when HHAs are found to be out of compliance with the Federal standards.

**Status:** While we appreciate CMS's update for 2011, we still consider the recommendations to be unimplemented. As of January 2011, the proposed rule described above was still under review at CMS and had not been published in the Federal Register for comments. We believe that surveyors should use multiple surveys to evaluate trends or historical results that might enable them to identify poor performance or aberrant patterns in the deficiencies, and also to enhance the review process, given that the current process uses only the most recent survey. We continue to monitor CMS's implementation of our recommendations.

### **Related Report:**

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

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Medicare Part A and Part B > Home Health Agencies > Outlier Payments

## Review Aberrant Medicare Home Health Outlier Payment Patterns (New)

**Background:** In October 2000, CMS adopted a prospective payment system (PPS) that pays a predetermined rate for 60-day episodes of home health care. The payments are adjusted for beneficiaries' health conditions and care needs, as well as geographical wage differences. There are no limits to the number of 60-day episodes that eligible beneficiaries may receive. Medicare makes additional payments, known as outlier payments, to home health providers that supply services to beneficiaries who incur unusually high costs.

**Findings:** We found that in 2008 Miami-Dade County accounted for more home health outlier payments than the rest of the country combined and that over 85 percent of home health providers that received outlier payments over \$100,000 per beneficiary were located in Miami-Dade County. In addition, 67 percent of home health providers that received total outlier payments over \$1 million were located in Miami-Dade County. We also found that in Miami-Dade County, Medicare outlier payments for home health claims with a primary diagnosis related to diabetes were eight times the national average. Finally, over half of home health providers in Miami-Dade County and the 23 other counties we identified were paid at least twice the national average for 3 or more of the 5 payment characteristics we reviewed.

**Recommendation:** CMS should review home health providers that exhibit aberrant outlier payment patterns and respond appropriately based on the findings.

**Management Response Summary:** CMS concurred with our recommendation, stating that its experience has shown that, beyond identifying claims that require prepayment review, the beneficiary interview is the best method of determining whether the beneficiary does not qualify for services. In its 2011 update of this recommendation, CMS reported that its Miami Field Office implemented a new Fraud Prevention and Early Abatement approach to home health care that focused on performing data analysis and beneficiary interviews for those highly suspect new home health providers.

**Status:** We will continue to monitor CMS's implementation of this recommendation in Miami Dade County and the 23 other counties we identified with high incidences of home health providers that exhibit aberrant outlier payment patterns.

**Related Report:**

2009 DEC     *Aberrant Medicare Home Health Outlier Payment Patterns in Miami-Dade County and Other Geographic Areas in 2008.* OEI-04-08-00570 [Report](#)

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# Ambulatory Surgical Centers

Medicare Part A and Part B > Ambulatory Surgical Centers > Survey and Certification

## Improve Quality Oversight of Ambulatory Surgical Centers

**Background:** Ambulatory surgical centers (ASC) are one of the fastest growing settings for ambulatory surgery in the Medicare program. CMS is responsible for the oversight of care provided in this health care setting. Quality oversight of ASCs revolves around the Conditions for Coverage (CFC), Medicare's set of minimum health and safety requirements. CMS requires that ASCs become Medicare certified by a State survey and certification agency or be privately accredited to show that they meet 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.

**Findings:** We found that the number of Medicare ASCs more than doubled from 1990 to 2000 and that major procedures performed in ASCs increased by 730 percent. Medicare's system of quality oversight was not sufficient, in that one-third of ASCs certified by State agencies had not been recertified in 5 or more years when our review was performed in 2000. CMS had done little to hold State certification agencies and accreditors accountable to the Medicare program and the public.

**Recommendations:** CMS should (1) determine an appropriate minimum cycle for surveying ASCs certified by State agencies, and (2) hold State agencies and accreditors fully accountable to the Medicare program for their performance in overseeing ASCs.

**Management Response Summary:** CMS generally concurred with our recommendations. In response to our first recommendation, CMS updated its *State Operations Manual* (section 2008F) on May 21, 2004, to state that "resurveys are generally conducted annually, but depending on national initiatives and budget constraints, the cycle may vary." The American Recovery and Reinvestment Act of 2009 (Recovery Act) allotted funds to allow States to survey one-third of all nonaccredited ASCs in fiscal year (FY) 2010. However, CMS has not yet mandated a minimum cycle for surveying ASCs certified by State agencies.

Regarding our second recommendation, CMS noted in a Notice of Final Rulemaking at [72 Fed Reg. 42470](#), August 2, 2007, (42 CFR §§ 410 and 416) that the revisions were the result of the February 2002 OIG report. Also, the preamble to the notice stated that, from a policy and operational perspective, it was unable to adjust the CFCs to match the levels of surgical services performed by ASCs, but that it "would expect each ASC's quality

assurance and performance improvement (QAPI) program to reflect the scope and severity of the surgical services they perform.” However, on November 24, 2010, CMS published 42 CFR Parts 410, 411, 412, 413, 416, 419, et al, in which CMS states that did not implement an ASC quality reporting program for calendar year (CY) 2008, CY 2009, or CY 2010.

In this regulation, CMS also states that the transition to the revised payment system in CY 2008 posed significant challenges to ASCs. CMS determined that it would be most appropriate to allow time for ASCs to gain some experience with the revised payment system before introducing other new requirements. Further, by implementing quality reporting under the Outpatient Prospective Payment System (OPPS) prior to establishing quality reporting for ASCs, CMS would gain experience with quality measurement in the ambulatory setting in order to identify the most appropriate measures for quality reporting in ASCs prior to the introduction of the requirement for ASCs.

Status: We continue to monitor CMS’s implementation of our recommendations.

**Related Report:**

2002 FEB     *Quality Oversight of Ambulatory Surgical Centers: A System in Neglect.*  
OEI-01-00-00450 [Report](#)

# Hospitals

Medicare Part A and Part B > Hospitals > Graduate Medical Education

## Revise Graduate Medical Education Payment Methodology

**Background:** The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), § 9202, and the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986), § 9314, changed the way Medicare reimburses hospitals for the direct costs of graduate medical education (GME). Under the revised methodology, costs are reimbursed on a “hospital-specific” prospective payment basis, which is based on a hospital’s GME costs per resident in a base year, usually the cost-reporting period that began during FY 1984.

**Findings:** CMS estimated that the revised GME methodology would result in substantial Medicare savings. Our review indicated that Medicare will pay a disproportionate share of GME costs because of two factors in the methodology. **Factor 1:** the revised system allows hospital cost centers with little or no Medicare patient utilization to receive disproportionately high importance in the calculation of GME reimbursement. **Factor 2:** the Medicare patient load percentage used to compute Medicare’s share of these costs is based on inpatient data only and is higher than Medicare’s overall share of GME costs as determined under the previous method, which also included ancillary and outpatient data.

**Recommendations:** CMS should (1) address Factor 1 by revising the regulations to remove from a hospital’s allowable GME base-year costs any cost center with little or no Medicare utilization and (2) address Factor 2 by submitting a legislative proposal to compute Medicare’s percentage of participation under the former method or a similarly comprehensive system.

<b>Savings:</b>	<b>Factor 1</b>	<b>\$39.2 million*</b>
	<b>Factor 2</b>	<b>\$125.6 million*</b>
	<b>Combined</b>	<b>\$157.3 million*</b>

*\*Estimated savings are based on 4 years of cost reporting beginning October 1, 1985. When the two proposed changes are handled as one combined calculation, the savings are less than those from calculating the effect of the changes separately.*

**Management Response Summary:** CMS did not concur with our recommendations, stating that it believed few Medicare savings would result from implementation of the

first recommendation and that a legislative proposal to implement the second recommendation was not appropriate because of pending changes to GME programs. We note that the Balanced Budget Act (BBA) and the Balanced Budget Refinement Act of 1999 (BBRA) contained provisions to slow the growth in Medicare spending on GME. In December 2009 and January 2011, CMS informed us that it is monitoring this area.

**Status:** We continue to recommend that CMS revise GME payment methodology to achieve further savings.

**Related Report:**

1994 APR *Nationwide Review of the Methodology for Identifying Medicare's Share of Graduate Medical Education Costs.* A-06-92-00020 [Report](#)

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Medicare Part A and Part B > Hospitals > Bad Debts

## Reduce or Eliminate Medicare Payments for Hospital Bad Debts

**Background:** Under Medicare's inpatient hospital PPS, hospitals are reimbursed for inpatient services rendered to Medicare beneficiaries by a fixed payment amount based on diagnosis-related groups (DRG). Medicare's payments to hospitals also include methods that support hospitals' financial viability in unusual circumstances such as special payments to hospitals that have a disproportionate share of low-income patients and additional outlier payments to hospitals for expenses associated with extremely costly patients. In addition, the Medicaid program pays the deductible and coinsurance amounts for certain categories of beneficiaries who are dually eligible for both Medicare and Medicaid in the same month.

Bad debts related to unpaid Medicare deductible and coinsurance amounts are reimbursed separately as pass-through items (i.e., reimbursed outside the DRG) subject to a 30-percent reduction, i.e., Medicare pays a portion of bad debts associated with unpaid beneficiary co-payments and deductibles to hospitals. Most Medicare Part A provider types are entitled to have their bad debts reimbursed at this rate. The 2011 deductible is \$1,132 for the first 60 days of a benefit period. Medicare's bad debt reimbursement criteria are at 42 CFR § 413.89(e).

**Findings:** In a June 1990 Management Advisory Report, the Office of Inspector General (OIG) advised the then Health Care Financing Administration that our audits were showing that hospital collection efforts of bad debts had often been less than adequate. Because Medicare would substantially pay the amounts, there was little incentive for hospitals to collect the unpaid deductible and coinsurance. This was occurring even though hospitals continued to earn significant profits.

Our more recent work (see report list below) continues to find that although regulations provide that hospitals must be able to establish that they made reasonable efforts to collect bad debts, hospitals still do not always follow Medicare's rules before reporting the unpaid deductible and coinsurance amounts for reimbursement by Medicare. As a result, hospitals continue to receive unallowable bad-debt payments.

**Recommendations:** CMS should consider various options, including (1) eliminating bad-debt payments, (2) reimbursing PPS hospitals for bad debts only if the hospitals lost money on their Medicare operations, and (3) seeking legislative authority to further modify bad-debt policies.

**Savings: \$8.46 billion over 5 years\***

\* The President's FY 2001 budget proposal to reduce bad-debt payments to hospitals and other providers estimated savings of \$340 million the first year and \$2.28 billion over 5 years. Savings of \$7.15 billion for FYs 2008–2012 were estimated in the President's FY 2008 budget proposal to eliminate bad-debt payments to all providers. Subsequently, the President's FY 2009 budget proposal estimated the savings would be \$8.46 billion for FY's 2009 – 2013.<sup>1</sup>

**Management Response Summary:** CMS has not concurred with the recommendations in this program area. In a February 10, 2003, proposed rule, CMS reiterated that it did not concur with the recommendations because the base period used to derive PPS rates did not include bad debts. The BBA provided for a reduction of bad-debt payments to providers, but the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) increased bad-debt reimbursement. The FY 2001 President's budget proposed reducing from 55 to 45 the percentage Medicare pays hospitals for bad debt and reducing other provider bad debt payments by 45 percent, with 5-year savings of \$2.28 billion. The President's FY 2008 and FY 2009 budgets attempted to implement the recommendation to eliminate bad-debt payments by including legislative proposals to phase out Medicare bad-debt payments for all Medicare providers over a 4-year period. The 5-year savings from the proposals were estimated at \$7.15 billion and \$8.46 billion respectively. However, the budget proposals were not enacted.<sup>2</sup>

**Status:** We continue to monitor CMS's implementation of our recommendations.

**Related Reports:**

- 2010 JUN *Review of Medicare Part A Bad Debts at Carolinas Medical Center for the Fiscal Year Ended December 31, 2005.* A-04-09-00055 [Report](#)
- 2010 JUN *Review of Medicare Part B Bad Debts at Carolinas Medical Center for the Fiscal Year Ended December 31, 2005.* A-04-09-00056 [Report](#)
- 2010 JUN *Review of Medicare Part A Bad Debts at Erlanger Medical Center for the Fiscal Year Ended June 30, 2005.* A-04-09-00057 [Report](#)
- 2010 JUN *Review of Medicare Part B Bad Debts at Erlanger Medical Center for the Fiscal Year Ended June 30, 2005.* A-04-09-00058 [Report](#)

<sup>1</sup> Footnote to savings updated to include President's budget proposal for FY 2001.

<sup>2</sup> Management Response Summary updated to include President's budget proposal for FY 2001.

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- 2003 JAN *Review of Medicare Bad Debts Claimed by the Baystate Medical Center for Fiscal Year Ended September 30, 1999.* A-01-02-00515 [Report](#)
- 2003 JAN *Medicare Inpatient and Outpatient Bad Debts Claimed by Montefiore Medical Center for Fiscal Year Ended December 31, 1999.*  
A-02-02-01031 [Report](#)
- 2003 JAN *Review of Medicare Bad Debts at Pitt County Memorial Hospital for the Fiscal Year Ended September 30, 1999.* A-04-02-02016 [Report](#)
- 2002 OCT *Review of Medicare Bad Debts for Florida Hospital for the Fiscal Year Ended December 31, 1999.* A-04-02-02011 [Report](#)
- 2002 OCT *Review of Medicare Inpatient Acute-Care Bad Debts at St. Joseph Hospital for Calendar Year 1999.* A-05-02-00039 [Report](#)
- 2002 OCT *Review of Medicare Inpatient Acute-Care Bad Debts at Ingalls Hospital for Fiscal Year 1999.* A-05-02-00052 [Report](#)
- 2002 OCT *Audit of Inpatient Bad Debts Claimed by Memorial Hermann Hospital in its Medicare Cost Report for the Fiscal Year Ended June 30, 2000.*  
A-06-02-00027 [Report](#)
- 2002 SEP *Review of Medicare Bad Debts for Hospital Inpatient Services Claimed by St. Luke's-Roosevelt Hospital Center for Fiscal Year Ended December 31, 1999.*  
A-02-02-01016 [Report](#)
- 2002 JUL *Review of Medicare Inpatient Bad Debts at United Hospital Center, Clarksburg, West Virginia, for Calendar Year 1999.* A-03-01-00022  
[Report](#)
- 2002 JUL *Review of Medicare Bad Debts at the University of California, San Francisco Medical Center.* A-09-02-00057 [Report](#)
- 2002 JUN *Review of Medicare Inpatient Bad Debts at Mercy Catholic Medical Center, Conshohocken, Pennsylvania, for Calendar Year 1999.* A-03-02-00002  
[Report](#)
- 2001 DEC *Review of Medicare Bad Debts at the University of Alabama at Birmingham Hospital.* A-04-00-06005 [Report](#)
- 1990 JUN *Options To Reform Payment for Medicare Bad Debts.* A-14-90-00339 [Report](#)

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Medicare Part A and Part B > Hospitals > Adverse Events

## Improve the Identification of Adverse Events in Hospitals (New)

**Background:** An adverse event is an incident in which harm is experienced by a patient as a result of medical care or in a health care setting. We conducted an in-depth examination of the five methods used in a two-county case review for identifying possible adverse events experienced by Medicare beneficiaries. These methods were: nurse reviews of medical records, interviews of Medicare beneficiaries, two types of analysis of hospital billing data, and reviews of internal hospital incident reports.

**Findings:** We found that all the methods that we reviewed were useful for identifying events that harmed Medicare beneficiaries in hospitals. Nurse reviews and analysis of present-on-admission (POA) indicators that hospitals include in Medicare billing data identified the highest number of actual events. However, physician reviewers determined that 61 percent of the possible events identified by the five screening methods were, as a result of review, determined to not be adverse events.

Shortcomings in two of the screening methods have implications for Medicare payments and Federal initiatives to identify, track, and monitor events. First, patient diagnosis codes were inaccurate or absent for 7 of the 11 Medicare hospital-acquired conditions (HAC) identified by physician reviewers. These problems could prevent Medicare from identifying HACs, result in Medicare overpayments, and inhibit use of billing data to monitor quality of care in hospitals. Second, reviewed hospitals did not generate incident reports for 93 percent of the events, including some of the most serious events involving death or permanent disability to the patient. The lack of such reports could prevent hospitals from tracking events as required by Federal regulation, and suggests that hospital incident-reporting systems may be an unreliable source of information for Patient Safety Organizations (PSO), entities that aggregate and analyze hospital data about events.

**Recommendations:** We recommend that (1) CMS and the Agency for Healthcare Research and Quality (AHRQ) explore opportunities to identify adverse events when conducting medical record reviews for other purposes, (2) CMS ensure that hospitals code claims accurately and completely to allow for identification of Medicare HACs, (3) CMS provide guidelines for State survey agencies that assess hospital compliance with requirements to track and monitor adverse events, and (4) AHRQ inform PSOs that internal hospital-incident reporting systems may be insufficient for providing information about events to PSOs.

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**Management Response Summary:** AHRQ concurred with the report as written. CMS concurred that there is a need for hospitals to code claims accurately and completely to allow for the accurate identification of HACs and agreed with the recommendations made to CMS. As a step toward implementing our second recommendation, CMS has established a process for providing coding advice to hospitals on the reporting of POA indicators that affect the payment of cases with HACs. To help ensure proper coding, the American Hospital Association's Editorial Advisory Board (of which CMS is a member) will receive questions on HACs and POA reporting and publish advice for correct coding for these conditions in the publication *Coding Clinic for ICD-9-CM*. This publication is used by all hospitals and reviewers, because it is recognized as the official CMS-approved source of coding instructions. As of April 8, 2010, the publication published coding advice on HACs and POA indicators, and it will continue to do so on a regular basis.

CMS should continue to promote proper coding, including encouraging hospitals to ensure physicians provide complete and specific diagnoses information in medical charts to allow coders full information to code claims. OIG and CMS are both conducting further research examining the accuracy of claims related to HACs. Toward implementing our third recommendation, CMS indicated in comments on another OIG report in 2010 that it is testing additional guidance to State survey agencies regarding tracking and monitoring adverse events. Toward implementing our fourth recommendation, AHRQ has provided guidance to PSOs in regard to adverse event definitions and recommended reporting elements.

**Status:** We will continue to monitor CMS and AHRQ's implementation of our recommendations. AHRQ should continue to provide guidance to PSOs including emphasizing the importance of internal incident-reporting data. OIG is conducting further research examining hospital participation and submission of event information to PSOs.

### **Related Report:**

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

### **See Also:**

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

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# Nursing Homes

Medicare Part A and Part B > Nursing Homes > Noncompliance

## Ensure the Appropriate Processing of Denial of Medicare Payment Remedies for Noncompliant Nursing Homes

**Background:** Denial of payment for new admissions (DPNA) is an enforcement remedy that CMS may use to address noncompliance with Federal quality-of-care standards in skilled nursing facilities (SNF). CMS is responsible for imposing denial-of-payment remedies but relies on its fiscal intermediaries (FI) to identify and reject relevant Medicare claims. Once CMS instructs an FI to put a remedy into effect, the FI creates an edit to identify and suspend claims meeting certain parameters. Those claims are reviewed and then paid, rejected, or returned to the facility as appropriate. The work of FIs is being transitioned to Medicare Administrative Contractors (MAC). We reviewed information and supporting documentation from CMS and FIs for a random sample of cases in which CMS imposed DPNA remedies during FY 2004.

**Findings:** We found that CMS and its FIs had incorrectly processed 74 percent of DPNA actions, with 40 percent of the cases resulting in overpayments to SNFs. These overpayments exceeded \$5 million. We identified DPNA processing errors, including CMS not providing FIs with the instructions on a timely basis or at all, CMS providing information to the wrong FIs, and FIs misinterpreting CMS's instructions. We also found that about half of claims involving readmissions lacked codes indicating readmission status, which made the claims incorrectly appear to be new admissions subject to the DPNA remedy.

**Recommendations:** CMS should (1) manage DPNA cases to ensure that DPNA instructions are sent timely and that FIs and MACs retrospectively review cases that are processed late to correct any payment errors, (2) address communication breakdowns by implementing a standard format to notify FIs or MACs that a DPNA remedy will be in effect, (3) require confirmation that instructions are received and understood.

**Management Response Summary:** CMS agreed with our recommendations and outlined specific actions to address each recommendation. The agency indicated that it would develop internal procedures to effectively communicate DPNA instructions to FIs and MACs 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 DPNAs. 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 stated 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.

**Status:** We continue to monitor CMS's progress in issuing guidance concerning DPNA instructions and protocols with contractors.

**Related Report:**

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

**See Also:**

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

# Hospices

Medicare Part A and Part B > Hospices > Survey and Certification

## Establish Specific Requirements for the Frequency of Hospice Certification

**Background:** The Social Security Act, § 1812(a), provides coverage of hospice care for beneficiaries who qualify for Medicare Part A and are terminally ill. In recent years, this Medicare benefit has grown in terms of patients served, expenditures, and number of hospices. Organizations that provide hospice care must be certified by a State agency or a recognized accreditation organization as meeting minimum participation standards prescribed by CMS. CMS uses Federal comparative surveys and annual performance reviews to evaluate State agencies' survey and certification operations.

**Findings:** We found that as of July 2005, 86 percent of hospices had been certified within required timeframes, while 14 percent averaged 3 years past due. Deficiencies were cited for 46 percent of the hospices surveyed and for 26 percent of the hospices investigated for complaints. The most frequently cited deficiencies for both surveys and investigations centered on patient care planning and quality. We also found that CMS and State agencies rarely used methods other than certification surveys and complaint investigations to monitor hospice performance and enforce standards. CMS and State agencies infrequently analyzed hospice performance data, although CMS had directed State agencies for FY 2006 to target 5 percent of the hospices most at risk for having quality problems. At the time of our review, CMS had not given State agencies any direct guidance or specific criteria to identify the at-risk hospices.

**Recommendation:** CMS should seek regulatory or statutory changes to establish specific requirements for the frequency of hospice certification.

**Management Response Summary:** CMS did not concur with our recommendation. It stated that it believed the issue should not be addressed in regulation and that it was primarily a statutory issue for consideration by Congress. CMS stated its belief 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. CMS has taken some steps to act on this recommendation by increasing surveillance of hospice facilities from every 8 years to every 6.5 years. (By comparison, surveillance of nursing homes occurs every 15 months.) CMS also instructed States' Survey Agencies to include the top 5 percent of "at risk" hospice agencies in their annual survey schedules. However, despite these steps, and given the increase in the number of hospice agencies, hospice beneficiaries, and associated dollars, concerns about care planning and quality

of care administered to hospice beneficiaries have remained, as reported in a subsequent OIG report in 2009 (referenced in the “See Also” section below). The issues at hospices are no less critical than those at nursing homes.

**Status:** We continue to recommend that CMS seek statutory changes for the frequency of hospice certification and seek regulatory or statutory changes to establish specific requirements for enforcement remedies for poor hospice performance.

**Related Report:**

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

**See Also:**

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

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Medicare Part A and Part B > Hospices > Noncompliance With Coverage Requirements

## Ensure That Hospice Claims for Beneficiaries in Nursing Facilities Comply With Medicare Coverage Requirements

**Background:** The Medicare hospice benefit allows a beneficiary with a terminal illness to forgo curative treatment for the illness and instead receive palliative care. The number of beneficiaries receiving hospice care has significantly increased in recent years, and some studies suggest that the use of hospice care has grown most rapidly in nursing facilities. Hospice benefit coverage requirements described at 42 CFR § 418 require an election statement, a plan of care, and a certification of terminal illness for patients receiving hospice services.

**Findings:** We found that 82 percent of hospice claims for beneficiaries in nursing facilities did not meet at least one Medicare coverage requirement, based on a medical record review of a stratified random sample of hospice claims for beneficiaries in nursing facilities in 2006. Medicare paid about \$1.8 billion for these claims. Thirty-three percent of claims did not meet election requirements, and 63 percent did not meet plan-of-care requirements. For 31 percent of claims, hospices provided fewer services than outlined in beneficiaries' plans of care. In addition, 4 percent of claims did not meet certification of terminal illness requirements.

**Recommendation:** CMS should strengthen monitoring practices for hospice claims.

**Management Response Summary:** CMS concurred with our recommendation. In its update for 2011, CMS said that it has taken steps to implement this recommendation. Specifically, CMS stated that it will instruct Medicare contractors to consider the coverage requirements in our report when prioritizing its medical review strategies or other interventions. CMS also stated that it is collecting more data on hospice claims and has added edits to reject claims that do not comply. The change request for the new edits, CR 6778, was issued on February 5, 2010. Additionally, CMS began conducting provider outreach calls in 2010 to improve compliance with Medicare requirements regarding hospice claims.

**Status:** We continue to monitor CMS's implementation of our recommendation. Although CMS stated that it has shared our report with providers, it has not offered concrete evidence that it has changed its monitoring practices. The noncompliance rate of 82 percent warrants systemic change, or at the minimum, specific strategies to address the problem.

**Related Report:**

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

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## Rural Health Clinics

Medicare Part A and Part B > Rural Health Clinics > Certification and Reimbursements

### Improve Oversight of Rural Health Clinics

**Background:** The Rural Health Clinic (RHC) program, created in 1977 by the Rural Health Clinic Services Act of 1977, is intended to increase access to health care in rural, medically underserved areas and to expand the use of midlevel practitioners in rural communities. In 1996, OIG and the General Accounting Office, now the Government Accountability Office (GAO), issued reports that raised concerns about the inappropriate growth and locations of RHCs. Both organizations recommended changes to ensure that RHCs are in areas that would otherwise be underserved. OIG reexamined this program and issued a followup report in 2005.

**Findings:** We found that between 1990 and 1995, the number of RHCs and associated Medicare and Medicaid expenditures grew substantially. The RHC program may have increased access to care in some areas but not in others. RHCs are paid based on their costs, which are difficult and sometimes impossible to verify or audit without significant resource expenditure by the Government. As of May 2003, 61 percent of RHCs were in areas that were not designated as shortage areas, and 39 percent were in urban areas.

**Recommendations:** CMS should, (1) in conjunction with the Health Resources and Services Administration (HRSA), modify the certification process to increase State involvement and ensure more strategic placement of RHCs; (2) expedite the issuance of the regulations under development, and (3) take immediate steps to improve the oversight and functioning of the cost reimbursement system, with a long-term goal of implementing an improved method of reimbursement.

**Management Response Summary:** CMS and HRSA generally concurred with our recommendations. The BBA refines the requirements for RHC designations and provider-based reimbursement. CMS developed a program memorandum consolidating and clarifying the policy about provider-based and freestanding designation conditions. CMS published a notice of proposed rulemaking at [73 Fed. Reg. 36696](#) (June 27, 2008) that addressed several of our recommendations. CMS has indicated that the final rule is still in the clearance process.

The Department of Health & Human Services (HHS) published a notice of proposed rulemaking at [73 Fed. Reg. 11232](#) (February 29, 2008) to revise and consolidate the criteria and processes for designating these shortage areas. On July 23, 2008, HRSA published a notice at [73 Fed. Reg. 42743](#) indicating that it had received many substantive

comments on the proposed rule and that it intended in the future to post a revised notice of proposed rulemaking for further review and public comment before issuing a final rule.

Section 5602 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) requires the establishment of a comprehensive methodology and criteria for designating medically underserved populations and health professional shortage areas. On May 11, 2010, HRSA published a notice of intent to form a negotiated rulemaking committee at [73 Fed. Reg. 26167](#). HRSA has directed the committee to develop a draft version of the interim final rule by July 1, 2011.

**Status:** We continue to monitor CMS's and HRSA's efforts to modify certification process requirements.

**Related Reports:**

2008 MAY     *Status of the Rural Health Clinic Program.* OEI-05-03-00170 [Report](#)

1996 JUL     *Rural Health Clinics: Growth, Access, and Payment.* OEI-05-94-00040 [Report](#)

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## Practitioners

Medicare Part A and Part B > Practitioners > Physicians > Global Surgery Fees

### Adjust Eye Global Surgery Fees to Reflect the Number of Evaluation and Management Services Actually Being Provided by Physicians

**Background:** The Medicare program pays for physicians' services furnished on or after January 1, 1992, based on a fee schedule that is updated periodically. Fee schedule amounts are based on resources such as physicians' time and intensity of the work, measured in relative value units (RVU), that are involved with furnishing services. CMS must review RVUs at least every 5 years (Social Security Act, § 1848(c)(2)(B)) and adjust them as it deems necessary to account for developments such as medical practice or coding changes, new data, or new procedures.

Global surgery fees on the fee schedule include payments for surgical services and the related pre- and post-operative evaluation and management (E&M) services that are provided during the global surgery period. These global fees are based, in part, on CMS's estimates of the number of pre- and post-operative E&M services that physicians typically provide to beneficiaries. CMS 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.

**Findings:** We found that for the eye global surgeries we sampled, the global surgery fees often did not reflect the number of E&M services that physicians provided to beneficiaries during the global surgery periods because CMS had not adjusted or recently adjusted the RVUs for most of the global surgery codes. The fees reflected the number of E&M services provided during the global surgery periods for 60 of the 300 sampled global surgeries. However, the fees for the remaining 240 global surgeries did not reflect the number of E&M services provided. Physicians provided fewer E&M services than were included in 201 global surgery fees and provided more E&M services than were included in 39 global surgery fees.

Using the net results of our audit, we estimated that Medicare paid \$97.6 million for E&M services that were included in eye global surgery fees but were not provided during the global surgery periods in CY 2005. This high-priority audit was included in the Joint OIG-CMS Health Care Integrity Strategy

**Recommendations:** CMS should (1) adjust the estimated number of E&M services within eye global surgery fees to reflect the number of E&M services

actually being provided to beneficiaries or (2) consider using the financial results of the audit, in conjunction with other information, during the annual updates of the physician fee schedule.

### **Savings: \$97.6 million\***

*\*This represents the estimated amount Medicare paid for E&M services that were included in eye global surgery fees but were not provided during the global surgery periods in CY 2005.*

**Management Response Summary:** In its comments on the draft of our 2009 report, CMS acknowledged the merit of our findings and said that it would work with the American Medical Association Relative Value Scale Update Committee (AMA RUC) and the relevant physician specialty societies to identify and correct those services in which the number of E&M services has changed during the global period. CMS believed that it would be prudent to conduct further analysis before proposing any changes in the current number of E&M services assigned to eye surgeries. CMS noted that we did not look at the intensity level of the E&M services that were actually performed.

CMS is working with the AMA RUC and the relevant physician specialty societies to identify and correct codes for services for which the number of E&M services has changed in the global period. CMS stated that it is reviewing and establishing revised values for hundreds of existing services as part of its reviews of potentially misvalued codes and in conjunction with work of the AMA RUC. In many cases, this involves changes to the E&M services included in the global period of surgical procedures. CMS plans to continue the periodic review and revision process, which is now required pursuant to section 3134 of the Affordable Care Act.

**Status:** 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 that are 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 their periodic review and revision process. We will monitor CMS's actions to address our recommendations.

### **Related 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 [Report](#)

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Medicare Part A and Part B > Practitioners > “Incident to” Services by Nonphysicians

## Identify and Monitor the Prevalence and Qualifications of Nonphysicians Who Perform Medicare Physician Services

**Background:** Medicare Part B pays for services that are billed by physicians but are performed by nonphysician practitioners. These services often are called “incident to” services, or services provided under the “incident to” rule, and are typically performed in a physician’s office. The “incident to” rule allows physicians to bill for services performed by any personnel, licensed or unlicensed. “Incident to” services must meet Medicare’s general criteria for medical necessity, documentation, and quality of care. Medicare does not require identifiers on claims indicating that the service was furnished “incident to.” Therefore, based on claims data analysis, it is not possible to determine the extent to which physicians are billing for services under “incident to.”

**Findings:** In the first quarter of 2007, we found that, when Medicare allowed physicians more than 24 hours of services in a day, half of the services were not performed personally by a physician. Nonphysicians performed the remaining services, which physicians may have billed as “incident to” services. Medicare allowed \$105 million for services that the physicians personally performed and approximately \$85 million for services that nonphysicians personally performed. Unqualified nonphysicians performed 21 percent of the services that physicians did not perform personally. These nonphysicians did not possess the necessary licenses or certifications, had no verifiable credentials, or lacked the training to perform the service.

**Recommendations:** CMS should (1) seek revisions to the “incident to” rule; and (2) require physicians who bill services to Medicare that they do not perform to identify the services on their Medicare claims using a service code modifier.

**Management Response Summary:** CMS concurred with our recommendation to seek revisions to the “incident to” rule. In its comments to our draft report, CMS indicated that it will provide improved guidance for documenting the qualifications of the person performing the services billed to Medicare by physicians and nonphysician practitioners who may bill services “incident to” their services. On October 9, 2009, CMS issued limited guidance CR Transmittal 574 to the MACs stating that MACs should use the information contained in this report to follow the processes and procedures already in CMS’s *Program Integrity Manual* concerning data analysis, contractor strategies and the progressive corrective action (PCA) 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.

**Status:** We continue to monitor CMS's implementation of our recommendations.

**Related Report:**

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

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Medicare Part A and Part B > Practitioners > Chiropractors > Noncovered Services

## Prevent, Detect, and Resolve Improper Payments For Noncovered Chiropractic Services

**Background:** Medicare pays only for medically necessary chiropractic services, which are limited to active/corrective manual manipulations of the spine to correct subluxations. When submitting claims, chiropractors must use the acute treatment modifier to identify services that are active/corrective treatment and must document services pursuant to CMS's *Medicare Benefit Policy Manual*. 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. Previous OIG work found significant vulnerabilities existed in connection with chiropractic claims, particularly concerning Medicare payments for maintenance therapy.

**Findings:** We found that (1) Medicare inappropriately paid \$178 million for chiropractic claims in 2006, representing 47 percent of claims meeting our review criteria; (2) efforts to stop payments for maintenance therapy have been largely ineffective; (3) claims data lack initial visit dates for treatment episodes, hindering the identification of maintenance therapy; and (4) chiropractors often do not comply with documentation requirements.

**Recommendation:** CMS should implement and enforce policies, such as a cap on allowed chiropractic claims, to prevent payments for maintenance therapy.

**Savings: \$178 million\***

*\*Based on OIG's medical review of 2006 chiropractic claims.*

**Management Response Summary:** CMS did not indicate agreement or disagreement with the recommendation. CMS stated that the objective data required to impose a national cap on the number of chiropractic services do not exist. Also, CMS indicated it is working through the policy and operational implications of requiring an additional modifier and will consider implementing one if feasible.

**Status:** We continue to recommend that CMS implement and enforce policies to prevent inappropriate payments for maintenance therapy. We will monitor CMS's efforts regarding the feasibility of requiring an additional modifier or other potential policy solutions.

**Related Report:**

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

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Medicare Part A and Part B > Practitioners > Physicians

## Educate Providers about Proper Documentation for Transforaminal Epidural Injection Services (New)

**Background:** Transforaminal epidural injections are a type of interventional pain management technique used to diagnose or treat pain. Medicare Part B physician payments for transforaminal epidural injections increased from about \$57 million in 2003 to \$141 million in 2007, an increase of almost 150 percent. Medicare Part B contractors are responsible for implementing program safeguards to reduce payment error. To safeguard payments, they may create local coverage determinations (LCD), implement electronic edits (system processes to ensure proper payment of claims), or conduct medical reviews.

**Findings:** We found that 34 percent of transforaminal epidural injection services allowed by Medicare in 2007 did not meet Medicare requirements, resulting in approximately \$45 million in improper payments. Medicare allowed an additional \$23 million in improper facility claims associated with these services. In addition, 19 percent of transforaminal epidural injection services had a documentation error. Services provided in offices were more likely to have documentation errors than those provided in ambulatory surgical centers or hospital outpatient departments.

We also found that in 2007, 9 of 14 contractors had an LCD for transforaminal epidural injection services but reported limited use of other safeguards. Only one contractor enforced all of its LCD requirements through edits. No contractor staff reported performing a medical review.

**Recommendation:** CMS should conduct provider education, directly and through contractors, about proper documentation.

**Savings:** TBD\*

\*Savings not estimated.

**Management Response Summary:** CMS concurred with our recommendation and outlined steps to improve its oversight of transforaminal epidural injection services. In its update for 2011, CMS stated that it will issue a Medicare Learning Network (MLN) article by April 2011. In addition, CMS stated that it will conduct educational outreach by May 2011.

**Status:** We will continue to monitor CMS's implementation of our recommendation.

**Related Report:**

2010 AUG *Inappropriate Medicare Payments for Transforaminal Epidural Injection Services.*  
OEI-05-09-00030 [Report](#)

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## Laboratory and Imaging Services

Medicare Part A and Part B > Laboratories and Imaging > Payments and Cost Sharing

### Review Payment Levels and Reinstate Beneficiary Cost Sharing and Notifications of Payment for Laboratory Services

**Background:** Medicare pays for most clinical laboratory tests (lab tests) based on fee schedules. As of July 1, 1984, these schedules were established by each carrier generally at 60 percent of the Medicare prevailing charge (the charge most frequently used by suppliers). Over the years, the Medicare fee schedule has gone through several adjustments. The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) reduced the cap for the Medicare clinical laboratory fee schedule from 84 percent beginning in 1994 to 76 percent by 1996. The BBA reduced fee schedule payments by lowering the cap to 74 percent of the median for fee schedule payments beginning in 1998, but the BIPA raised the fee schedule amounts to 100 percent of the median for “new tests” performed on or after January 1, 2001. In 2007, laboratory tests accounted for 3 percent of all Medicare Part B payments.

**Findings:** Our 1996 audit, which followed up on issues that we brought to management’s attention in 1990, found that Medicare continued to pay clinical laboratories more than was paid to physicians for the same tests and encouraged the periodic evaluation of fee schedule rates to ensure that they are in line with the prices physicians pay for clinical laboratory services. The report also raised implications stemming from the absence of beneficiary cost sharing, which is a standard provision of the Medicare program, and provider practices that lead to aberrations in billing and utilization.

We noted that although physicians order clinical laboratory tests, laboratories bill the Medicare program directly. As a result, physicians generally do not have knowledge of how tests are billed to Medicare. Further, Medicare beneficiaries have no incentive to question utilization levels because there is no deductible or coinsurance for clinical laboratory services, and Medicare pays 100 percent of the allowed charge. In addition, Medicare contractors have reduced or eliminated the notices that they formerly sent to beneficiaries concerning the payments made to laboratories on their behalf. CMS recently confirmed that it has no global policy requiring contractors to notify beneficiaries of the payments made to laboratories on their behalf.

(See also the background and findings provided in the following Compendium item that describes a 2009 report recommending that CMS seek legislative authority to establish a new process for setting accurate and reasonable payment rates for lab tests.)

**Recommendations:** CMS should (1) review payment levels for laboratory tests and (2) reinstate beneficiary deductibles and coinsurance, (including notifications of amounts paid on their behalf).

**Savings: \$2.4 billion annually.\***

*\* Savings from potential fee schedule adjustments were not estimated. The Congressional Budget Office's (CBO) December 2008 "Budget Options Volume I: Health Care" (p.159) estimated that the 10-year savings from making laboratory services subject to standard deductible and coinsurance requirements would be \$23.8 billion, resulting in average annual savings of \$2.4 billion.*

**Management Response Summary:** In its comments on the draft of our 1996 report, CMS partially concurred with our recommendations and noted that it had taken steps to reduce payments for laboratory tests. The BBA required the Secretary of HHS to request that the Institute of Medicine (IOM) conduct a review of Part B lab test payments. As a result of the IOM's recommendations, section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that CMS conduct a demonstration that applies competitive bidding to clinical laboratory tests that would otherwise be paid under the Medicare Part B fee schedule.

In December 2005, CMS submitted to Congress the initial report on the demonstration. However, before CMS could complete the demonstration, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), § 145(a), repealed the project for Medicare clinical laboratory tests paid under the Medicare Part B fee schedule. In addition, section 145(b) of MIPPA specifies that the annual clinical laboratory fee schedule update will be reduced each year from 2009 through 2013 by 0.5 percentage points. The update for 2009 equals a 4.5-percent increase for payments made under the Medicare Part B Clinical Laboratory Fee Schedule.

CMS did not concur with our 1996 recommendation to reinstate beneficiary coinsurance and deductible provisions for laboratory services, noting that the President's 1996 budget statement did not include such a proposal and that a legislative change would be necessary to add beneficiary coinsurance and a deductible provisions to lab services. We note that CBO's \$23.8 billion 10-year estimate of savings from making laboratory services subject to standard deductible and coinsurance requirements was based on an option that would require that independent laboratories 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.

**Status:** Although legislation has reduced the prices for individuals' tests, we recommend that CMS continue to evaluate payment levels for laboratory tests. Because of the potential for physicians and beneficiaries to not always be fully aware of which tests laboratories bill to Medicare, we also continue to recommend reinstatement of beneficiary cost sharing, which is a standard provision of the Medicare program, including routine notification to beneficiaries of amounts billed and paid on their behalf.

**Related Reports:**

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

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Medicare Part A and Part B > Laboratories > Payment Rates

## Establish a New Payment Rate-Setting Process for Laboratory Tests

**Background:** Medicare Part B covers most outpatient clinical diagnostic laboratory tests and pays 100 percent of their costs because there are no beneficiary copayments or deductibles for lab tests. In 2007, lab tests accounted for 3 percent of all Medicare Part B payments. Payments are determined by the Clinical Laboratory Fee Schedule, which comprises rates established by each regional carrier, subject to the National Limit Amount (NLA) cap mandated by COBRA. At the time of our report, the NLA was set at 74 percent of the median carrier rate. Carriers pay laboratories the lower of the laboratories' charges or the carrier rate as capped by the NLA.

**Findings:** We found that carrier rates for nearly all lab tests varied. Eighty-three percent of carrier rates were at the NLA, and 89 percent of lab test claims were paid at the NLA. Variation from the NLA was inconsistent within each carrier and thus did not appear to reflect geographic differences in costs. Carriers pay different rates for the same lab test, so Medicare payments also vary. Medicare paid more than \$3.4 billion for lab tests in 2007. Finally, Medicare payments would have been \$3.5 billion if all of the tests had been paid at the NLA. Setting all carrier rates at 73 percent of the median carrier rate would have eliminated variation without a change in overall Medicare payments.

(See also the background and findings provided in the preceding section for two earlier reports and recommendations to review payment levels and reinstate beneficiary cost sharing and notification of payment for laboratory services.)

**Recommendation:** CMS should seek legislative authority to establish a new process for setting accurate and reasonable payment rates for lab tests.

### Savings: Budget neutral to \$1 billion\*

*\*If CMS were able to set payment rates at 50 percent of the median carrier rate, Medicare payments would have been reduced to \$2.4 billion, a reduction of \$1 billion. If CMS were able to set payment rates at 73 percent of the median carrier rate, overall payments would remain the same, but variations would be eliminated.*

**Management Response Summary:** CMS did not agree with our recommendation to seek legislation that would allow it to set accurate and reasonable payment rates for lab tests. CMS said it would take our recommendation into consideration as it continues to monitor the effects of its payment policies.

**Status:** We continue to encourage CMS to pursue legislation that would set accurate and reasonable payment rates for lab tests.

**Related Report:**

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

**See Also:**

2002 JAN *Common Working File Edits for Unauthorized Laboratory Tests.*  
OEI-05-00-00050 [Report](#)

1990 OCT *Ensuring Appropriate Use of Laboratory Services.* OEI-05-89-89150  
[Report](#)

1989 MAR *Medicare Reimbursement for Outpatient Laboratory Services.*  
OAI-04-88-01080 [Report](#)

## Claims Processing

Medicare Part A and Part B > Claims Processing > Modifier 59

### Review Use of Modifier 59 With Billing Codes and Ensure Correct Payments

**Background:** In January 1996, CMS began the Medicare National Correct Coding Initiative (NCCI) 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 carrier's claims-processing systems. Specifically, NCCI edits contain pairs of Healthcare Common Procedure Coding System (HCPCS) codes that generally should not be billed together by a provider for a beneficiary on the same date of services. Code pairs are arranged in a "column 1 and column 2" format. Claims given the column 2 code are generally not payable with the column 1 code. Under certain circumstances, a provider may bill for two services in an NCCI code pair and include a modifier on that claim that would bypass the edit and allow both services to be paid. Modifier 59 could be attached in such an instance. Modifier 59 is used to indicate that a provider performed a distinct procedure or service for a beneficiary on the same day as another procedure or service.

**Findings:** Medicare allowed payments for 40 percent of code pairs in FY 2003 that did not meet program requirements, resulting in \$59 million in improper payments. Modifier 59 was used inappropriately with 15 percent of the code pairs because the services were not distinct from each other. We also found that 11 percent of code pairs billed with modifier 59 were paid when modifier 59 was billed with the incorrect code. In addition, most carriers did not conduct reviews of modifier 59; for those that did, we found that providers had an error rate of 40 percent or more for services billed with modifier 59.

**Recommendations:** CMS should (1) encourage carriers to conduct prepayment and postpayment reviews of the use of modifier 59 and (2) ensure that the carriers' claims-processing systems pay claims with modifier 59 only when the modifier is billed with the correct code.

**Savings: \$59 million\***

*\*Based on a national projection of Medicare claims, \$59 million was improperly paid for services in FY 2003 that did not meet Medicare program requirements.*

**Management Response Summary:** 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, CMS reported in its comments that it was unable to implement system edits to ensure correct coding at the time of the report. 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 comments, CMS indicated that it would explore the development of an edit for modifier 59. However, upon further analysis in this area, CMS discovered that the implementation of creating 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.

**Status:** We continue to monitor CMS's efforts to implement edits to ensure correct coding.

**Related Report:**

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

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Medicare Part A and Part B > Dialysis Facilities > Quality of Care

## Improve the Availability of Quality-of-Care Data on Dialysis Treatments

**Background:** Patients with end stage renal disease (ESRD) rely on dialysis treatment to compensate for kidney failure. In 2000, OIG and GAO issued reports documenting problems with CMS's oversight of ESRD dialysis facilities. Since then, national aggregate data suggest that dialysis care has improved overall. However, questions remain about the quality of care provided at some ESRD facilities. To help monitor and improve quality of care, CMS oversees ESRD facilities through contracts with State survey and certification (S&C) agencies and ESRD networks. Our work assessed the extent to which data were available to help networks identify facilities with quality improvement needs.

**Findings:** We found that between 2004 and 2005, although networks had access to multiple sources of data about quality of care, each source had limitations in its ability to help networks identify facilities with quality improvement needs. Limitations included lack of facility-specific, comprehensive, or current clinical performance measures (CPM). We also found that CMS had acted to provide a streamlined source of data that could help networks identify facilities with quality improvement needs; however, the source had not been implemented.

**Recommendation:** CMS should develop facility-specific quality improvement information and increase its efforts to regularly collect data on all of the CPMs that were identified by CMS to address quality-of-care issues in the ESRD program.

**Management Response Summary:** CMS did not indicate whether it concurred with our recommendation. The agency said that it had made progress in collecting data to improve the quality of care in the ESRD program and indicated that opportunities for improvement remain. CMS said that steps had been taken to improve quality of care in the ESRD program, including the development of CPMs, definition of the core data set, and proposed regulations that would require facilities to electronically submit CPMs on ESRD patients. CMS also said that it would develop a new Web-based data collection system called Consolidated Renal Operations in a Web-enabled Network (CROWNWeb), which would consolidate data sources into one system.

On April 15, 2008, CMS published the final rule *Conditions for Coverage for End Stage Renal Disease Facilities* at [73 Fed. Reg. 20370](#) which established new conditions that facilities must meet to be certified under the Medicare program. The rule stated that beginning February 2, 2009, ESRD facilities must electronically collect and report to CMS

on an ongoing basis the administrative and CPM data annually for eligible ESRD patients via CROWNWeb. In February 2009, CMS began implementing the CROWNWeb System with a number of providers/facilities and plans to expand reporting to more providers/facilities as soon as practicable. In December 2009, CMS reported that it had implemented Phase II of the CROWNWeb System rollout with an increased number of providers and facilities.

Section 153(c) of the MIPPA requires that CMS establish a quality program that results in payment reductions for providers that do not meet performance standards. Pursuant to this, CMS published in January 2011 a final rule at [76 Fed. Reg. 628](#) for the ESRD Quality Incentive Program that promotes improvement in the quality of care that beneficiaries receive. This rule is effective January 1, 2012. CMS plans to expand reporting to an additional 360+ providers/facilities in the spring of 2011 and has targeted June 2011 for national implementation of CROWNWeb.

**Status:** We continue to monitor CMS's implementation of our recommendation, as CMS expands the reporting to more providers and facilities.

**Related Report:**

2006 NOV *Availability of Quality of Care Data in the Medicare End Stage Renal Disease Program.* OEI-05-05-00300 [Report](#)

**See Also:**

2007 JUN *OIG Testimony before House Committee on Ways and Means: "OIG Work Related to Payment and Quality at Dialysis Facilities."* [Testimony](#)

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Medicare Part A and Part B > Dialysis Facilities > Drug Pricing

## Review Trends in End Stage Renal Disease Drug Pricing to Address Future Medicare Payment Concerns (New)

**Background:** At the time of the report’s release, Medicare paid ESRD dialysis facilities based on a PPS known as the composite rate. ESRD drugs not covered under the composite rate, such as epoetin alfa and darbepoetin alfa, were billed separately and were referred to as “separately billable drugs.” Medicare paid for most separately billable drugs at 106 percent of their average sales prices (ASP). Effective January 1, 2011, as required by Federal law, CMS began implementing a new system that combines composite rate payments with payments for items and services that were previously separately billable (including separately billable drugs) to create a single bundled payment. Federal law also requires that the base rate for ESRD bundled payments be annually updated to reflect the changes over time in the prices of goods and services used to provide ESRD care. CMS has decided to base these price updates on wage and price proxy data from the Bureau of Labor Statistics (BLS). For the ESRD drugs portion of the new bundled rate, CMS plans to use the Producer Price Index (PPI) for Prescription Drugs to estimate price changes.

**Findings:** We found that aggregate acquisition costs for ESRD drugs at both types of dialysis facilities were below ASP-based Medicare payment amounts. Over the past several years, average acquisition costs for 7 of the 11 drugs under review have decreased among responding independent dialysis facilities. We also found that, during a period when acquisition costs for many ESRD drugs decreased, the PPI—the index that CMS plans to use as the basis for future payment changes—increased by 39 percent. This means that if CMS had used the PPI for Prescription Drugs to update payment amounts for 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 \$113 million higher than actual payments under the current ASP-based system.

**Recommendation:** CMS should develop a more accurate method for estimating changes in the prices of ESRD drugs. Specifically, CMS should develop a new method that more accurately reflects historical trends in the pricing of drugs that make up the pharmaceutical category of the ESRD market basket price index.

**Management Response Summary:** CMS did not concur with our recommendation. In its response to the draft report, CMS stated that the downward trajectory of average acquisition costs documented in OIG’s analysis was influenced largely by changes in CMS’s payment mechanism for separately billable ESRD drugs. Specifically, CMS believes that the decrease in the average acquisition cost of epoetin alfa during the

period under review was caused by an above-market Medicare payment amount in the baseline year of OIG's analysis (2003) and the subsequent decrease in the payment amount for epoetin alfa after the ASP-based system was implemented. CMS stated that, as a result, OIG's figures are not suitable for inferring future price trends as the market for epoetin alfa becomes more competitive. CMS published ESRD final and proposed rules at [75 Fed. Reg. 49030](#) and [75 Fed. Reg. 49215](#) (42 CFR § 413), August 12, 2010, in which CMS described its intent to use the BLS's PPI for Prescription Drugs to proxy drug price growth in the ESRD market basket. The term "ESRD market basket" refers to the mix of goods and services used to produce ESRD care. CMS will monitor the ESRD market basket to ensure that growth trends in the PPI represent an appropriate price proxy when compared to growth trends in ASP.

**Status:** We remain concerned that Medicare could end up paying too much for these drugs once the bundled payment is implemented, potentially costing the program and its beneficiaries hundreds of millions of dollars a year. Therefore, we will continue to monitor CMS's implementation of our recommendation, including re-evaluating its use of PPI data.

**Related Report:**

2010 SEPT *End Stage Renal Disease Drugs: Facility Acquisition Costs and Future Medicare Payment Concerns.* OEI-03-09-00280 [Report](#)

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# Medical Equipment and Supplies

Medicare Part A and Part B > Medical Equipment and Supplies > Supplier Enrollment and Fees

## Ensure That Medical Equipment Suppliers Comply With Medicare Enrollment Standards; Require Fee Payments

**Background:** Durable medical equipment prosthetics, orthotics, and supplies (DMEPOS)—which include items such as hospital beds, wheelchairs, respirators, walkers, and artificial limbs—are provided to Medicare beneficiaries by commercial suppliers that are reimbursed by Medicare. CMS contracts with the National Supplier Clearinghouse (NSC) to manage the enrollment and reenrollment of Medicare DMEPOS suppliers. Medicare allowed almost \$11 billion for medical equipment and supplies in FY 2007.<sup>3</sup> OIG conducted two reviews of DMEPOS suppliers to determine compliance with Medicare enrollment standards. We conducted unannounced site visits at 1,581 DMEPOS suppliers in three South Florida counties in 2006 and at 905 DMEPOS suppliers in Los Angeles County in 2007 to evaluate compliance with selected Medicare requirements related to enrollment standards.

**Findings:** In South Florida, we found that 491 of 1,581 suppliers (31 percent) failed to maintain physical facilities or were not open and staffed during our unannounced site visits, contrary to regulations containing the DMEPOS supplier standards. Suppliers in Miami-Dade County represented 64 percent of the suppliers we visited but accounted for 80 percent of suppliers that did not maintain physical facilities or were not accessible during business hours.

In Los Angeles County, we found that 115 of 905 suppliers (13 percent) did not maintain physical facilities or were not open and staffed during our site visits. Another 79 suppliers (9 percent) were open but did not meet at least one of the two additional requirements for the standards we reviewed. In addition, we found that 124 suppliers (14 percent) met the four requirements for the standards we reviewed, but their claims shared an atypical characteristic. More than half of the Medicare beneficiaries for these 124 suppliers did not receive other Medicare services (such as an office visit) from the physicians who ordered the DMEPOS within the 6-month period preceding the DMEPOS claim. Findings in both reports demonstrated continued vulnerabilities in the Medicare DMEPOS benefit.

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<sup>3</sup> Revised from a prior estimate of about \$10 billion in 2005.

**Recommendations:** CMS should (1) strengthen the Medicare DMEPOS supplier enrollment process, ensuring that suppliers meet Medicare supplier standards, e.g., (a) increase prepayment review of DMEPOS claims, (b) require suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years, and (c) establish a minimum number of hours of operation and minimum inventory requirements for product and service types; and (2) require DMEPOS suppliers to (a) pay an additional Medicare enrollment fee if, during a site visit conducted during business hours, the supplier's facility is closed or inaccessible.

**Savings:** TBD\*

\*Savings not estimated.

**Management Response Summary:** In its comments on our first report, issued in 2007, CMS either agreed with the options we recommended for strengthening the Medicare DMEPOS supplier enrollment process or stated that it would consider them. In assessing each newly enrolled or existing supplier, the agency has taken action to implement some of the suggested options, including revising the NSC contractual requirements to increase the number of unscheduled site visits, deactivating suppliers that have not billed the Medicare programs for 12 months, adding additional DMEPOS supplier standards, requiring DMEPOS suppliers to post a surety bond, enhancing review of new DMEPOS enrollment applications in South Florida, prioritizing reenrollment applications over processing new applications in highly vulnerable areas of the country, and conducting targeted background checks on suppliers with high fraud potential.

CMS published a final rule at [76 Fed. Reg. 5862](#) (February 2, 2011)<sup>4</sup> to implement several provisions of the Affordable Care Act. Specifically, the rule will impose temporary moratoriums on supplier enrollment, screening requirements for enhanced enrollment and reenrollment, application fees for providers and suppliers, and requirements for suspension of payments pending credible allegations of fraud in both the Medicare and Medicaid programs.

The Medicare DMEPOS competitive bidding program included enrollment safeguards and provides a mechanism for CMS to better screen suppliers when granting billing privileges. CMS fully implemented accreditation for all suppliers of DMEPOS by September 30, 2009. On October 6, 2009, CMS announced a seven-State stopgap

<sup>4</sup> Revised to provide Federal Register citation.

program to address fraud. The stopgap program is focused on high-volume, high-risk DMEPOS suppliers, physicians, beneficiaries, and equipment and supplies.

On November 1, 2007, CMS began a 2-year demonstration project involving DMEPOS suppliers in specific counties. This demonstration has concluded, and CMS is evaluating the results of the demonstration to determine if more frequent reenrollment requirements in high-vulnerability areas should be implemented. CMS published a proposed rule at [73 Fed. Reg. 4503](#) (January 25, 2008), 42 CFR part 424, to clarify and enhance supplier standards.

In its comments on our second report, which was issued in February 2008, CMS said that suppliers must pay a fee to the accrediting organization for an initial site visit and that “criminal background checks are conducted as required by State standards.” In our final report we noted, however, that our recommendation was that site inspection and application fees would be paid to the Federal Government, not the accrediting organization. The Final Rule published in February 2011 establishes a \$500 application fee for suppliers and providers and will impose temporary moratoriums on supplier enrollment.

**Status:** We continue to monitor CMS’s implementation of program safeguards in the area of DMEPOS, including actions related to temporary moratoriums on supplier enrollments and statutory delay for implementation of competitive bidding.

### Related Reports:

- 2008 FEB *Los Angeles County Suppliers’ Compliance With Medicare Standards: Results From Unannounced Visits.* OEI-09-07-00550 [Report](#)
- 2007 MAR *South Florida Suppliers’ Compliance With Medicare Standards: Results From Unannounced Visits.* OEI-03-07-00150 [Report](#)

### See Also:

- 2011 MAR OIG Testimony Before the House of Representatives Committee on Energy & Commerce, Subcommittee on Oversight and Investigations: “Medicare Strike Force.”<sup>5</sup> [Testimony](#)
- 2010 MAR OIG Testimony Before the House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies: “Miami Strike Force.” [Testimony](#)

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<sup>5</sup> Revised to provide a hyperlink to the March 2011 testimony.

2007 APR    OIG Testimony Before the House Committee on Energy and Commerce,  
Subcommittee on Health: “Medicare Integrity and Enrollment Safeguards  
for Medical Equipment Suppliers.” [Testimony](#)

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Medicare Part A and Part B > Medical Equipment and Supplies > Oxygen

## Reduce the Rental Period for Home Oxygen Equipment

**Background:** The Social Security Act, § 1834(a)(5), authorizes Medicare payment for home oxygen equipment under its durable medical equipment (DME) benefit. Medicare covers stationary oxygen concentrators and portable oxygen delivery systems, which were payable on a rental-only basis from 1989 (the year in which Medicare implemented the DME fee schedule) until 2006. Since January 1, 2006, the rental period has been 36 months, and Medicare discontinues payments to home oxygen providers after 36 months.

**Findings:** Based on the 2006 median fee schedule amount, Medicare will allow \$7,215 for 36 months for concentrators that cost \$587, on average, to purchase. Beneficiaries will incur \$1,443 in coinsurance. Based on our analysis, minimal servicing and maintenance for concentrators and portable equipment are necessary.

**Recommendation:** CMS should work with Congress to further reduce the rental period for oxygen equipment.

### Savings: \$3.2 billion\*

*\*If Medicare rental payments for oxygen concentrators were limited to 13 months, the program and its beneficiaries would save about \$3.2 billion over a period of 5 years.*

**Management Response Summary:** CMS concurred with our recommendation. However, reducing the rental period for most oxygen equipment from 36 to 13 months requires a statutory change. Although bills have been introduced in the past, none has passed.

**Status:** We continue to encourage CMS to work with Congress to reduce the rental period for oxygen equipment.

### Related Report:

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

Medicare Part A and Part B > Medical Equipment and Supplies > National Provider Identifiers

## Ensure That National Provider Identifiers on Medical Equipment and Supply Claims Are Valid and Active

**Background:** Medicare beneficiaries are eligible to receive medical equipment and supplies deemed medically necessary by a physician under Medicare Part B coverage. In 2007, Medicare allowed almost \$11 billion for medical equipment and supplies. COBRA required CMS to establish unique physician identification numbers (UPIN) for all physicians who provide services to Medicare beneficiaries. A physician was allowed to obtain only one UPIN, but a UPIN may have been associated with more than one practice setting. The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) required CMS to create national provider identifiers (NPI) to replace UPINs for Medicare claims processing. Medicare instructions require a supplier to provide its own identification number, as well as that of the referring physician. From May 2005 to May 2008, Medicare accepted claims that included UPINs only, NPIs only, or a combination of both.

**Findings:** We found that Medicare allowed more than \$6 million for medical equipment and supply claims with invalid referring physician UPINs in 2007. We also found that Medicare allowed almost \$28 million for claims with inactive referring physician UPINs in 2007, including \$5 million for claims with dates of service after the dates of death of the referring physicians. Medicare also allowed more than \$300,000 for claims with invalid referring physician NPIs in 2007.

**Recommendations:** CMS should (1) implement claims-processing system changes to ensure that NPIs for referring physicians and suppliers listed on medical equipment and supply claims are valid and active, (2) emphasize to suppliers the importance of using accurate NPIs for referring physicians and suppliers when submitting Medicare claims, and (3) 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: \$34 million\*

*\*Actual amounts in our findings are \$6.1 million for Medicare-allowed amounts for claims with invalid referring physician UPINs and \$27.8 million for Medicare-allowed amounts for claims with inactive referring physician UPINs.*

**Management Response Summary:** CMS concurred with our recommendations and has begun implementing a series of procedures to reject claims from DMEPOS suppliers in which the ordering or referring provider is not enrolled in the Provider Enrollment

Chain, and Ownership System (PECOS) and/or is not of the type/specialty that may order or refer in the Medicare program. As part of Phase 1 of this process, CMS moved all DMEPOS supplier enrollment records into PECOS, making them automatically checked against the Medicare Exclusions Database (MED) file. If the checking process detects any excluded suppliers, CMS takes appropriate action to revoke their billing privileges. CMS also implemented procedures to require the NPI as the identifier of the ordering/referring providers in all claims.

Completed in October 2009, Phase 1 sends informational messages from CMS to DMEPOS suppliers whose claims fail the ordering/referring provider edits described above, and CMS pays the claims. Phase 2, when implemented, will deny payment for those claims that fail the edits.

**Status:** CMS is delaying<sup>6</sup> the implementation of Phase 2 of Change Request (CR) 6417 and CR 6421 to give physicians and nonphysician practitioners who order items or services for Medicare beneficiaries, or who refer Medicare beneficiaries to other Medicare providers or suppliers, sufficient time to enroll in Medicare or take the action necessary to establish a current enrollment record in Medicare prior to Phase 2 implementation. CR 6417 is "Expansion of the Current Scope of Editing for Ordering/Referring Providers for Claims Processed by Medicare Carriers and Part B MACs," and CR 6421 is "Expansion of the Current Scope of Editing for Ordering or Referring Providers for DMEPOS Supplier Claims Processed by DME MACs." We continue to monitor CMS's implementation of the recommendations associated with our review.

### **Related Report:**

- 2010 APR *Medicare Payments for Medical Equipment and Supply Claims With Identical Referring Physician and Supplier National Provider Identifiers.*  
OEI-04-10-00110 [Report](#)
- 2009 FEB *Medicare Payments in 2007 for Medical Equipment and Supply Claims With Invalid or Inactive Referring Physician Identifiers.*  
OEI-04-08-00470 [Report](#)

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<sup>6</sup> The March 16, 2011 online version of this Compendium item was revised based on status information subsequently provided by CMS.

**See Also:**

- 2010 JUL     OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security: “Preventing and Recovering Medicare Payment Errors.” [Testimony](#)
- 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](#)

Medicare Part A and Part B > Medical Equipment and Supplies > Nursing Homes

## Ensure That Part B Payments are Appropriate for Beneficiaries' Medical Equipment During Non-Part A Nursing Home Stays

**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 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 DME unless the nursing home qualifies as the beneficiary's home. Pursuant to the Social Security Act, section 1861(n), a nursing home is excluded from qualifying as a beneficiary's home for DME payments when the nursing home is engaged primarily in providing skilled nursing care. Only a small number of nursing homes or distinct parts of nursing homes may qualify as a beneficiary's home.

**Findings:** We found that \$30 million was inappropriately allowed for DME during non-Part A SNF stays in 2006. Also, we found that Medicare allowed an additional \$11.9 million for DME provided during non-Part A stays in Medicaid nursing facilities (NF) and distinct part nursing homes. CMS and States reported that they do not maintain primary level-of-care designations for nursing homes. Such designations could facilitate accurate claim submission by suppliers and proper claim adjudication by payment contractors.

**Recommendations:** CMS should (1) implement a process or processes to identify patients entering nursing homes with rented DME, and (2) determine which NFs and distinct part nursing homes primarily provide skilled care, thus not qualifying as a beneficiary's home for DME payment purposes.

### Savings: \$30 million\*

*\*Suppliers received payments totaling \$30,485,842 for the 309,626 DME claims allowed for Medicare beneficiaries during non-Part A stays in nursing homes certified as SNFs or dually certified as SNF/NFs. Because these nursing homes were primarily providing skilled care or rehabilitation, they could not be considered the beneficiaries' homes, a prerequisite for DME coverage.*

**Management Response Summary:** CMS said that it agreed with the underlying objectives of our recommendations but did not concur. To address these two recommendations, CMS suggested alternative approaches using claims processing edits. In the final report, we deferred to CMS on the appropriate methods to use to address these recommendations. Although we asked CMS to provide specific information on these alternative approaches in its final management decision, we never received it.

In its December 2009 status update, CMS indicated that billing system changes were under development and were scheduled to be implemented with the July 2010 quarterly release. However, as of October 2010, billing system changes were still being developed.

In its 2011 update, CMS stated that it secured the Minimum Data Set data from OIG and shared it with the Recovery Audit Contractors (RAC) in February 2010. Further, CMS stated that it considers this recommendation closed and continues to nonconcur.

**Status:** CMS has not provided specific information regarding steps that it or its contractors are taking to identify patients entering a nursing home with rented DME or, more importantly, to identify nursing homes in which DME should not be paid for, as the nursing homes provide primarily a skilled level of care. CMS previously reported that it would use alternative approaches and that it would also develop billing system changes to address OIG's concerns. However, CMS has not explained or provided information about such alternative approaches and, as of October 2010, it had yet to create and implement its planned billing system changes. We continue to monitor CMS's implementation of our recommendations, and we request an update on its activities in this regard.

#### **Related Report:**

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

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Medicare Part A and Part B > Medical Equipment and Supplies > Wheelchairs

## Adjust Acquisition Costs and Services for Power Wheelchairs

**Background:** Medicare beneficiaries are eligible to receive power wheelchairs under Medicare Part B coverage of DME. Medicare beneficiaries receive power wheelchairs from suppliers that bill the Medicare program for reimbursement. In 2007, about 173,300 Medicare beneficiaries received power wheelchairs at a total cost of \$686 million.

Medicare's fee schedule amounts are based on manufacturer-suggested retail prices. They include reimbursement for wheelchair acquisition cost and services performed in conjunction with providing the wheelchair, such as assembling and delivering it and educating the beneficiary about its use. OIG compared Medicare payments for power wheelchairs with suppliers' acquisition costs and determined the number and types of services that suppliers performed in conjunction with providing power wheelchairs to Medicare beneficiaries.

**Findings:** The findings of this evaluation show that CMS's current methodology for developing power wheelchair fee schedule amounts does not reflect actual acquisition costs. We found that during the first half of 2007, Medicare and its beneficiaries paid almost two times the average amount that suppliers paid to acquire complex rehabilitation power wheelchair packages and almost four times the average amount to acquire standard power wheelchairs. Complex rehabilitation power wheelchair packages include a power wheelchair plus special power options (such as a powered seating system) and accessories. Medicare's average allowed amount of \$4,018 for standard power wheelchairs was 383 percent of suppliers' average acquisition cost.

The Competitive Bidding Acquisition Program would have reduced the average Medicare payment for standard power wheelchairs to \$3,073, amounting to 293 percent of suppliers' average acquisition cost. To offset the Competitive Bidding Acquisition Program's delay, Medicare's 2009 fee schedule amount was reduced to \$3,641, exceeding the average competitively bid price by \$568.

Suppliers of standard power wheelchairs reported performing an average of five services per chair (such as assembly, delivery, and educating the beneficiary about its use), while suppliers of complex rehabilitation power wheelchair packages reported performing an average of seven services. Medicare and its beneficiaries paid suppliers an average of \$2,970 beyond the suppliers' acquisition costs to cover general business costs and to perform an average of five services. Medicare and its beneficiaries paid an average of \$5,627 beyond the suppliers' acquisition costs to cover general business costs and for performing an average of seven services.

**Recommendation:** CMS should determine whether Medicare’s fee schedule amounts for standard and complex rehabilitation power wheelchairs should be adjusted by (1) using information from the Competitive Bidding Acquisition Program, (2) seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes, and/or (3) using its inherent reasonableness authority.

**Savings: \$84 million\***

*\*We based our estimated savings on the assumption that in 2007 more than 147,000 Medicare beneficiaries received power wheelchairs. Based on the current fee schedule, which was reduced by 9.5 percent, each wheelchair was reimbursed at an average of \$568 greater than the amount by which the current Medicare fee schedule exceeded the average competitively bid price.*

**Management Response Summary:** CMS concurred with our recommendation and with two of our recommended methods to determine whether Medicare’s fee schedule amounts for standard and complex rehabilitation power wheelchairs should be adjusted. CMS said that it plans to use information from the Competitive Bidding Acquisition Program for its analysis 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 inherent reasonableness authority until the results of the supplier bids for power wheelchairs under the Competitive Bidding Acquisition Program have been assessed.

**Status:** We continue to monitor CMS’s implementation of our recommendation.

**Related Report:**

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

**See Also:**

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

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Medicare Part A and Part B > Medical Equipment and Supplies > Support Surfaces

## Ensure That Claims for Pressure-Reducing Support Surfaces Meet Coverage Criteria

**Background:** Pressure-reducing support surfaces are used in the care or prevention of pressure ulcers. Pressure ulcers, also known as bed sores or decubitus ulcers, occur commonly among the elderly and individuals with spinal cord injuries. Support surfaces are covered under Medicare Part B as DME. CMS categorizes support surfaces into three groups based on the complexity of their features. Group 2 is the largest, accounting for 80 percent of all support surface payments. OIG assessed the appropriateness of Medicare payments for group 2 pressure-reducing support surfaces and identified the program safeguards that are in place to ensure proper payments.

**Findings:** Based on a review of medical record documentation and supplier documentation, we found that 86 percent of group 2 support surface claims for the first half of 2007 did not meet Medicare coverage criteria. This amounted to an estimated \$33 million in inappropriate payments during that time. We also found that CMS contractors had only limited safeguards in place to prevent improper payments for group 2 support surfaces. CMS contractors reported that they relied primarily on two claims processing edits to prevent improper payments for support surfaces. One of the edits checked for the KX modifier, which suppliers use to indicate that claims meet Medicare coverage criteria and that adequate documentation exists. In our sample, even though all but one of the claims included the KX modifier, we found that 80 percent of the claims did not meet clinical coverage criteria.

None of the CMS contractors conducted any widespread medical reviews of support surface claims. Also, only half of the CMS contractors responsible for supplier education conducted any educational activities in recent years that focused on group 2 support surfaces.

**Recommendations:** CMS should (1) ensure that claims for group 2 support surfaces meet Medicare coverage criteria and are paid appropriately by (a) reviewing the use of the KX modifier as a program safeguard, and (b) conducting additional statistical analyses to monitor payments for group 2 support surfaces; and (2) take appropriate action regarding the claims in our sample that were inappropriate.

**Management Response Summary:** CMS concurred with our recommendations. It mentioned that it is reviewing the utility and use of the KX modifier, including its application in DME claims. CMS also stated that it plans to share our recommendation

regarding conducting additional statistical analyses with price data analysts and coding contractors for their consideration in monitoring group 2 pressure-reducing support surface claims. CMS said that once it reviews the inappropriate claims and better understands their nature, it will forward them to the contractors.

CMS's 2011 update to its response to our recommendations stated 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. The contractor has completed its review of claims and will produce a report. CMS will share the results with DME MACs this year.

**Status:** We continue to monitor CMS's implementation of our recommendations.

**Related Report:**

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

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Medicare Part A and Part B > Medical Equipment and Supplies > Wound Therapy Pumps

## Adjust Reimbursement for Negative Pressure Wound Therapy Pumps

**Background:** Negative pressure wound therapy pumps are portable or stationary devices used for the treatment of ulcers or wounds that have not responded to traditional wound treatment methods. When Medicare started covering pumps in 2001, it covered only one model, which was produced and supplied by a single manufacturer. Since then, a number of manufacturers have introduced pump models and are charging substantially less for them. CMS requires suppliers to communicate with beneficiaries' clinicians to determine whether the beneficiaries still qualify for Medicare coverage of the pumps. This review compares the prices that suppliers paid for new negative pressure wound therapy pump models to Medicare's purchase prices.

**Findings:** Suppliers paid an average of \$3,604 for new pump models, compared with Medicare's reimbursement rate of \$17,165. Medicare reimbursed suppliers for these pumps based on a purchase price that was four times the average price paid by suppliers. Suppliers acquired one-quarter of the new pump models by leasing, renting, or exchanging them. We found that suppliers reported not always communicating with almost one-quarter of beneficiaries' clinicians, as required.

**Recommendations:** CMS should reduce Medicare's reimbursement amount for the pump and consider the following methods to reduce the reimbursement amount: (1) use its inherent reasonableness authority to reduce the reimbursement amount for the pump, and include the pump in the second round of the Competitive Bidding Acquisition Program; (2) continue to monitor the growth of the new pump market; (3) educate suppliers of new pump models on the importance of communication with beneficiaries' treating clinicians; and (4) follow up on the claims that we identified that may be inappropriate.

**Management Response Summary:** CMS concurred with three of our four recommendations and partially concurred with one. CMS said that it will consider the recommendation about including pumps when designing the second round of the Competitive Bidding Acquisition Program. It noted that it has worked on a number of regulatory and administrative initiatives related to the prescription, coding, and coverage of pumps in response to the significant growth in expenditures for these items. CMS concurred that it has the authority to adjust payment rates using Medicare's inherent reasonableness authority. It said that it will consider whether it would be able to gather valid and reliable data to make a determination that 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 that it will monitor and track trends in utilization of pumps and track the market share among pump suppliers. CMS also concurred with our recommendation to educate pump suppliers on the importance of communication with clinicians who treat beneficiaries. CMS concurred with our recommendation to follow up on pump claims that may be inappropriate and said that it is working with its contractors to strengthen its oversight in this area.

**Status:** We continue to monitor CMS's implementation of our recommendations.

**Related Report:**

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

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Medicare Part A and Part B > Medical Equipment and Supplies > Appeals Process

## Strengthen the Appeal Process for Medicare Equipment Suppliers

**Background:** CMS may deny or revoke a DME supplier's billing privileges if the supplier fails to comply with Medicare standards. In March 2007, OIG issued a report about South Florida suppliers and referred 491 suppliers that it had identified as likely being noncompliant with Medicare standards to CMS. CMS revoked these suppliers' billing privileges and some appealed. OIG conducted a review of the evidence that hearing officers reviewed as part of the suppliers' appeals and the results of the appeals.

**Findings:** We found that nearly half of the 491 revoked South Florida suppliers appealed and received hearings. Hearing officers reinstated billing privileges for 91 percent of the suppliers. We found that because there are no criteria regarding the types of evidence necessary to reinstate the billing privileges of suppliers, hearing officers reinstated the suppliers' billing privileges based on a variety of evidence. Finally, we found that two-thirds of suppliers whose billing privileges were reinstated subsequently had their privileges revoked or inactivated and that some individuals connected to reinstated suppliers had been indicted.

**Recommendation:** CMS should strengthen the appeal process by developing criteria on the types of evidence required for hearing officers to reinstate suppliers' billing privileges.

**Management Response Summary:** CMS concurred with our recommendation. CMS agreed that it should consider establishing guidelines for the evaluation of evidence that a hearing officer would review. However, CMS said that any 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 will establish guidelines for evaluating evidence and participate in a work group to develop evidentiary criteria for inclusion in regulatory guidance for hearing officers.

**Status:** 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. We encourage CMS to develop criteria for the types of evidence required for hearing officers to reinstate suppliers' billing privileges.

**Related Report:**

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

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Medicare Part A and Part B > Medical Equipment and Supplies > Inhalation Drugs

## Eliminate Medicare's Vulnerability to Fraudulent or Excessive Inhalation Drug Claims

**Background:** Medicare Part B covers inhalation drugs when they are used in conjunction with DME. A multiagency, multijurisdictional task force formed in 2007 to detect, prosecute, and prevent Medicare fraud by DME suppliers in South Florida identified inhalation drugs as one area vulnerable to fraud, particularly fraud committed by suppliers paying physicians to write fraudulent prescriptions and paying beneficiaries to accept unnecessary medication. We conducted a review that compared Medicare utilization and spending for inhalation drugs among beneficiaries and suppliers in South Florida to that among beneficiaries and suppliers in the rest of the country, as well as to LCD guidelines set by the Medicare program.

**Findings:** We found that even though just 2 percent of Medicare beneficiaries live in South Florida, the area accounted for 17 percent of Medicare's total spending for inhalation drugs in 2007. In addition, on 62 percent of South Florida inhalation drug claims, the beneficiaries did not have Medicare-billed office visits or other services in the preceding 3 years with the physicians who reportedly prescribed the drugs. Medicare spent an average of five times more per beneficiary on inhalation drugs in South Florida than in the rest of the country, with the greatest spending differences attributable to the more expensive brand-name drugs levalbuterol and budesonide. In addition, 75 percent of South Florida beneficiaries who received budesonide had Medicare-reimbursed budesonide claims that exceeded the utilization guidelines, compared to 14 percent in the rest of the country.

**Recommendations:** CMS should (1) ensure that its contractors are enforcing the coverage guidelines for inhalation drugs and (2) eliminate Medicare's vulnerability to potentially fraudulent or excessive inhalation drug claims in South Florida.

**Management Response Summary:** CMS concurred with our recommendations. CMS said that through its Program Integrity Miami field office and the DME Stop Gap Plan, it has identified and begun to address many of the issues cited in our report. CMS noted that a "medically unlikely" edit for budesonide was implemented in September 2008. Additionally, CMS described efforts by its Miami and Los Angeles field offices to identify suppliers whose beneficiaries had no clinical relationship with the physicians listed on DME claims and revoke the Medicare billing numbers for suppliers not meeting supplier standards. CMS indicated that it will reinforce with its contractors the necessity to enforce the LCD for inhalation drugs.

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**Status:** Stronger CMS action, such as ensuring that claim edits are put in place, may be necessary to close our recommendation that CMS ensure that all Program Safeguard Contractors (PSC), particularly the PSC covering Florida, are enforcing the guidelines for maximum milligrams per month for all inhalation drugs, especially budesonide. We will continue to monitor CMS's progress in the area of DME Medicare fraud control. Based on our December 2010 report on inhalation drugs, it does not appear that CMS has fully completed either of the recommendations. Further followup is necessary to ensure that both of these recommendations are met.

**Related Report:**

2009 APR *Aberrant Claim Patterns for Inhalation Drugs in South Florida.*  
OEI-03-08-00290 [Report](#)

**See Also:**

2010 DEC *Questionable Billing for Brand-Name Inhalation Drugs in South Florida.*  
OEI-03-09-00530 [Report](#)

2010 MAR *OIG Testimony Before the House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies: "Miami Strike Force."* [Testimony](#)

2009 AUG *Beneficiary Utilization of Albuterol and Levalbuterol Under Medicare Part B.*  
OEI-03-07-00440<sup>7</sup> [Report](#)

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<sup>7</sup> Revised to include related report OEI-03-07-00440.

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Medicare Part A and Part B > Medical Equipment and Supplies > Capped Rentals

## Reduce Erroneous Billing for Capped Rental Durable Medical Equipment (New)

**Background:** DME is medical equipment that can withstand repeated use, serves a medical purpose, is not useful in the absence of an illness or injury, and is appropriate for home use. Capped rental DME is DME 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. Examples include power mobility devices, hospital beds, continuous positive airway pressure devices, commodes, and walkers. During beneficiaries’ use of capped rental DME, Medicare will pay for maintenance and servicing, including repairs, depending on when the capped rental DME was first rented, who owns the DME, and what types of repairs need to be made.

The implementation on January 1, 2006 of the Deficit Reduction Act of 2005 (DRA) altered Medicare coverage of routine maintenance and servicing of capped rental DME. 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 allow for 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 suppliers of DME equipment recover from the rental charge the expenses they incur in maintaining in working order the equipment they rent out. We analyzed capped rental DME claims for rental periods beginning on or after implementation of the DRA to identify erroneously allowed routine maintenance and servicing claims for the period 2006 through 2008.

Pursuant to section 1833(e) of the Social Security Act, Medicare should not pay for claims that lack documentation of necessity, service, or delivery; nor should it pay for repairs to DME still under manufacturer or supplier warranties.<sup>8</sup>

**Findings:** We found that from 2006 to 2008, Medicare erroneously allowed \$2.2 million for routine maintenance and servicing of capped rental DME with rental periods after implementation of the DRA. During this same period, Medicare erroneously allowed nearly \$4.4 million for repairs for beneficiary-rented capped rental DME. We also found that in 2007, Medicare allowed nearly \$27 million for repair claims for beneficiary-owned capped rental DME that failed to meet payment requirements and allowed nearly \$29 million for questionable repair claims.

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<sup>8</sup> Background section revised to include additional information from the report.

Finally, we found that supplier practices adversely affected some beneficiaries with high-cost repairs.

**Recommendations:** CMS should (1) implement an edit (a system process to ensure proper payment of claims) to deny claims for routine maintenance and servicing of capped rental DME with rental periods beginning after January 1, 2006; (2) implement an edit to deny claims for repair of beneficiary-rented capped rental DME; (3) improve enforcement of existing payment requirements for beneficiary-owned capped rental DME; (4) consider whether to require MACs to track accumulated repair costs of capped rental DME; (5) develop and implement safeguards to ensure that beneficiaries have access to the services they require; and (6) take appropriate action on erroneously allowed claims for maintenance and servicing, repair, and payment errors.

**Savings:** TBD\*

\*Savings not estimated.

**Management Response Summary:** CMS agreed that maintaining strong and effective controls to ensure accurate payment of capped rental DME claims is essential. CMS responded positively to each of our six recommendations and indicated that it will work to improve its comprehensive oversight of capped rental maintenance and servicing. In its update for 2011, CMS said that it is implementing a corrective action plan to address the recommendations. CMS plans in 2011 to issue an educational MLN article for providers and suppliers. In addition, CMS plans to conduct an educational outreach call with the provider and supplier community to reinforce documentation requirements and issue a Joint Signature Memorandum/Technical Direction Letter (JSM/TDL) to DME MACs, instructing them to consider the issues identified in OIG's report. CMS sent a similar JSM/TDL to RACs on October 29, 2010.

Status: We will continue to monitor CMS's implementation of our recommendations.

### Related Report:

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

Medicare Part A and Part B > Medical Equipment and Supplies > Wheelchairs > Claims Requirements

## Ensure That Medicare Power Wheelchair Suppliers Meet Documentation Requirements (New)

**Background:** OIG conducted a review to determine the extent to which Medicare power wheelchair claims met documentation requirements. Medicare covers more than 650 power wheelchair models and assigns each model to one of Medicare's 42 power wheelchair procedure codes (K0813–K0864). The procedure code assignment is based on the model's performance, patient weight capacity, seat type, portability, and power seating system capability. Two types of power wheelchairs, standard and complex rehabilitation, accounted for over 80 percent of all Medicare power wheelchair expenditures in the first half of 2007. Medicare requires power wheelchair suppliers to maintain specific documentation to support the beneficiary's need for, and the appropriateness of, the power wheelchair.

**Findings:** We found that 60 percent of Medicare claims for standard and complex rehabilitation power wheelchairs in the first half of 2007 did not meet one or more documentation requirements. In addition, suppliers submitted incomplete documents almost three times as often as they failed to submit required documents. Of the documents that suppliers failed to submit, one of the most frequently omitted was the specialty evaluation report. This report is important because it documents the medical necessity for the power wheelchair and each recommended option and accessory.

**Recommendations:** CMS should (1) improve compliance with Medicare's power wheelchair documentation requirements by recovering overpayments and considering further actions against suppliers that do not meet documentation requirements, and (2) take appropriate action on sampled claims found to be in error.

**Savings:** TBD\*

*\*Savings not estimated.*

**Management Response Summary:** CMS concurred with our recommendations. CMS noted that it has multiple efforts underway or planned that align with each of the methods we suggested that they consider to improve compliance with Medicare's power wheelchair documentation requirements. On May 5, 2010, CMS issued a JSM/TDL to the MACs instructing them that clinical review judgment may not override statutory, regulatory, ruling, national coverage decision, or local coverage decision provisions, and that all documentation and policy requirements must be met before clinical judgment applies. On June 17, 2010, CMS issued a second JSM/TDL to the MACs with a link to the

OIG report and specific claims information instructing them to consider the issues identified in the OIG report. On October 29, 2010, CMS issued a third JMS/TDL to the RACs with a link to the OIG report and specific claims information for their consideration.

In addition, on June 7, 2010, CMS conducted an outreach call to provide additional education to suppliers and providers on power mobility device (PMD) documentation requirements. CMS also revised its brochure on PMDs that included specific documentation requirements. CMS will issue an MLN article by March 2011 to increase education for suppliers and providers regarding documentation requirements.

**Status:** We will continue to monitor CMS's implementation of our recommendations.

**Related Reports:**

- 2009 DEC *Medicare Power Wheelchair Claims Frequently Did Not Meet Documentation Requirements.* OEI-04-07-00401 [Report](#)
- 2009 JUL *Miscoded Claims for Power Wheelchairs in the Medicare Program.* OEI-04-07-00403 [Report](#)

## Part B Prescription Drugs

Medicare Part A and Part B > Part B Prescription Drugs > Payments for New Generic Drugs

### Expedite the Price Update Process To Ensure That Medicare Payments for Drugs With Newly Available Generic Versions Accurately Reflect Market Prices

**Background:** In March 2008, a generic version of irinotecan hydrochloride (hereinafter referred to as irinotecan), an injectable drug used to treat patients with colorectal cancer, became available for sale in the United States. Medicare Part B covers irinotecan as a drug administered by a physician. Medicare pays for most Part B-covered drugs based on the ASP reported by manufacturers within 30 days after the end of each calendar quarter. There is therefore a two-quarter lag between the time when sales reflected in the ASP occur and the time when they become the basis for Medicare payments. Sections 1847A(d)(1) and (2) of the Social Security Act, as added by the MMA, direct OIG to undertake reviews that compare ASPs to widely available market prices and average manufacturer prices (AMP).

**Findings:** We compared the first-quarter 2008 Medicare payment to manufacturer prices for irinotecan and found that the Medicare payment amount for irinotecan exceeded the OIG-calculated average manufacturer sales price by 145 percent in March 2008. Lower-priced generic versions accounted for 86 percent of irinotecan sales in March 2008. We estimated that had Medicare payments for irinotecan been based on the average manufacturer sales price in March 2008, Medicare expenditures for the drug would have been reduced by \$6.5 million in that month alone.

**Recommendation:** CMS should expedite the process to ensure that the Medicare payments for drugs with newly available generic versions accurately reflect market prices.

**Savings: \$6.5 million\***

*\*See findings section above.*

**Management Response Summary:** CMS concurred with our recommendation. CMS expressed its commitment to ensuring accurate payments for drug products under the ASP methodology and will review any specific suggestions OIG may have to further this goal. CMS noted that the third-quarter 2008 Medicare payment for irinotecan was \$74.75, representing a 40 percent decrease from the previous quarter (\$126.24). CMS also noted that this decrease results in a payment differential per unit for the third quarter

that is substantially lower than the differential for March 2008, demonstrating that the ASP methodology reflects market-based prices over time.

**Status:** OIG considers that the underlying pricing issues identified in this report are not limited to irinotecan. Medicare payment amounts for drugs with new generic versions will continue to be temporarily higher than manufacturer sales prices, sometimes substantially. We continue to recommend that CMS expedite the process to ensure that the Medicare payment amounts for drugs with newly available generic versions accurately reflect market prices.

**Related Report:**

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

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Medicare Part A and Part B > Part B Prescription Drugs > Payments, Data, and Noncompliance

## Adjust Payment Amounts and Ensure Timely Reporting of Drug Pricing Data

**Background:** Since January 2005, Medicare Part B has been paying for most covered drugs using a reimbursement methodology based on ASPs. An ASP is 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, net of any price concessions.

The Social Security Act, § 1847A(d)(2)(B), mandates that OIG compare ASPs to AMPs, which are the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. The purpose of such reviews is to identify whether the ASP for a drug exceeds the AMP by a certain percentage (currently 5 percent). If so, section 1847A(d)(3)(A) provides that the Secretary of HHS has the authority to disregard the ASP for that drug and substitute the payment for the drug code with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP.

Since the ASP reimbursement methodology for Part B drugs was implemented in January 2005, OIG has issued quarterly pricing comparisons in accordance with its congressional mandate. Although CMS has acknowledged the Secretary's authority to adjust ASP payment limits based on the findings of OIG's pricing comparisons, CMS has yet to make any changes to Part B drug reimbursement as a result of our statutorily-required reviews.

**Findings:** In reference to our CY 2008 rollup report, we identified 80 Medicare Part B drug codes that would have been eligible for price adjustment in one or more quarters in 2008. Additional codes may have been eligible for price adjustments; however, missing or unavailable pricing data prevented us from examining certain drug codes. Of the 80 drug codes that met the threshold for price adjustment, more than 40 percent would have met the 5-percent threshold during multiple quarters of 2008. If reimbursement amounts for all 80 codes had been lowered to 103 percent of the AMPs during the applicable quarters, Medicare and its beneficiaries would have saved an estimated \$21.9 million.

**Recommendations:** CMS should (1) develop a process to adjust payment amounts based on the results of OIG's pricing comparisons, (2) lower Medicare reimbursement amounts for drugs that meet the 5-percent threshold, and (3) continue to explore and undertake a range of efforts to ensure that drug manufacturers are submitting the required AMP data in a timely manner,

including collaborating with OIG regarding administrative remedies for noncompliance.

**Savings: TBD\***

*\*Based on reviews of ASP and AMP data submitted by manufacturers for the first through fourth quarters of 2008, reductions for the codes identified could have saved \$21.9 million.*

**Management Response Summary:** At the time our rollup report for CY 2008 was issued, CMS concurred with developing a process to adjust payment amounts based on the results of OIG's pricing comparisons. It also concurred with continuing to explore and undertake a range of efforts to ensure that drug manufacturers are submitting the required AMP data in a timely manner, including collaborating with OIG regarding administrative remedies for noncompliance. CMS has taken steps to ensure that certain pricing data are reported in a timely manner, including terminating manufacturers' rebate agreements for failure to report AMPs and referring manufacturers with nontimely AMPs to OIG for the purposes of evaluating civil money penalties (CMP).

CMS did not concur with our recommendation to lower Medicare reimbursement amounts for drugs that meet the 5-percent threshold. CMS stated that in light of the drug price volatility identified by OIG, making price substitutions could have a significant negative impact on both providers and beneficiaries. CMS expressed a desire to better understand differences between ASPs and AMPS, engage stakeholders affected by potential price substitutions, and provide adequate notice when developing its price substitution policies. CMS published a proposed rule at [75 Fed. Reg. 40040](#) (July 13, 2010) that among other things, specified the criteria under which it would substitute prices for drugs that meet the 5-percent threshold (pp. 40156 - 40159). Subsequently, in the final rule at [75 Fed. Reg. 73170](#) (November 29, 2010), the agency opted not to finalize the price substitution policy from the proposed rule (pp. 73470 – 73471), thereby suspending any plans to lower reimbursement amounts based on the results of OIG's statutorily required pricing comparisons.<sup>9</sup>

**Status:** We continue to recommend that Medicare reimbursements for eligible codes be lowered pursuant to Social Security Act, § 1847A(d)(3). OIG will continue to assist CMS in developing a price substitution policy and in taking appropriate action against manufacturers that fail to comply with AMP reporting requirements.

<sup>9</sup> Revised the paragraph to provide specific page numbers for the price substitution proposal and comments.

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**Related Report:**

2010 FEB *Comparison of Average Sales Prices to Average Manufacturer Prices: An Overview for Calendar Year 2008.* OEI-03-09-00350 [Report](#)

**See Also:**

2011 FEB *Comparison of Second-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2010.* OEI 03-11-00030 [Report](#)

2010 NOV *Comparison of First-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2010.* OEI 03-10-00440 [Report](#)

2010 SEP *Drug Manufacturers' Noncompliance With Average Manufacturer Price Reporting Requirements.* OEI-03-09-00060 [Report](#)

2010 JUL *Comparison of Fourth-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2010.* OEI 03-10-00350 [Report](#)

2010 APR *Comparison of Third-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2010.* OEI 03-10-00150 [Report](#)

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

2010 JAN *Comparison of Second-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2009.* OEI-03-09-00640 [Report](#)

2009 AUG *Comparison of First-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2009.* OEI-03-09-00490 [Report](#)

2009 AUG *Comparison of Fourth-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2009.* OEI-03-09-00340 [Report](#)

2009 APR *Comparison of Third-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2009.* OEI-03-09-00150 [Report](#)

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- 2009 FEB *Comparison of Second-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2008.* OEI-03-09-00050 [Report](#)
- 2008 DEC *Comparison of First-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2008.* OEI-03-08-00530 [Report](#)
- 2008 DEC *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2007.* OEI-03-08-00450 [Report](#)
- 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](#)

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Medicare Part A and Part B > Part B Prescription Drugs > Pricing Data

## Improve Manufacturer Reporting of Average Sales Price Data (New)

**Background:** CMS continues to cover a limited number of outpatient prescription drugs under its Medicare Part B benefit. Since January 2005, CMS has been paying for most Part B-covered drugs using a reimbursement methodology based on ASP. ASP is defined as 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, net of any price concessions. Pursuant to section 1927 of the Social Security Act, manufacturers with a Medicaid drug rebate agreement in effect must, among other things, provide CMS with pricing information, including the ASPs for their Part B-covered drugs, on a quarterly basis.

Manufacturers that report ASPs are required to submit each quarter's ASPs to CMS no later than 30 days after the close of that quarter. As a result, there is a lag between the time when sales reflected in the ASP occur and the time when these sales become the basis for Medicare payment amounts. To fulfill their reporting requirements, manufacturers typically mail a compact disc containing ASP data to CMS. CMS staff manually enter all ASP data received from manufacturers, then calculate the Medicare payment amounts for Part B-covered drugs. CMS posts these payment amounts on its Web site 2 weeks before the start of the applicable quarter (approximately 6 to 7 weeks after the submission deadline).

**Findings:** We found that for each quarter under review, over 40 percent of manufacturers submitted ASPs late. However, at least 95 percent of manufacturers submitted ASP data to CMS within 10 days after the deadline. Further, no more than 2 percent of manufacturer submissions each quarter were more than 30 days late.

We also found that although CMS implemented several oversight procedures related to payment for Part B-covered drugs, it still uses methods that may inhibit efficiency and result in potential errors. For example, CMS relies on manual processes for collecting ASP data, although it uses an automated system to collect prices for the Medicaid program.

Manufacturers that do not have Medicaid drug rebate agreements in effect are not required to report ASP data. We found that some reported ASP submissions were associated with manufacturers that were not required to provide these prices under the current system. If these manufacturers chose not to report ASPs, CMS would be unable to calculate ASP-based Medicare payment amounts for these drug codes.

**Recommendations:** CMS should (1) develop an automated system for the collection of ASP data and (2) seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs.

**Savings:** TBD\*

*\*Savings not estimated.*

**Management Response Summary:** CMS concurred with our recommendation to develop an automated system for the collection of ASP data. CMS did not concur with our recommendation to seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs. However, CMS stated that it will consider this recommendation as it continues to monitor the effects of current payment policies. The President's budget for FY 2010 did not include any proposals to require manufacturers to submit ASPs regardless of whether they had Medicaid drug rebate agreements.

**Status:** We continue to support our recommendation that CMS seek a legislative change to the ASP reporting requirements as a way to ensure that Medicare payment amounts are reflective of all Part B-covered drugs. We will continue to monitor CMS's implementation of our recommendations.

#### **Related Report:**

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

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Medicare Part A and Part B > Part B Prescription Drugs > Chemotherapy Administration

## Ensure That Medicare Part B Chemotherapy Administration Claims Are Correctly Paid

**Background:** Medicare Part B pays for a limited amount of prescription drugs, including chemotherapy agents, and pays physicians separately for their administration. CMS does not specify the particular drugs that qualify for the chemotherapy administration rate, leaving that decision to the carriers with which it contracts to process these Part B physician claims. For the purposes of our review, any chemotherapy administration claim that fell on a service date on which no qualifying drug was billed was classified as an unmatched chemotherapy administration claim.

**Findings:** Although unmatched claims exceeded \$60 million from 2005 to 2007, Medicare data are insufficient to determine consistently whether chemotherapy administration payments are appropriate. We also found that lacking a national definition of “qualifying drug,” carriers have implemented inconsistent chemotherapy administration coding policies and review procedures.

**Recommendations:** CMS should (1) establish a process to determine the specific drugs that qualify for the chemotherapy administration payment rate, and (2) ensure that drug administration claims are coded and paid correctly.

**Savings:** TBD\*

*\*Based on a review of 2005 to 2007 Part B claims data.*

**Management Response Summary:** CMS did not concur with our recommendations. 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.

**Status:** We continue to recommend that CMS 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.

### Related Report:

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

**Part II:**

**Medicare Part C and Part D  
and Medicare Administration**

## Part II: Medicare Part C and Part D and Medicare Administration

### Part C (Medicare Advantage)

Medicare Part C > Payments > Capitation Rates

#### Modify Payments to Medicare Advantage Organizations

**Background:** The Balanced Budget Act of 1997 (BBA) established the Medicare+Choice (M+C) program with the primary goal of providing a wider range of health plan choices to Medicare beneficiaries. The BBA also modified the payment methodology under the program to correct excess payments, reduce geographic variations in payments, and align payments to reflect beneficiaries' health status. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which increased payments, redesignated the M+C program as Medicare Advantage (MA). Participating managed care organizations are designated as MA organizations.

**Findings:** The 1997 data and estimates used as the basis to calculate monthly capitation payments to MA organizations were flawed, resulting in higher-than-necessary payments. Based on numerous reviews (which are summarized in our September 2000 report), studies by other agencies, and MA organization data, we concluded that from calendar year (CY) 1997 through CY 2000, MA organizations received more funds than necessary to deliver the Medicare package of covered services. Medicare payments funded excessive administrative costs, and MA organizations did not account for investment income earned on Medicare funds.

Improper payments made in Medicare fee-for-service (FFS) expenditures also contributed to the flaws in the 1997 managed care base rates. Our review of Medicare's 1996 and 1997 financial statements identified substantial FFS improper payments. The standardized county rates for 1997 were calculated using 1996 base FFS expenditure data, and the overpayment errors were carried over into the 1997 managed care rates. We estimated the 1996 FFS error rate as 14 percent of FFS benefit payments.

**Recommendation(s):** The Centers for Medicare & Medicaid Services (CMS) should modify monthly capitation rates to a level fully supported by empirical data.

**Savings: \$1.97 billion\***

*\*Estimated savings are based on the 3.077-percent overstatement of 1997 base rates applied to the 2006 managed care payments.*

**Management Response Summary:** CMS did not concur with our recommendation to modify payments to MA organizations, noting that the BBA and the Balanced Budget Refinement Act of 1999 (BBRA) had increased these payments.

**Status:** Improvements have been made to modify payment rates to levels supported by empirical data. For example, the Health Care and Education Reconciliation Act of 2010, § 1102 (amending § 3201 of the Patient Protection and Affordable Care Act (Recovery Act)), freezes MA payments in 2011 and further reduces MA benchmarks relative to current levels beginning in 2012. However, recent Office of Inspector General (OIG) work confirms that additional adjustments are needed. In January 2011, we issued a report following up on our prior work on interest income associated with repayments to MA organizations. The interest income that MA organizations earn on prepayments from Medicare, in effect, constitutes a portion of their total Medicare-related income. Based on the results of our followup review, we recommended that CMS (1) pursue legislation to adjust the timing of Medicare's prepayments to MA organizations to account for the time that these organizations invest Medicare funds before paying providers for medical services or (2) develop and implement regulations that require MA organizations to reduce their revenue requirements in their bid proposals to account for anticipated investment income. CMS has not agreed to implement either recommendation; however, the empirical results of the audit indicate that the recommended adjustments are warranted.

### **Related Report:**

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

See also:

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

Medicare Part C > Marketing Activities > Regulations and Guidance

## Address Vulnerabilities Within Sales Agents' Marketing of Medicare Advantage Plans (New)

**Background:** The MMA replaced the M+C program with the MA program and made qualified prescription drug coverage available to Medicare beneficiaries by contracting with private companies known as plan sponsors to provide health insurance plans under MA. Plan sponsors may offer multiple MA plans and market through advertisements and sales agents to attract Medicare beneficiaries to enroll in their plans. In addition, field marketing organizations (FMO) typically provide sales agents with enrollment leads and marketing assistance.

Between January 2008 and September 2009, enrollment in MA plans increased from 9.2 million Medicare beneficiaries to over 11.2 million, nearly a quarter of the more than 45 million Medicare beneficiaries. In response to Medicare beneficiaries' and consumer advocates' complaints of aggressive, deceptive, and fraudulent marketing practices, Congress held three hearings between June 2007 and June 2008 examining MA plan marketing. In July 2008, Congress enacted the Medicare Improvements for Patient and Providers Act of 2008 (MIPPA), which prohibited or limited certain marketing activities by plan sponsors or sales agents. Later in 2008, CMS promulgated regulations implementing these prohibitions and limitations, including specific regulations concerning sales agent compensation and qualifications.

**Findings:** We selected six MA plan sponsors for review, and we determined that all five of the sponsors employing independent sales agents had compensation practices that resulted in inappropriate financial incentives for sales agents and FMOs. Five of the six sponsors did not ensure that all of their sales agents were qualified under CMS's regulations. We also found that the number and types of beneficiary complaints remained unchanged after CMS's implementation of sales agent marketing regulations.

**Recommendations:** CMS should (1) issue regulations concerning FMO payments, (2) issue regulations requiring plan sponsors to contact all new enrollees to ensure they understand plan rules, and (3) issue guidance clarifying that plan sponsors should terminate unlicensed sales agents immediately upon discovery.

**Management Response Summary:** In its comments on the final report, CMS concurred with our recommendation that it issue additional regulations concerning FMO payments and said that it will consider additional and more specific regulations. CMS maintains that the CMS agent/broker compensation regulations apply to FMOs

and that it is therefore unnecessary for it to issue regulations specifically targeting FMO compensation payments. CMS stated, however, that it believes it is appropriate to clarify guidance on payments to third-party marketing organizations like FMOs in the next revision of the *Medicare Marketing Guidelines*.

CMS also concurred with our recommendation to issue regulations requiring plan sponsors to contact all new enrollees to ensure they understand plan rules. Regulations (42 CFR part 422) require that organizations establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the plan and understand plan rules. Therefore, all sponsors are required to conduct outbound education and verification calls to ensure that beneficiaries who request enrollment understand plan rules.

Finally, CMS concurred with our recommendation to issue guidance clarifying that sponsors should terminate unlicensed sales agents immediately upon discovery. CMS published a proposed rule at [75 Fed. Reg. 71190](#) (November 22, 2010) which would require sponsors to terminate unlicensed sales agents upon discovery and notify any beneficiaries who were enrolled in their plans by unlicensed agents. CMS believes that the changes it proposed in 75 Fed. Reg. 71190 are consistent with the statute and with the beneficiary protections specified in CMS's regulations implementing MIPPA.

**Status:** We continue to monitor CMS's implementation of our recommendations.

**Related Report:**

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

## Medicare Part D (Prescription Drug Program)

Medicare Part D > Bids and Payments > Sponsor Accountability

### Ensure Accuracy of Prescription Drug Plan Sponsors' Bids and Prospective Payments

**Background:** The Medicare prescription drug program provides an optional outpatient drug benefit to Medicare beneficiaries. CMS contracts with private insurance companies, known as Part D sponsors, to provide prescription drug coverage for beneficiaries who choose to enroll. During 2006, the first year of the benefit, Part D expenditures totaled more than \$47 billion.

CMS makes monthly prospective payments to sponsors for providing prescription drug coverage to Medicare beneficiaries. These payments are based on estimates that sponsors provide in their approved bids before the plan year begins. CMS makes prospective payments to sponsors in the form of three separate subsidies to cover the Federal Government's share of the cost of direct, catastrophic, and low-income prescription drug benefits. The amounts of the three subsidies are based on sponsors' approved bids. After the close of the plan year, CMS must reconcile these prospective payments with sponsors' actual costs to determine whether sponsors owe money to Medicare, Medicare owes money to sponsors, or payment to CMS or to a sponsor is required to share the risk of unexpected losses (or the benefit of unexpected profits).

**Findings:** In October 2007, we issued a report that estimated that Part D sponsors owed Medicare a net \$4.4 billion for the 2006 benefit year. Eighty percent of sponsors owed money to Medicare, and 20 percent of sponsors were to receive money from Medicare. The majority of the funds that sponsors owed were a share of excess profits that they must return to Medicare pursuant to risk-sharing requirements. CMS had no mechanisms in place to collect funds owed by sponsors until it had completed reconciliation, which at the time of our review was scheduled to occur more than 9 months after the 2006 plan year had ended. CMS also had no mechanism in place to adjust prospective payments before reconciliation.

A subsequent report issued in September 2009 found that sponsors owed a net \$18 million to Medicare for reconciliation of the 2007 benefit year.

We found that sponsors continue to make large unexpected profits in addition to expected profits that they included in their bids. We also found that CMS collected almost all of the funds that sponsors owed from the 2006 benefit year to Medicare in November and December 2007. We reported in 2007 that CMS had not collected \$14 million from five sponsors for 2006. However, CMS noted that it has since collected amounts owed.

**Recommendations:** The recommendations of our 2009 report were similar to those of our 2007 report, including that CMS should (1) ensure that sponsors' bids more accurately reflect their costs of providing the benefit to Medicare beneficiaries, (2) hold sponsors more accountable for inaccuracies in the bids, (3) determine whether changes to the risk corridors (triggers that protect plans from unexpected losses and allow the Government to share in unexpected gains) are appropriate, (4) determine whether alternative methodologies would better align payments with sponsors' costs for the low-income cost-sharing and reinsurance subsidies

**Management Response Summary:** In response to our first recommendation, CMS concurred and stated that it has already incorporated plan-level experience in its current bid-desk review. In response to our second recommendation, CMS stated that it has the authority to ensure Part D sponsors' compliance with the operational requirements of the Part D program. However, CMS subsequently indicated that it did not concur with this recommendation. In response to our third recommendation, CMS stated that it has reviewed the statutory risk corridors and risk-sharing percentages and does not believe that changes would be appropriate. Further, CMS noted that it estimates that because plans' bids dropped significantly for the 2008 benefit year, the Government, on average, will owe plans for the 2008 reconciliation. In response to our fourth recommendation, CMS concurred and stated that it was considering changing the method for paying the low-income cost-sharing subsidy.

**Status:** We will continue to monitor the actions CMS takes to further address our recommendations, including that CMS use its current authority to hold sponsors more accountable for inaccuracies in their bids. However, we note that CMS's current authority may not allow it to impose sanctions in all situations that lead to inaccuracies in the bids.

**Related Reports:**

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

2007 OCT     *Medicare Part D Sponsors: Estimated Reconciliation Amounts for 2006.*  
OEI-02-07-00460 [Report](#)

Medicare Part D > Information for Beneficiaries > Reliability of Estimated Costs

## Ensure the Accuracy of Plans' Drug Prices on the Medicare Prescription Drug Plan Finder (New)

**Background:** The Medicare prescription drug program provides an optional prescription drug benefit for Medicare beneficiaries. CMS contracts with private insurance companies, known as Part D sponsors, to provide outpatient prescription drug coverage for beneficiaries who choose to enroll. Medicare created the Plan Finder, an online tool to help beneficiaries compare and select Part D plans. The plans' drug prices are a significant factor in selecting a plan. Drug prices listed on the Plan Finder that do not reflect actual drug costs may cause beneficiaries to enroll in a plan based on incorrect information, incur unexpected costs, or decline to enroll in a Part D plan. The plan Finder indicates on the plan drug details screen that "actual drug costs at the pharmacy may vary slightly." To determine whether Plan Finder drug prices accurately reflect actual drug costs, we compared plans' retail prices listed on the Plan Finder for 10 drugs commonly used by Medicare beneficiaries to actual drug costs on corresponding prescription drug event (PDE) claims for the same period (September 24 to October 7, 2007).

**Findings:** Drug prices posted on the Plan Finder exceeded actual drug costs for 92 percent of the claims. The median amount by which the Plan Finder exceeded the actual price was 28 percent. The Plan Finder price was less than the actual price for 7 percent of claims and equaled the actual price for only 1 percent of claims. Percentage differences between Plan Finder prices and actual costs were generally greater for the generic drugs we reviewed, while dollar differences were greater for the brand-name drugs reviewed.

**Recommendation:** CMS should modify the disclaimer on the Plan Finder search results screen to indicate that drug cost estimates may differ more than "slightly" from actual drug costs.

**Management Response Summary:** CMS did not concur with our recommendation. CMS asserts that the current disclaimer on the Plan Finder indicating that drug cost estimates may differ slightly from actual drug costs is sound and that modification to the disclaimer is unwarranted. Subsequently, CMS said that the review's methodology has limitations regarding the relationship between prices displayed on the Plan Finder and the prices charged at the point of sale because we conducted a general search rather than a pharmacy-specific search in the Plan Finder. Consequently, CMS considers that findings of frequent price differences between Plan Finder and PDE data are misleading. CMS continues to recommend that beneficiaries perform a general (non-pharmacy-

specific) search to find the least expensive plan for their needs. For the past 3 years, CMS has compared drug pricing displayed on the Plan Finder to prices charged at the point of sale (pharmacy). The results of these analyses have been presented on [www.medicare.gov](http://www.medicare.gov) as ratings of Part D plans.

**Status:** We continue to encourage CMS to modify the disclaimer on the Plan Finder search results screen to indicate that drug cost estimates may differ more than “slightly” from actual drug costs. We also encourage CMS to raise beneficiaries’ awareness of potential significant discrepancies between drug prices displayed on the Plan Finder and actual drug costs.

**Related Report:**

2009 JUL      *Accuracy of Part D Plans’ Drug Prices on the Medicare Prescription Drug Plan Finder.* OEI-03-07-00600 [Report](#)

Medicare Part D > Information for Beneficiaries > Accuracy Compared to Guidelines

## Ensure That Marketing Materials for Medicare Prescription Drug Plans Comply With Program Guidelines

**Background:** CMS's Medicare Marketing Guidelines specify what information the marketing materials must include when describing prescription drug plan (PDP) coverage. To help ensure accuracy and expedite the review of certain marketing materials, CMS created model documents, which include uniform text that contains pertinent information. Before PDP sponsors distribute marketing materials, they must submit them to CMS under one of its review processes: standard review or "file & use." The guidelines also outline CMS's oversight activities in monitoring marketing materials, including requiring identification numbers on materials. We assessed CMS's oversight of PDP marketing materials based on its oversight strategy.

**Findings:** We found that CMS's oversight for PDP marketing materials is limited. For example, CMS did not complete a retrospective review of file & use marketing materials for 2006 until April 2008. Although CMS completed standard reviews of marketing materials in a timely manner, the reviews lacked consistency across regions. Identification numbers from 45 percent of the materials we reviewed failed to match the numbers in CMS's system. CMS also lacked a systematic way to track materials. We also found that CMS's model documents were not consistent with its guidelines. Also, we found that overall, PDP marketing materials did not meet CMS guidelines. Eighty-five percent of marketing materials failed to meet at least one element of the guidelines.

**Recommendation:** CMS should revise model documents to ensure consistency between the model documents and the guidelines.

**Management Response Summary:** CMS concurred with our recommendation. In its update for 2011, CMS reported that it has developed a standard operating procedure for the review of marketing materials and that it has implemented a tracking system for non-English and alternative formal materials, which are given a unique material ID.

**Status:** We continue to monitor CMS's implementation of its commitment to revise the model documents to better align with the guidelines.

**Related Report:**

2008 SEP     *Marketing Materials for Medicare Prescription Drug Plans.*  
OEI-01-06-00050 [Report](#)

Medicare Part D > Information for Beneficiaries > Preparation for Coverage Gap

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

**Background:** Medicare Part D provides an optional outpatient drug benefit to beneficiaries. During the coverage year, the financial responsibilities of beneficiaries, plan sponsors, and CMS vary during four distinct coverage phases: annual deductible, initial coverage, coverage gap, and catastrophic coverage. 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. Some research suggests that beneficiaries who entered the Medicare Part D coverage gap may have changed their prescription drug use behavior because they were responsible for 100 percent of their drug costs during the coverage gap. OIG studied the prescription drug use of beneficiaries who entered the coverage gap without financial assistance in 2006.

**Findings:** Seven 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 coverage 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 coverage gap. 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.

**Recommendations:** CMS should (1) support outreach and education targeted at beneficiaries who make more prescription drug purchases before entering the coverage gap (such as by encouraging plan sponsors to augment outreach and beneficiary education efforts, supplementing those efforts by working with beneficiaries to explore cost-saving strategies, and targeting these beneficiaries for counseling about choosing the most cost-effective plan in the following year) and (2) target low-income subsidy outreach to beneficiaries who entered the coverage gap in previous years without financial assistance.

**Management Response Summary:** CMS concurred with one of our two recommendations. 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 based on the prior year's PDE data. We continue to recommend that targeting beneficiaries who had more prescription drug purchases before the coverage gap for outreach and education would assist those beneficiaries in identifying cost-saving strategies. CMS concurred with our second recommendation and 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 December 2009 update, CMS indicated that it had taken several steps to refine outreach methods. However, the actions CMS said it would take may not fully address our concerns. In its update for 2011, CMS indicated that 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.

**Status:** CMS has not yet fully addressed our concerns. We continue to recommend focusing on a specific category of beneficiaries for outreach and using prescription drug utilization data to identify potential beneficiaries for the subsidy.

**Related Report:**

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

Medicare Part D > Data Management > Tracking and Oversight of Costs

## Track Beneficiaries' True Out-of-Pocket Costs

**Background:** The Medicare Prescription Drug program, known as Medicare Part D, provides an optional outpatient prescription drug benefit for beneficiaries. Beneficiary, Medicare, and plan sponsor cost-sharing obligations vary across four phases of the standard Part D benefit: deductible, initial coverage, coverage gap, and catastrophic coverage. Part D plans are responsible for tracking beneficiaries' true out-of-pocket (TrOOP) costs. 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. Medicare beneficiaries enrolled in Part D plans may also have other prescription drug coverage. 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. The amount of beneficiaries' TrOOP costs affects their cost sharing as well as CMS payments to Part D plans.

**Findings:** We found 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 in 2006 to submit PDE data to CMS in accordance with CMS requirements. We also found that CMS has conducted limited oversight of Part D plans' tracking of TrOOP costs.

**Recommendations:** CMS and its contractors should (1) ensure that Part D plans collect, process, and submit all of the data that are required to track enrollees' TrOOP costs in a timely manner; (2) consider options for increasing the number of data-sharing agreements and for seeking to expand its authority to collect data under those agreements; and (3) begin or complete implementation of oversight activities regarding tracking TrOOP costs.

**Management Response Summary:** CMS agreed that the report identified potential issues linked to the accurate tracking of TrOOP costs and that more work is needed to ensure that Part D plans are calculating TrOOP costs correctly. The agency did not concur with our three recommendations but noted 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.

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 expected to receive a significant number of reports of prescription drug data via the section 111 process. CMS also stated in its March 2009 status update that it was conducting audits of one-third of the MA and Medicare PDPs. The audit protocol includes a review to verify that PDPs are accurately calculating TrOOP costs. In CMS's December 2009 status update, it indicated that as of November 2009, it had started its financial audits for 2006 and 2007. However, until one-third of financial audits are completed and show that TrOOP is calculated correctly, our recommendations are not fully implemented.

**Status:** We continue to monitor CMS's implementation of oversight activities related to the tracking of TrOOP costs.

**Related Report:**

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

Medicare Part D > Program Integrity > Sponsors' Compliance Plans

## Ensure Adequacy of Sponsors' Compliance Plans

**Background:** The MMA established Medicare Part D to provide outpatient prescription drug benefits under the Medicare program beginning January 1, 2006. Part D prescription drug coverage is provided by private entities known as plan sponsors. Federal regulations at 42 CFR § 423.504(b)(4)(vi) require that PDP sponsors have compliance plans in place to protect the integrity of Medicare funds by preventing fraud, waste, and abuse and that these compliance plans address eight elements. In June 2005, CMS issued a summary document, *Review of Sponsor Fraud, Waste, and Abuse Responsibilities*, and in April 2006 issued its *Prescription Drug Benefit Manual*, Chapter 9, which outlined requirements that compliance plans must address to ensure that the eight elements established by the regulation are met.

In December 2006, we released a report on PDP sponsors' compliance plans, finding that most compliance plans did not address all of CMS's requirements or recommendations, and in October 2008, we issued a followup report. In August 2008, the Government Accountability Office (GAO) released a report saying that some PDP sponsors had not completely implemented fraud and abuse programs and that CMS oversight had been limited.

**Findings:** In our 2008 followup, we found that CMS conducted only one audit of a PDP sponsor's compliance plan in 2007. CMS instructed PDP sponsors to complete compliance plan self-assessments, but we found that CMS did not verify sponsors' responses. The self-assessments were based on requirements and recommendations in CMS's *Prescription Drug Benefit Manual*, Chapter 9. However, some self-assessments did not include all of the compliance plan requirements that are in Chapter 9. Although CMS followed up with 23 PDP sponsors that attested that they had not implemented one or more of the compliance plan requirements in the self-assessments, CMS did not request supporting documentation to confirm that these PDP sponsors corrected their compliance plans.

**Recommendation:** CMS should conduct audits to verify that PDP sponsors' compliance plans meet requirements (covering all of the compliance plan requirements that are contained in regulations and in Chapter 9 of CMS's *Prescription Drug Benefit Manual*).

**Management Response Summary:** CMS concurred with our recommendation in the 2006 report that it should ensure that PDP sponsors' compliance plans address all

requirements set forth in regulation and provide sufficient detail in their compliance plans to demonstrate implementation of compliance plan requirements.

In its comments on our 2008 report, CMS agreed that it is important to conduct reviews of compliance plans but said that because of critical funding shortfalls, it had to reprioritize its program integrity oversight activities and was not able to conduct compliance plan audits before our report was issued. CMS said that it would begin a limited number of desk audits of Part D sponsors' compliance plans in September 2008. As more resources become available, CMS said, it would include more audits, onsite reviews, and other more comprehensive fraud-prevention activities. However, in response to an October 2009 review, CMS acknowledged that there had been a delay in starting the compliance plan audits.

In December 2009, CMS reported that Medicare Prescription Drug Integrity Contractors (MEDIC) had conducted compliance plan audits of 16 stand-alone PDP sponsors in fiscal year (FY) 2009. In an effort to strengthen its compliance oversight activities, CMS restructured the MEDIC program for FY 2010 contract year, with one MEDIC focusing solely on compliance activities for the entire country and being responsible for conducting compliance plan audits in addition to other compliance-related activities. CMS also informed us that the MEDICs had approval to conduct compliance plan audits in FY 2010 for PDP and MA organizations to include assessing an entity's compliance with CMS requirements in 42 CFR §§ 422.504(b)(4)(vi) and 422.503(b)(4)(vi), which contain measures to detect, correct, and prevent fraud, waste, and abuse.

In its 2011 update of our recommendation, CMS said it conducted program compliance audits in the fall of 2010 that included reviews of Part D sponsors' compliance plans.

**Status:** We will continue to monitor CMS's implementation of our recommendation as it analyzes and takes appropriate action, if needed, on the findings of those audits.

### **Related Reports:**

2008 OCT     *Oversight of Prescription Drug Plan Sponsors' Compliance Plans.*  
OEI-03-08-00230 [Report](#)

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

### **See Also:**

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

Medicare Part D > Program Integrity > Safeguard Strategies

## Implement a Safeguard Strategy To Prevent and Detect Fraud and Abuse in Prescription Drug Plans

**Background:** CMS is responsible for safeguarding the Medicare Part D program against fraud and abuse. CMS is statutorily required to perform financial audits of PDPs that are contracted to provide outpatient prescription drug benefits to beneficiaries. Beyond this, CMS has discretion in structuring program safeguards.

We identified six major safeguards conducted by CMS during FY 2006: implementation of a complaint process, data-monitoring, financial audits, monitoring PDP sponsors' compliance with contract requirements, oversight of PDP sponsors' efforts to reduce fraud and abuse, and providing education and guidance to stakeholders on fraud and abuse identification. During FY 2006, CMS had contracted with one MEDIC to perform some of these functions. We reviewed a variety of documents and conducted interviews with CMS and MEDIC staff members to determine the status of safeguards at the time of our review.

**Findings:** We found that CMS implemented safeguards throughout FY 2006; however, further development or application of these activities is needed. CMS relied largely on complaints to identify potential fraud and abuse, but some complaints were not investigated in a timely manner. Limits to legal authority, jurisdiction, and CMS's ability to monitor enrollees switching plans had complicated efforts to safeguard Medicare Part D PDPs.

**Recommendation:** CMS should develop a comprehensive safeguard strategy for Medicare Part D PDPs.

**Management Response Summary:** CMS did not indicate whether it concurred with the recommendation in our draft report. In its March 2009 status update to OIG, CMS reported that it had developed a corrective action plan to address OIG's recommendation and had completed the following activities: (1) implementing a regional TriMEDIC structure in which the three MEDICs work together to analyze data and identify national fraud schemes, (2) assigning a Government Task Leader to each regional MEDIC to oversee and monitor all MEDIC activities, and (3) rewriting the MEDIC Umbrella Statement of Work (SOW) to further refine CMS's coordination and oversight of the MEDICs.

In 2009, CMS restructured the MEDIC program, designating one MEDIC to focus solely on compliance activities for the entire country and the other to concentrate on efforts

against fraud, waste, and abuse. CMS expects this specialization to reduce administrative barriers and to enable it to leverage efficiencies, strengthening CMS's compliance and fraud prevention efforts.

CMS states that it is concerned about the risks that potential fraud poses to the Part D program. The agency says that it continues to take actions to address the program's needs. Providing improved access to data will enable the MEDICs to identify, prevent, and fight fraudulent activity in the Part D program. Currently, MEDICs use an integrated data repository to access information on Part D prescription drug events and Parts A and B claims data. CMS is building "One PI," a system that will pull data from this integrated data repository and from other systems.

CMS has issued guidance and clarification to MA organizations and PDP sponsors indicating that sponsors must apply training on fraud, waste, and abuse to all entities with which they are partnering to provide benefits or services under the Part C and the Part D programs, not just to their own organizations' direct employees.

**Status:** We continue to recommend that CMS implement a comprehensive safeguard strategy for Medicare Part D PDP sponsors. We will continue to monitor CMS's implementation of its safeguard strategy.

### **Related 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 [Report](#)

### **See Also:**

2010 MAR     *OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security: "Oversight Challenges in the Medicare Prescription Drug Program."*  
[Testimony](#)

Medicare Part D > Program Integrity > Fraud Prevention, Detection, and Response

## Ensure That Plan Sponsors Have Comprehensive and Effective Programs To Detect and Deter Fraud and Abuse

**Background:** The MMA established Medicare Part D to provide outpatient prescription drug benefits under the Medicare program beginning January 1, 2006. Part D prescription drug coverage is provided by private entities known as plan sponsors. Part D expenditures for 2007 were about \$49.5 billion. As of August 2008, 26 million beneficiaries were enrolled in Part D, and two-thirds were in stand-alone drug plans. Plan sponsors are private companies that contract with CMS to provide Part D drug coverage to beneficiaries. Sponsors are required to have a comprehensive program to detect and deter fraud and abuse. When potential fraud or abuse is found, sponsors must conduct an inquiry and initiate corrective action and are advised to refer incidents to a MEDIC for investigation. The only fraud and abuse information that CMS requires sponsors to report is the quarterly number of fraud and abuse complaints they receive from beneficiaries. We analyzed data for the first 6 months of 2007 from 86 of 91 stand-alone drug plan sponsors.

**Findings:** We found that 24 of 86 Part D stand-alone plan sponsors did not find any potential fraud and abuse incidents and that most such incidents were associated with only a small number of plan sponsors. We also found that inappropriate billing was the most prevalent type of potential fraud and abuse and that pharmacies were associated with most of the incidents. We found that of the 62 plan sponsors that identified potential fraud and abuse, not all conducted inquiries, initiated corrective actions, or made referrals for investigation.

**Recommendations:** CMS should (1) review Part D plan sponsors to determine why certain sponsors have especially high or low volumes of potential fraud and abuse incidents, (2) 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, (3) require Part D plan sponsors to maintain and report information about the results of sponsors' fraud and abuse programs, and (4) use this information to help determine the effectiveness of the programs.

**Management Response Summary:** CMS concurred with our first and second recommendations. It did not indicate whether it concurred with our third recommendation, and it did not address our fourth recommendation. With regard to the first recommendation, in its 2011 update, CMS said that it provided our findings to

the MEDICs, but it did not report the results of the MEDICs' reviews. CMS revised the reporting requirements to provide the Part D sponsors with specific parameters for tracking and properly labeling any incidents. With regard to the second recommendation, CMS provided the data in our report to the MEDICs for investigation but did not report the results.

**Status:** CMS has taken some steps toward implementing our recommendations. We will continue to monitor this implementation and will attempt to determine whether the results of the MEDICs' reviews address our recommendations.

**Related Report:**

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

**See Also:**

2010 MAR OIG Testimony Before the Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security: "Oversight Challenges in the Medicare Prescription Drug Program."  
[Testimony](#)

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Medicare Part D > E-Prescribing > Connectivity Standards

## Ensure that Plan Sponsors Completely Implement E-Prescribing Standards to Support Connectivity with Prescribers and Dispensers (New)

**Background:** The MMA established the Medicare Part D e-prescribing program, which stipulates that plan sponsors must implement e-prescribing standards specified by the Secretary of Health & Human Services (HHS). On behalf of the Secretary, CMS established e-prescribing standards. These standards facilitate the communication of prescription information between prescribers (e.g., doctors); plan sponsors; and dispensers (e.g., pharmacies). The plan-to-prescriber standards include: Accredited Standards Committee (ASC) X12N 270/271, SCRIPT 8.1, and Formulary & Benefits Standard 1.0. The plan-to-dispenser standard is Telecommunication 5.1. CMS required that plan sponsors implement ASC X12N 270/271 and Telecommunication 5.1 by January 2006 and SCRIPT 8.1 and Formulary & Benefits Standard 1.0 by April 2009. We surveyed all plan sponsors for plan year 2008 between August and September 2008 to determine the extent of their implementation of the standards.

**Findings:** Based on plan year 2008 sponsors' responses to our survey, we found that nearly 80 percent of sponsors reported at least partial plan-to-prescriber connectivity but that few reported complete connectivity. We found that problems in implementing Formulary & Benefits Standard 1.0—one of the plan-to-prescriber standards—limit complete plan-to-prescriber connectivity. Moreover, plan sponsors reported incomplete implementation of Formulary & Benefits Standard 1.0 because their systems are not fully compatible with the standard. Finally, we found that most sponsors had complete plan-to-dispenser connectivity. Only 5 percent of sponsors reported no plan-to-dispenser connectivity.

**Recommendations:** CMS should (1) ensure that plan sponsors completely implement the plan-to-prescriber and plan-to-dispenser standards and (2) collaborate with plan sponsors and industry representatives to address barriers to full implementation of Formulary & Benefits Standard 1.0.

**Management Response Summary:** In its comments on the draft report, CMS concurred with both of our recommendations. In response to the first recommendation, CMS indicated it will continue to educate sponsors about e-prescribing requirements. CMS indicated that if necessary, it will use available compliance mechanisms to bring plan sponsors into compliance. With regard to the second recommendation, CMS indicated that it plans to continue collaboration with the National Council for

Prescription Drug Programs to continually update and develop new e-prescribing standards.

**Status:** We will continue to monitor CMS's implementation of our recommendations.

**Related Report:**

2009 OCT     *Part D E-Prescribing Standards: Early Assessment Shows Partial Connectivity.*  
OEI-05-08-00320 [Report](#)

Medicare Part D > Program Integrity > MEDICs' Authority and Access to Data

## Improve Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse (New)

**Background:** The MMA established Medicare Part D to provide prescription drug benefits under the Medicare program beginning January 1, 2006. Prior to implementing Part D, CMS developed a strategy to help combat Part D fraud and abuse. One of the key aspects of this strategy was the use by MEDICs of innovative techniques for data analysis. Beginning in FY 2007, CMS awarded contracts to three regional MEDICs to address potential fraud and abuse related to the Part D benefit. According to the MEDICs' SOW and their individual task orders, MEDICs' 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.

**Findings:** Most incidents of potential Part D fraud and abuse in FY 2008 were identified through external sources rather than through proactive methods. Problems with accessing and using data hindered the MEDICs' ability to identify and investigate potential fraud and abuse incidents. All MEDICs reported that they need both PDE data and Medicare Part B data to effectively identify and investigate instances of potential fraud and abuse. However, MEDICs did not receive access to PDE data until August 2007, nearly a year after their contracts began. In addition, two MEDICs were not given access to Part B data until the fall of 2008, and the third MEDIC did not receive access to Part B data before its contract ended. MEDICs' lack of authority to directly obtain information such as prescriptions and medical records from pharmacies, pharmacy benefit managers, and physicians hindered their 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 are not required to refer them. Finally, CMS did not give MEDICs approval to conduct audits of plan sponsors' compliance plans in FY 2008.

**Recommendations:** CMS should (1) authorize MEDICs to directly obtain information that they need to identify and investigate potential fraud and abuse from entities such as pharmacies, pharmacy benefit managers, and physicians, even if statutory or regulatory change is required to do so.

**Management Response Summary:** CMS did not concur with our recommendation to authorize MEDICs to directly obtain information needed to identify and investigate potential fraud and abuse from entities such as pharmacies, pharmacy benefit managers, and physicians, even if statutory or regulatory change is required to do so. CMS stated that it recognizes the value of the recommendation but that the current structure is appropriate given the structure of the Part D program and the contractual relationship with the plans. CMS concurred with our recommendation that when referring fraud and abuse incidents to law enforcement, plan sponsors should also report that information to the MEDICs. CMS stated that those expectations are outlined in Chapter 9 of the *Part D Drug Benefit Manual*.

**Status:** We will continue to monitor CMS's implementation of our recommendations.

**Related Report:**

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

Medicare Part D > Prescription Drugs > Prescriber Identifiers

## Ensure the Validity of Prescriber Identifiers on Medicare Part D Drug Claims (New)

**Background:** The MMA established Part D to provide an optional prescription drug benefit for all Medicare beneficiaries. CMS contracts with private companies, called plan sponsors, to administer the benefit through Part D drug plans. Part D plans must submit to CMS an electronic record, called a PDE record, for each covered prescription filled for their enrollees. CMS requires that most PDE records contain an identifier for the drug's prescriber. Acceptable prescriber identifiers include National Provider Identifiers (NPI), Drug Enforcement Administration (DEA) registration numbers, Unique Physician Identification Numbers (UPIN), and State license numbers.

**Findings:** We found 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 were either (1) not listed in the NPI, DEA number, or UPIN registry databases; or (2) had been deactivated or retired before January 1, 2006. For 17 percent of the PDE records that contained invalid prescriber identifiers, the identifiers did not conform to length or format specifications. These PDE records represented \$213 million in payments by Medicare drug plans and enrollees. Our review also revealed that 10 of the nearly 530,000 invalid identifiers accounted for 17 percent or \$237 million of all drug claims with invalid prescriber identifiers in 2007.

**Recommendations:** CMS should conduct periodic reviews to ensure the validity of prescriber identifiers used on PDE records. In addition, CMS should require Part D plans to institute procedures to (1) identify invalid identifiers in the prescriber identifier field on Part D drug claims and (2) flag for review Part D drug claims that contain invalid identifiers in the prescriber identifier field.

**Management Response Summary:** CMS concurred with both of our recommendations. CMS stated that it agrees that invalid prescriber identifiers can hinder program oversight efforts for monitoring prescribing practices but that invalid prescriber identifiers are not an automatic indication of invalid prescriptions or pharmacy claims. OIG agrees with CMS that invalid prescriber identifiers do not automatically indicate invalid prescriptions or pharmacy claims.

In its update for 2011, CMS said that it will evaluate its authority to mandate use of the NPI as the standardized prescriber identifier for PDE records and expects to undertake rulemaking as necessary to address the use of that single prescriber identifier for PDE

records. To the extent that CMS implements a requirement for the use of a single prescriber identifier, it also expects to implement a process for verifying the accuracy of that number.

After the implementation of the NPI in 2008 as the standard identifier on electronic health care transactions, CMS completed an initial review of 2009 PDE data and learned that the NPI was reported on over 75 percent of PDEs. In September 2010, CMS awarded a contract to investigate the issues identified in its analysis and to periodically review and evaluate the use of prescriber identifiers on PDE records. CMS stated that it would implement a process to periodically review and evaluate trends associated with the validity of prescriber identifiers on PDE records. In the March 2011 hearing before the Senate Committee on Homeland Security and Governmental Affairs, CMS stated that it plans to require that all Part D claims include a valid NPI, which would be enforced by system checks on claims data that CMS receives from Medicare drug plans. CMS says it intends to begin systems checks in 2012 that validate the NPI format on claims data it receives from drug plans. In addition, starting in 2012, CMS intends to require that Part D plans validate that prescriptions for Schedule II drugs are within the prescriber's scope of practice by ensuring that the NPI included on pharmacy claims submissions links to or includes a valid DEA number. These safeguards are outlined in the draft 2012 Call Letter for Part D plan sponsors, which CMS released on February 18, 2011.

**Status:** CMS's efforts to determine the validity, medical necessity, or appropriateness of Part D prescriptions and drug claims may be limited without valid prescriber identifiers. We will continue to monitor CMS's implementation of our recommendations.

### **Related Report:**

2010 JUNE *Invalid Prescriber Identifiers on Medicare Part D Drug Claims.*  
OEI-03-09-00140 [Report](#)

## Medicare Administration

Medicare Administration > Information Systems > Controls and Corrective Actions

### Improve Medicare Systems Controls

**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 information technology (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.

**Findings:** Information systems controls were considered a significant deficiency in the FY 2010 financial statement audit because: (1) CMS did not ensure that all Medicare contractors performed periodic reviews of user access, and unauthorized wireless access to Medicare networks was observed; (2) shared system maintainers had not completed their implementation of CMS-required computer system security configuration settings, including their performance of user security administration reviews; (3) segregation of duties conflicts continued to exist at its central office between the business function and information security administration function of CMS's Office of Financial Management (OFM) for the Financial Accounting and Control System (FACS); (4) CMS has not provided guidance to the Medicare Administrative Contractors (MACs) on how to establish segregation of duties between business processes for the shared systems applications.

**Recommendations:** CMS should (1) strengthen its IT systems by ensuring that system and security settings have been implemented and monitored for compliance; (2) ensure that appropriate segregation of duties is established in all systems that support Medicare and financial processing to prevent excessive or

inappropriate access; (3) address the FACS deficiency by moving the FACS application security administration process and configuration management process from personnel within OFM to its Office of Information Systems; and ensure that all changes to Medicare and financial applications follow the National Institute of Standards and Technology (NIST) guidance regarding reviewing and approving all changes.

**Management Response Summary:** According to CMS's Financial Report for FY 2010, CMS has continued making progress to remediate specific information security weaknesses and continues to focus its efforts in FY 2011 on addressing the remaining significant deficiencies.

**Status:** OIG completed the Chief Financial Officers audit for FY 2010 and noted that improvement was made concerning the FY 2009 material weakness 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 our FY 2011 financial statement audit, we will review CMS's corrective action plan to ensure that it adequately addresses our findings and recommendations.

**Related Report:**

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 2010.*  
A-17-10-02010 [Report](#)

Medicare Administration > Information Systems >

## Financial Management: Improve CMS's Financial Reporting Systems and Processes

**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. To meet these needs, financial management systems must be in place to process and record financial events effectively and efficiently and to provide complete, timely, and reliable financial information. 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.

**Findings:** The FY 2010 financial statement audit noted a significant deficiency in financial reporting systems and processes because CMS: (1) did not critically assess its process for managing the cross-functional teams of financial management, information technology, actuarial, general counsel, operations, and other personnel to better monitor business activities, generate and share financial and other information, and identify situations where accounting evaluation or decision making may be required to arrive at and document an appropriate conclusion in a timely manner; (2) did not perform a claims-level detailed look-back analysis of the \$27 billion accrual for Medicaid Entitlement Benefits Due and Payable (EBDP) to determine the reasonableness of the various State calculations of unpaid claims; (3) needed to do more to ensure that its monitoring activities regarding Comprehensive Error Rate Testing (CERT) and Payment Error Rate Measurement (PERM) programs were well understood, susceptible to replication, and highly credible; (4) lacks a single integrated accounting system, which impairs CMS's ability to efficiently and effectively support and analyze financial reports even though CMS continued its efforts to implement the Healthcare Integrated General Ledger Accounting System (HIGLAS); (5) needs improvements in both the prevention and detection controls performed by and as oversight of the Medicare contractors; and (6) has not developed auditable estimates for the statement of social insurance (SOSI) that fairly present the financial condition of the Trust Funds, which may require revisiting provisions of Federal accounting standards and reformulating the assumptions used in SOSI and the Trustees Report to help improve the usefulness of the estimates provided.

**Recommendations:** CMS should: (1) establish specific policies and procedures and a protocol to address situations or transactions that require cross-functional involvement to ensure that interim and year-end financial statements are accurate and complete; (2) 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 to OFM on routine and recurring basis; (3) establish a process to perform a claims-level detailed look-back analysis of the Medicaid EBDP to determine the reasonableness of the methodology used to estimate the accrual; (4) continue to improve the integrity and efficiency of the various error rate development and analysis tools; (5) continue to implement an integrated financial management system to promote consistency and reliability in accounting and financial reporting; and (6) continue and broaden discussions with key stakeholders and standard setting bodies on the presentation of the SOSI.

**Management Response Summary:** CMS concurred with these recommendations made in the FY 2010 financial statement audit report. In FY 2010, the agency continued to improve its financial management performance in many areas and continues to focus its efforts in FY 2011 to address the remaining significant deficiencies.

**Status:** We acknowledge that CMS is developing corrective actions for the FY 2010 audit findings, and, as part of our FY 2011 financial statement audit, we will review CMS's corrective action plan to ensure that it adequately addresses our findings and recommendations.

**Related Report:**

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 2010.*  
A-17-10-02010 [Report](#)

**See Also:**

2010 NOV *Department of Health and Human Services Fiscal Year 2010 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 2010.* A-17-10-00001 (pp. II-7, II-11) [Report](#)

Medicare Administration > Contractors

## Improve the Performance Evaluation Process for Program Safeguard Contractors

**Background:** The Health Insurance Portability and Accountability Act of 1996 (HIPAA), § 202, authorized CMS to contract out program integrity functions for the Medicare program and required a competitive process for awarding contracts. CMS entered into the first contract under this authority in 1999. Entities awarded such contracts are called Program Safeguard Contractors (PSC). Once under contract, PSCs are awarded task orders to carry out specific duties.

**Findings:** We found that performance evaluation reports issued by CMS from 1999 to 2004 contained minimal information about PSC 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 PSCs may have been achieving, they provided limited information on which to base task order renewal decisions. We also found that 72 percent of final performance evaluation reports were issued on time. However, 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 PSCs whether the contracts would be renewed. The unavailability of milestone dates prevented us from identifying where delays occurred in the evaluation process.

**Recommendations:** CMS should (1) address PSC results in performance evaluation reports that include (a) quantitative as well as qualitative information and (b) information about required fraud and abuse detection and deterrence activities, (2) ensure that all draft and final reports are issued on time, and (3) establish a means to track and save evaluation milestone dates.

**Management Response Summary:** CMS partially concurred with our recommendations. The agency disagreed with our recommendations about the areas that should be addressed in PSC performance evaluation reports. In April 2009, CMS said that it has been collecting and tracking quantitative data about PSCs in its CMS Analysis, Reporting, and Tracking System (CMS ARTS) database. It did not indicate that the data have been included in performance evaluation reports, nor did it provide documentation showing that the data are now used in performance evaluation reports. Although the umbrella SOW was revised, it no longer contains a timetable for issuing draft and final reports. CMS also indicated that it complies with the time constraints associated with contract renewal dates so that only PSC contracts with acceptable performance are renewed. However, it has not explained how it ensures that

performance evaluation reports are issued by the time the task order renewal notices are due, and it has not provided documentation showing how or whether this has been accomplished.

CMS also reported in its March 2009 status update that it had developed a milestone date chart reflecting the significant evaluation dates. However, because of resource constraints, the chart is updated manually, and CMS has not been able to enhance CMS-ARTS to capture this information. The purpose of central tracking is to identify where delays occur so that improvements can be made in the agency's performance evaluation process. Thus, we continue to recommend that the milestones be tracked in a central system that can be accessed by management.

In its December 2009 update, CMS indicated that it had contracted to develop a template for monthly reporting, including fraud and abuse activities. CMS also began to transition PSCs and MEDICs to new Zone Program Integrity Contractors (ZPIC). Eventually, the new contractors will be responsible for ensuring the integrity of all Medicare-related claims under Parts A, B, C, and D and for coordinating Medicare and Medicaid (Medi-Medi) data matches. (Part A and Part B include, for example, hospital, skilled nursing, home health, durable medical equipment (DME), and other provider and supplier claims. Part C includes MA health plans, and Part D includes PDPs.) The first two ZPIC contracts were awarded to Health Integrity (Zone 4) and SafeGuard (Zone 7), and CMS is in the final stages of awarding more contracts.

**Status:** We will continue to monitor CMS's implementation of its safeguard strategy.

**Related Report:**

2006 MAR *Medicare's Program Safeguard Contractors: Performance Evaluation Reports.*  
OEI-03-04-00050 [Report](#)

Medicare Administration > Contractors

## Follow Up On Recovery Audit Contractors' Fraud Referrals (New)

**Background:** OIG conducted a review of fraud referrals by Recovery Audit Contractors (RAC) during the RAC 3-year demonstration project. Contracted by CMS, RACs are responsible for identifying improper payments of Medicare Part A and Part B claims. RACs conduct postpayment reviews to identify overpayments and underpayments and attempt to recoup any overpayments they identify. They receive contingency fees based on the amount of improper payments identified. 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. RACs do not receive contingency fees for cases they refer that are determined to be fraud. Thus, there may be a disincentive for RACs to refer cases of potential fraud.

**Findings:** We found that between March 2005 and March 2008, RACs referred two cases of potential fraud to CMS. However, CMS reported that it received no potential fraud referrals from RACs during this period. We also found that during the demonstration project, RACs received no formal training from CMS regarding the identification and referral of potential fraud.

**Recommendation:** CMS should implement a system to track fraud referrals.

**Management Response Summary:** CMS concurred with our recommendation and stated that it is developing a system to track the RAC claims review process. In its update for 2011, CMS reported that it and OIG had developed a Memorandum of Understanding (MOU) regarding fraud referrals as well as a referral template for the Medicare FFS Recovery Auditing program. CMS said that it has used the referral template and sent fraud referrals to OIG. CMS also said that it has developed an internal database to track all Medicare FFS Recovery Auditing fraud referrals made to OIG.

**Status:** Section 6411 of the Affordable Care Act expanded the RAC program, giving it additional responsibilities to address improper payments. In August 2010, CMS expanded RAC reviews to encompass medical necessity; during the RAC demonstration, medical necessity reviews yielded 40 percent of the improper payments that RACs identified. 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.

**Related Report:**

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

Medicare Administration > Contractors

## Determine the Collection Status of Medicare Overpayments Identified by Program Safeguard Contractors (New)

**Background:** OIG conducted a review regarding the overpayment amounts that have been collected as a result of PSC activities. The PSCs' identification and referral of overpayments to claims processors for collection is important because it can lead to the recovery of funds to the Medicare program. In our report, we determined the collection status as of June 2008 of overpayments referred by PSCs for collection in CY 2007. At the time of our review, PSCs were not required to keep track of the amount that claims processors collect on PSC overpayment referrals. CMS is transitioning PSCs to seven ZPICs and is providing ZPICs an incentive to keep track of the amount claims processors collect on ZPIC overpayment referrals.

**Findings:** Overpayments referred for collection by PSCs in 2007 did not result in significant recoveries to Medicare. PSCs referred 4,239 overpayments totaling \$835 million to claims processors in 2007, but only 7 percent (\$55 million of \$835 million) had been collected by claims processors as of June 2008. Of the \$55 million collected, 27 percent was for Part A claims, 56 percent was for Part B claims excluding durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), and 17 percent was for Part B DMEPOS claims.

As of June 2008, 53 percent (\$446 million) of the \$835 million in overpayment dollars that PSCs referred to claims processors for collection in 2007 was sent to the Department of the Treasury's cross-servicing program for collection. However, this program does not have a high rate of return. Claims processors reported that collection was not complete for \$40 million, or 5 percent of the \$835 million in overpayments that PSCs referred for collection. Another 5 percent of the PSC overpayment dollars will not likely be collected by claims processors because the provider stopped billing, filed for bankruptcy, went out of business, or was deceased. For 17 percent of the PSC overpayment dollars, collection was on hold pending investigation or appeal.

As of June 2008, 6 percent of the PSC overpayment dollars was no longer owed by providers because of revisions that claims processors made to overpayment collection 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.

**Recommendations:** CMS should (1) regularly collect all necessary information to determine the overpayments that PSCs and ZPICs refer to claims processors for collection, the collection status of these overpayments, and the percentage of overpayments in each category of collection status; (2) require PSCs, ZPICs, 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 (3) 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.

**Management Response Summary:** CMS concurred with all three recommendations. At the time of our review, PSCs were not required to keep track of the amount claims processors collect on PSC overpayment referrals. CMS is transitioning PSCs to seven ZPICs and is providing ZPICs with an incentive to keep track of the amount claims processors collect on ZPIC overpayment referrals. CMS is also now providing incentives to claims processors to provide collection information to ZPICs. According to CMS staff, CMS also expects ZPICs in high-fraud regions to focus on quick response to fraud and administrative actions. In October 2009, CMS added the data field of amount of overpayments recovered to the CMS ARTS template for monthly reporting, which is a required submission for the PSCs and ZPICs. Pursuant to the Affordable Care Act, CMS recently added the number of overpayments recovered to CMS ARTS. A Joint Signature Memorandum was issued on May 19, 2010, instructing Medicare contractors to recover the overpayments for which claims processors could not provide collection information.

**Status:** We will continue to monitor CMS's implementation of our recommendations, including requiring ZPICs to keep track of the amount claims processors collect on ZPIC overpayment referrals..

**Related Report:**

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

edicare Administration > Contractors

## Determine Medicare Overpayments Identified by Program Safeguard Contractors (New)

**Background:** OIG conducted a review to determine the number, dollar amount, and claim type of Medicare overpayments that PSCs identified and referred to claims processors for collection in 2007.

**Findings:** In total, the 18 PSCs referred 4,239 overpayments totaling \$835 million to claims processors for collection in 2007. However, two PSCs were responsible for 62 percent of this amount. PSCs differed substantially in the dollar amount of overpayments that they referred for collection in 2007, referring from \$3 million to \$266 million with a median of \$15 million.

We also found that although Part B payments represented 29 percent of PSCs' oversight responsibility (\$87 billion of \$296 billion), Part B overpayments accounted for 89 percent of PSCs' overpayment dollars referred for collection (\$747 million of \$835 million). Part A payments represented 71 percent of PSCs' oversight responsibility (\$209 billion of \$296 billion), and Part A overpayments accounted for 11 percent of PSCs' overpayment dollars referred for collection (\$88 million of \$835 million).

CMS is transitioning PSCs to seven ZPICs. Each ZPIC will be responsible for all claim types in its geographic zone.

**Recommendations:** OIG recommended that CMS (1) determine why certain PSCs have low levels of overpayment dollars referred for collection compared to their oversight responsibility and (2) determine why certain PSCs have low Part A overpayment dollars referred for collection compared to their Part B overpayment dollars referred for collection.

**Management Response Summary:** CMS concurred with both recommendations and stated that the change to the new ZPIC contracting strategy should address OIG's concerns. As of February 2011, CMS has not awarded all ZPIC contracts.

**Status:** OIG will continue to monitor CMS's implementation of our recommendations including whether the ZPIC contracting strategy will address our recommendations.

**Related Report:**

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

Medicare Administration > Language Access Services

## Increase Medicare Providers' and Plans' Implementation of Standards for Culturally and Linguistically Appropriate Services (New)

**Background:** Language access services are designed to promote effective communication between Limited English Proficient (LEP) persons and non-LEP persons. 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 the Office of Minority Health's (OMH) Culturally and Linguistically Appropriate Services in Health Care (CLAS) standards address the provision of language access services. OCR guidance recommends a four-factor assessment to help health care providers determine what language access services to offer. OMH's CLAS standards can help providers become responsive to the cultural and linguistic needs of diverse populations. Four of the fourteen CLAS standards focus on the provision of language access services. These standards are (1) providing services during all business hours, (2) providing verbal offers and written notices of rights to services, (3) assuring the competence of language assistance provided by staff, and (4) providing written materials and signage translated into appropriate languages.

We conducted two companion studies, one on Medicare providers and another on Medicare plans, to examine the extent to which they conducted the four-factor assessment recommended by OCR; offered language access services consistent with OMH CLAS standards; and reported benefits and encountered obstacles in providing such services.

**Findings:** In our review of Medicare providers, we found that 69 percent of providers conducted the four-factor assessment recommended by OCR guidance when determining what language access services to offer. However, only 33 percent of providers offered services consistent with all four of OMH's CLAS standards on language access services. Seventy-three percent of providers reported benefits to offering language access services and 54 percent reported obstacles (e.g., a lack of training resources for staff, costs of providing language access services, and the broad range of languages spoken in the providers' communities). Few providers reported data on the costs of providing language access services, and the data provided were not comparable.

In our review of Medicare plans, we found that 88 percent of plans conducted the four-factor assessment recommended by OCR guidance when determining what language access services to offer. However, a lower percentage (67 percent) of plans offered services consistent with all four of OMH's CLAS standards on language access services,

largely because Medicare plans did not verbally inform LEP persons of their right to language access services. Forty-nine percent of Medicare plans reported benefits to offering language access services and 57 percent reported obstacles. We could not compare data on the costs of providing language access services because plans use different methods to calculate costs.

**Recommendations:**

Medicare providers. To improve Medicare providers' awareness and implementation of CLAS standards and to help providers offer language access services, (1) OCR should inform providers about OMH's CLAS standards, (2) OMH should increase outreach to providers to familiarize them with CLAS standards, and (3) OMH should offer model translated written materials and signs to providers.

Medicare plans. To improve Medicare plans' awareness and implementation of CLAS standards, OMH should collaborate with CMS to inform Medicare plans that they should notify LEP persons both verbally and in writing of their right to receive language access services. CMS has an established infrastructure for communicating with Medicare plans.

**Savings: TBD\***

\* *Savings not estimated.*

**Management Response Summary:** For the report on Medicare providers, OCR and OMH concurred with our recommendations, and CMS indicated that it did not have any substantive comments. In its comments on the draft report, OMH stated 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 also planned to partner with medical provider networks (e.g., Quality Improvement Organizations (QIO)) to link their Web sites to OMH's CLAS standards Web site. As of January 2011, OMH is continuing to work on these activities. In response to the second recommendation, OMH is developing products, including signage, that CMS will disseminate to Medicare providers through the existing Medicare Learning Network (MLN).

For the report on Medicare plans, OMH and CMS both concurred with our recommendation. 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 how they apply to Part C and Part D organizations. However, the

memorandum did not address OIG's specific recommendation that CMS instruct Medicare plans to provide both verbal and written notices to beneficiaries of their right to receive language access services.

**Status:** We will continue to monitor OCR, OMH, and CMS implementation of our recommendations.

**Related Reports:**

2010 JULY *Guidance and Standards on Language Access Services: Medicare Providers.*  
OEI-05-10-00050 [Report](#)

2010 JULY *Guidance and Standards on Language Access Services: Medicare Plans.*  
OEI-05-10-00051 [Report](#)

Medicare Administration > Program Integrity

## Improve CMS Reporting to the Healthcare Integrity and Protection Data Bank (New)

**Background:** The Healthcare Integrity and Protection Data Bank (HIPDB) is a national data bank containing reports of adverse actions against health care practitioners, providers, and suppliers. The HIPDB plays an important role in preventing the employment of potentially fraudulent or abusive health care providers. Federal and State government agencies and health plans are required to report to the HIPDB. CMS takes several types of adverse actions 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.

**Findings:** We found that CMS took adverse actions against providers, but did not report all of these actions to the HIPDB as required. It failed to report 148 adverse actions imposed against laboratories in 2007 and 30 adverse actions imposed against managed care and prescription drug plans between January 1, 2006, and July 31, 2009. None of the adverse actions against DME suppliers taken after 2008 had been reported to HIPDB at the time of our review. However, as of April 30, 2009, the HIPDB contained 5,125 adverse actions against DME suppliers imposed from 1998 through 2008. None of the 45 nursing homes terminated from participating in the Medicare program from 2004 through 2008 were reported to the HIPDB until 2009, well after the required reporting timeframe. The Division of National Systems, the group within CMS responsible for reporting adverse actions against certified provider types, did not report any actions between 2001 and 2008.

**Recommendation:** CMS should report all adverse actions 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.

**Management Response Summary:** CMS concurred with our recommendation. It described planned efforts to report adverse actions imposed against nursing facilities, laboratories, and DME suppliers, including working with the Health Resources and Services Administration (HRSA), which maintains the HIPDB, 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 DME suppliers had been updated through August 2010.

**Status:** In its update for 2011, CMS did not provide information on its efforts to report adverse actions against provider types other than DME suppliers (e.g., Medicare providers, nursing facilities, laboratories, managed care plans, and prescription drug plans). We will continue to monitor CMS's implementation of our recommendation.

In addition to maintaining the HIPDB, HRSA maintains a similar database of adverse actions against practitioners, the National Practitioner Data Bank (NPDB). Section 6403 of the Affordable Care Act 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 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.

**Related Report:**

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

# Part III: Medicaid Program

## Part III: Medicaid Program

### Federal and State Partnership

Medicaid > Federal/State Partnership > Enhanced Payments

#### **Limit Enhanced Payments to Cost and Require That Medicaid Payments Returned by Public Providers Be Used To Offset the Federal Share**

**Background:** Title XIX of the Social Security Act authorizes Federal grants to States for Medicaid programs that provide medical assistance to certain low-income and disabled people. The Federal Government and States share in the administration and cost of the program. The Federal Government pays its share of medical assistance expenditures to the States according to a defined formula, which yields the Federal medical assistance percentage (FMAP). The FMAP can range from 50 percent to 83 percent, depending on each State's relative per capita income.

Medicaid is subject to upper payment limits (UPL). The UPL is an estimate of the maximum amount that would be paid to a category of Medicaid providers (usually hospitals and nursing homes) under payment principles established for the Medicare program. Generally, State payments that exceed UPLs do not qualify for Federal matching funds.

The differences between the States' allowable Medicaid payments and the UPLs are called enhanced payments. Under Medicaid UPL rules, States are permitted to provide enhanced payments to non-State-owned government providers, such as county or local public-owned nursing facilities and hospitals, and the enhanced payments qualify for Federal matching payments.

**Findings:** Audits issued in 2001 explored States' use of enhanced payments to local public-owned facilities. We found that the enhanced payments were not based on the actual cost of providing services to Medicaid beneficiaries; were not directly related to increasing the quality of care provided by the public facilities that received the enhanced payments; and were not always retained by the facilities to provide services to Medicaid beneficiaries

We found that some or all of the enhanced payments were returned by the providers to the States through intergovernmental transfers (exchanges of funds among or between different levels of government) to be put to other uses. The States were then able to use the funds for any purpose, including drawing down new Federal matching funds for Medicaid and other Federal programs. Some of the funds that were transferred back to the States were earmarked for use in health-care-related service areas but not necessarily for Medicaid-covered services approved in the State plans.

In effect, for the portions of the enhanced payments that were returned to the States, the States did not incur the health care expenditures for which Federal matching funds were claimed. As a result, the Federal Government and Federal taxpayers paid disproportionately more than their statutory share of Medicaid in those States without corresponding benefits to the intended beneficiaries.

We noted that accountability was generally lost at the point that funds were transferred to the States' general revenue accounts, thereby placing the funds at risk of being used for reasons other than their intended purpose.

Subsequently, we issued reports in 2004 and 2005 of audits of nursing facilities that were identified by State survey and certification reviewers as having serious deficiencies in patient care. The facilities had all been required to return substantial portions of their enhanced payments to the States to be used for other purposes. As a result, the facilities were underfunded. We recommended that the States allow the facilities to retain sufficient funding to cover the costs of providing an adequate level of care to their residents.

**Recommendations:** The Centers for Medicare & Medicaid Services (CMS) should (1) provide States with definitive guidance for calculating the UPL, which should include using facility-specific UPLs that are based on actual cost report data, and (2) require that the return of Medicaid payments by a county or local government to the State be declared a refund of those payments and thus be used to offset the Federal share generated by the original payment.

**Savings: \$3.87 billion over 5 years\***

*\*In its January 2007 Notice of Proposed Rulemaking, CMS estimated that if payments to providers operated by units of government were limited to cost and payments returned by providers were considered refunds, Federal Medicaid outlays would be reduced by \$120 million in the first year and by \$1.2 billion in the fifth year. CMS estimated that the final rule would result in a reduction of Federal Medicaid outlays of \$3.87 billion over 5 years.*

**Management Response Summary:** In its comments on our September 2001 report, CMS partially concurred with our recommendations, stating that it would consider further reforms if it finds that States, under UPL rules, are continuing to use public health care facilities as transfer agents to leverage Federal Medicaid funding.

On January 18, 2007, CMS published a proposed rule at [72 Fed. Reg. 2236](#) that effectively addressed our concerns. The rule was 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 ....”

However, 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 25, 2007. 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.

On May 23, 2008, the U.S. District Court for the District of Columbia found that the Department of Health & Human Services (HHS) had violated the Congressional moratorium on finalization of the regulation in Public Law 110-28, vacated the rule, and remanded the matter to HHS. Accordingly, at [75 Fed. Reg. 73972](#) (November 30, 2010), CMS formally withdrew the final rule and restored the previous regulation text so that the regulatory language impacted by the May 29, 2007, final rule would appear in the CFR as it did prior to issuance of the final rule.

The American Recovery and Reinvestment Act of 2009 (Recovery Act) provided that it was the sense of Congress that the Secretary of HHS should not promulgate the regulation.

In CMS’s update of recommendations of this edition of the Compendium it had no new comments to offer on this matter.

**Status:** As an issue of accountability, we continue to monitor CMS’s progress in limiting enhanced payments to public providers to cost and requiring that Medicaid payments returned by public providers be used to offset the Federal share. As we stated in June 2005 testimony before the Senate Committee on Finance (citation below), current policies and practices limit the ability of Congress, HHS, and State and local governments to manage, account for, and assess the benefits of Medicaid dollars.

**Related Reports:**

- 2001 SEP *Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers.* A-03-00-00216 [Report](#)
- 2001 JUN *Medicaid Enhanced Payments to Hospitals and the Use of Intergovernmental Transfers in North Carolina.* A-04-00-00140 [Report](#)
- 2001 MAY *Medicaid Enhanced Payments to Public Hospital Providers and the Use of Intergovernmental Transfers by the Alabama State Medicaid Agency.* A-04-00-02169 [Report](#)
- 2001 MAR *Illinois' Use of Intergovernmental Transfers to Finance Enhanced Medicaid Payments to Cook County for Hospital Services.* A-05-00-00056 [Report](#)
- 2001 MAR *Medicaid Supplemental Payments to Public Hospital District Nursing Facilities and the Use of Intergovernmental Transfers by Washington State.* A-10-00-00011 [Report](#)
- 2001 FEB *The Commonwealth of Pennsylvania's Use of Intergovernmental Transfers to Finance Medicaid Supplementation Payments to County Nursing Facilities.* A-03-00-00203 [Report](#)
- 2001 FEB *Medicaid Enhanced Payments to Public Providers and the Use of Intergovernmental Transfers by the State of Nebraska.* A-07-00-02076 [Report](#)
- 2001 MAR *Medicaid Enhanced Payments to Public Providers and the Use of Intergovernmental Transfers by the Alabama State Medicaid Agency.* A-04-00-02165 [Report](#)

**See Also:**

- 2005 JUN *Office of Inspector General (OIG) 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 [Report](#)
- 2005 MAR *Adequacy of Washington State's Payments to Newport Community Hospital, Long Term Care Unit.* A-10-04-00001 [Report](#)
- 2005 MAR *Adequacy of Tennessee's Medicaid Payments to Nashville Metropolitan Bordeaux Hospital, Long-Term Care Unit.* A-04-03-03023 [Report](#)

2004 JUN     *Adequacy of Medicaid Payments to Albany County Nursing Home.*  
A-02-02-01020 [Report](#)

## Improper Payments

Medicaid > Improper Payments > School-Based Services > State Claims for Federal Share Unallowable

### Ensure Compliance With Requirements for Medicaid School-Based Health Services

**Background:** The Social Security Act, § 1903(c), provides that Medicaid payment for school-based health services is allowable for covered Medicaid services that are included in an individualized education plan or individualized family service plan established pursuant to the Individuals With Disabilities Education Act (IDEA). In August 1997, CMS issued a guide entitled *Medicaid and School Health: A Technical Assistance Guide*. According to the guide, school-based health services included in a child's plan may be covered if all relevant statutory and regulatory requirements are met.

**Findings:** Our reviews through fiscal year (FY) 2010 found that States' claims for the Federal share of Medicaid included school-based services that did not always fully comply with Federal and State standards. We identified Medicaid overpayments for school-based health services with the Federal share of the overpayments totaling an estimated \$1.4 billion. Many of the services claimed lacked a referral by an appropriate medical professional or were not provided by or under the direction of a qualified provider. These unallowable claims generally occurred because States did not provide sufficient guidance to and oversight of local education agencies, and rates were not developed in accordance with applicable Federal cost allocation requirements or CMS program guidelines.

**Recommendations:** States should (1) disseminate CMS guidance and other information to the local education agencies in a timely manner, (2) monitor local education agencies to ensure compliance with Federal and State requirements, and (3) 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:** TBD\*

\* Our reviews have identified Medicaid overpayments for school-based health services with the Federal share of the overpayments totaling an estimated \$1.4 billion.

**Management Response Summary:** CMS concurred with our recommendations to address overpayments and has taken recovery action, or claims have been settled by the Department of Justice (DOJ). We note through our continuing work in this area that

CMS has also undertaken a significant effort 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 May 2010, CMS issued school-based services financial management review guide #28 for use by its staff, titled *Claims for IDEA-Related School Based Services*.

**Status:** We will continue to monitor CMS's efforts to ensure that States comply with our recommendations. Although CMS developed a review guide for its staff to use in reviewing school-based claims in May 2010, it has not yet taken steps to provide guidance for dissemination by States to local education agencies in an effort to reduce unallowable claims. Office of Inspector General (OIG) reviews that continue to identify unallowable claims point to the need for such guidance.

### Related Reports:

- 2010 SEPT *Review of New Jersey's Medicaid School-Based Health Claims Submitted by Public Consulting Group, Inc.* A-02-07-01052 [Report](#)
- 2010 APR *Review of New Jersey's Medicaid School-Based Health Claims Submitted by Maximus, Inc.* A-02-07-01051 [Report](#)
- 2010 MAR *Review of Arizona's Medicaid Claims for School-Based Health Services* A-09-07-00051 [Report](#)
- 2009 APR *Review of Timeliness of West Virginia's Retroactive Claims for Medicaid School-Based Services.* A-03-06-00201 [Report](#)
- 2008 FEB *Review of New Jersey's Medicaid School-Based Rates.* A-02-04-01017 [Report](#)
- 2007 OCT *Medicaid School-Based Services in Utah – Review of Payment Rates.* A-07-06-04069 [Report](#)
- 2007 MAY *Review of Medicaid Reimbursement Rate for School-Based Health Services in Maryland.* A-03-05-00206 [Report](#)
- 2006 DEC *Review of Nevada's Medicaid School-Based Administrative Expenditures for Calendar Years 2003 and 2004.* A-09-05-00054 [Report](#)
- 2006 SEPT *Review of Medicaid School-Based Administrative Costs in Minnesota From July 1, 2003 June 30, 2004.* A-05-05-00040 [Report](#)
- 2006 JUN *Review of Medicaid School-Based Services in Kansas-Bundled Rate Development.* A-07-05-01018 [Report](#)

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2006 MAY	<i>Medicaid School-Based Services in Kansas-Adjustment of the Bundled Rates.</i> A-07-06-01030 <a href="#">Report</a>
2006 MAY	<i>Review of Medicaid Claims for School-Based Health Services in New Jersey.</i> A-02-03-01003 <a href="#">Report</a>
2006 FEB	<i>Review of School-Based Health Services in Kansas.</i> A-07-03-00155 <a href="#">Report</a>
2006 JAN	<i>Audit of LaPorte Consortium's Administrative Costs Claimed for Medicaid School-Based Services.</i> A-06-02-00051 <a href="#">Report</a>
2005 DEC	<i>Audit of Medicaid School-Based Services in Texas.</i> A-06-02-00047 <a href="#">Report</a>
2005 SEPT	<i>Review of Medical Transportation Claims Made by the New York City Department of Education.</i> A-02-03-01023 <a href="#">Report</a>
2005 AUG	<i>Review of Illinois Medicaid School-Based Administrative Costs for State Fiscal Year 2001.</i> A-05-02-00050 <a href="#">Report</a>
2005 JUN	<i>Review of Medicaid Speech Claims Made by the New York City Department of Education.</i> A-02-02-01029 <a href="#">Report</a>
2005 APR	<i>Medicaid School-Based Administrative Activities in Kansas.</i> A-07-03-00154 <a href="#">Report</a>
2005 JAN	<i>Review of Vermont Medicaid School-Based Services for the Period October 2001 Through September 2002.</i> A-01-03-00004 <a href="#">Report</a>
2005 JAN	<i>Review of Maine's Medicaid Retroactive Claims for School-Based Health Services, January 2001 Through June 2003.</i> A-01-04-00004 <a href="#">Report</a>
2004 SEP	<i>Medicaid School-Based Health Services Administrative Costs - Massachusetts July 1999 Through June 2001.</i> A-01-02-00016 <a href="#">Report</a>
2004 AUG	<i>Review of Medicaid Transportation Claims Made by School Health Providers in New York State.</i> A-02-03-01008 <a href="#">Report</a>
2004 MAY	<i>Audit of Medicaid Fee-for-Service Payments to Local Education Agencies in North Carolina for the Period July 1, 1999 Through June 30, 2000.</i> A-04-01-00005 <a href="#">Report</a>
2004 FEB	<i>Review of Medicaid Speech Claims Made by School Health Providers in New York State.</i> A-02-02-01030 <a href="#">Report</a>

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2004 FEB	<i>Audit of the Iowa Department of Human Services' Claim for Medicaid School-Based Administrative Costs.</i> A-07-02-02099 <a href="#">Report</a>
2004 FEB	<i>Medicaid Payments for School-Based Health Services, Rhode Island, for the Period July 1999 Through June 2001.</i> A-01-02-00014 <a href="#">Report</a>
2004 JAN	<i>Audit of Houston Administrative Costs Claimed for Medicaid School-Based Health Services.</i> A-06-02-00037 <a href="#">Report</a>
2003 DEC	<i>Review of Illinois Medicaid School-Based Services for the Period July 1, 2000 Through June 30, 2001.</i> A-05-02-00049 <a href="#">Report</a>
2003 JUL	<i>Review of Washington State's Medical Assistance Costs Claimed for School-Based Health Services Provided in State Fiscal Year 2000.</i> A-10-02-00008 <a href="#">Report</a>
2003 JUL	<i>Medicaid Payments for School-Based Health Services - Massachusetts Division of Medical Assistance - July 1999 Through June 2000.</i> A-01-02-00009 <a href="#">Report</a>
2003 MAY	<i>Review of Rate Setting Methodology Medicaid School-Based Child Health Program Costs Claimed by the Connecticut Department of Social Services July 1997 Through June 2001.</i> A-01-02-00006 <a href="#">Report</a>
2003 APR	<i>Review of Payments for Transportation Services Made to Special Service School Districts Under New Jersey's Medicaid Program.</i> A-02-02-01022 <a href="#">Report</a>
2003 APR	<i>Audit of Medicaid School-Based Services in Oklahoma.</i> A-06-01-00083 <a href="#">Report</a>
2003 MAR	<i>Review of Medicaid School-Based Services Claimed During State Fiscal Year 2000 by Maryland's Medicaid Program.</i> A-03-01-00224 <a href="#">Report</a>
2003 MAR	<i>Review of Wisconsin Medicaid School-Based Services Program for the Year Ending June 30, 2000.</i> A-05-02-00023 <a href="#">Report</a>
2002 DEC	<i>Followup Review of a Finding Contained in a New York State Office of the State Comptroller Audit Report on Duplicate School Health Claims to Medicaid Made by the New York City Board of Education.</i> A-02-02-01018 <a href="#">Report</a>
2002 OCT	<i>Audit of Oklahoma Medicaid School-Based Services Provided Free to Other Students and Not Exempt Under the Individuals with Disabilities Education Act.</i> A-06-01-00077 <a href="#">Report</a>

- 2002 AUG *Review of Oregon's Medicaid Payments for School-Based Health Services Direct Care in State Fiscal Year 2000.* A-10-01-00006 [Report](#)
- 2002 JUN *Review of Medicaid School Based Child Health Service Costs Claimed by Connecticut Department of Social Services October 1999 - September 2000.* A-01-01-00006 [Report](#)
- 2002 MAY *Review of Washington State's Administrative Costs Claimed for Medicaid School-Based Health Services in State Fiscal Year 2000.* A-10-01-00011 [Report](#)
- 2001 NOV *Medicaid Monthly Payments for School-Based, Health-Related Services in North Carolina.* A-04-00-02161 [Report](#)

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Medicaid > Improper Payments > Home Care > Medicaid as Payer of Last Resort

## Prevent Duplicate Medicaid and Medicare Home Health Payments

**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. 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. We examined Medicaid and Medicare claims during 2005 in five selected States to determine the extent to which improper home-health-related payments for dual-eligible beneficiaries occurred.

**Findings:** In four of the five States, we found that Medicaid 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.

We also found that 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.

We also found that each of the five States 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.

**Recommendation:** CMS should ensure that Medicaid does not pay providers for Medicare-paid nonroutine medical supplies and therapeutic services.

**Savings: \$1 million\***

*\*The estimate of \$1 million that Medicaid inappropriately paid for nonroutine medical supplies and therapeutic services in four of the five States reviewed in 2005 was not projected to all States.*

**Management Response Summary:** CMS said that it “did not disagree” with our recommendation to ensure that Medicaid does not pay providers for Medicare-paid nonroutine medical supplies and therapeutic services and indicated that it recognized the importance of preventing duplicate Medicaid and Medicare billings. CMS's 2011 update of its response to this recommendation indicated that since the report was issued, many States have been able to obtain Medicare crossover claims data. Furthermore, CMS indicated that it is coordinating with State program integrity directors to identify additional data elements that can be used to correctly adjudicate Medicare and Medicaid crossover claims for home health services.

**Status:** We will continue to monitor CMS's actions to address duplicate claims for nonroutine medical supplies and therapeutic services.

**Related Report:**

2008 MAY *Duplicate Medicaid and Medicare Home Health Payments: Medical Supplies and Therapeutic Services.*  
OEI-07-06-00640 [Report](#)

**See Also:**

2009 FEB *Memorandum Report: Medicaid and Medicare Home Health Payments for Skilled Nursing and Home Health Aide Services.*  
OEI-07-06-00641 [Report](#)

Medicaid > Improper Payments > Personal Care Services

## Enforce Federal Medicaid Payment Policies for Personal Care Services

**Background:** Personal care services (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. 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 (Social Security Act § 1905(a)(24); 42 CFR § 440.167: 42; CFR § 441.301(b)(1)(ii); and 42 CFR § 440.70(c)).

We reviewed Medicaid PCS and institutional claims and Medicare institutional claims for services provided from October 1 through December 31, 2005, in five States: Minnesota, New Mexico, North Carolina, Texas, and Washington. We compared the dates of service for paid PCS claims with the dates of service for paid Medicaid and Medicare institutional stays to identify Medicaid payments for PCS provided during institutional stays.

**Findings:** OIG found that in the first quarter of FY 2006, the five States reviewed paid nearly \$500,000 in error for PCS provided during periods of institutionalization.

Three of the five States had billing practices allowing PCS providers to bill for services on dates for which no PCS were provided, which could mean that nearly \$11 million in that quarter may have been paid in error.

Although all five States reported having Medicaid controls to prevent payments for PCS provided during institutional stays, the controls did not fully prevent erroneous payments.

**Recommendations:** CMS should (1) enforce Federal Medicaid payment policies that prohibit Medicaid reimbursement for PCS provided over a range of dates if the range includes dates on which the beneficiary was institutionalized and (2) work with States to reduce erroneous Medicaid payments for PCS provided during institutional stays.

**Management Response Summary:** CMS concurred with our second recommendation to reduce Medicaid payments for PCS provided during institutional stays. However, CMS did not concur with our recommendation to prohibit Federal Medicaid reimbursement for PCS claims billed with date ranges that include days on which no PCS were provided. CMS said that Federal reimbursement policies are

sufficient to prohibit such payments when States have effective controls in place. We revised the recommendation in the final report to say that CMS should enforce its policies. CMS's 2011 update of its response to our recommendations 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 developed data-mining algorithms for Medicaid claims data to detect PCS provided during institutional stays in several States.

**Status:** We continue to encourage CMS to enforce policies to reduce erroneous Medicaid payments for PCS during institutional stays. As a related matter, OIG is conducting additional reviews to determine whether States' claims for the Federal share of PCS are appropriate, i.e., whether the services met Federal and State requirements.

**Related Report:**

2008 AUG *Payments Made in Error for Personal Care Services During Institutional Stays.*  
OEI-07-06-00620 [Report](#)

**See Also:**

2008 OCT *More Than 24 Hours in a Day Billed for Personal Care Services in Four States.*  
OEI-07-06-00621 [Report](#)

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# Prescription Drugs

Medicaid > Pharmacy Reimbursement > Brand-Name Drugs

## Ensure That Medicaid Reimbursement for Brand-Name Drugs Accurately Reflects Pharmacy Acquisition Costs

**Background:** States generally reimburse pharmacies for brand-name drugs at the estimated acquisition costs (EAC) of the drugs plus a dispensing fee. State Medicaid agencies are responsible for determining the EAC. Historically, most States have based their EACs solely or in part on the average wholesale price (AWP) minus a percentage discount, which varies by State. The AWP is a list price compiled from manufacturers and other data sources by commercial organizations, e.g., First DataBank, for use by the pharmaceutical community. The AWP is not defined in law or regulation.

The majority of States have used the pricing compendium published by First DataBank as their source to obtain AWP data. In connection with a legal settlement, First DataBank announced that it will discontinue publishing the AWP no later than September 26, 2011. Although First DataBank will cease publication of the AWP, States may choose to obtain AWP in pricing compendia published by other companies, such as Micromedex's Red Book. We are conducting a review to assess States' plans for selecting new pricing benchmarks, evaluate the advantages and disadvantages of replacing AWP with alternative approaches, and determine what guidance CMS has provided or anticipates providing to States related to these issues.

OIG produced significant work spanning two decades showing that the AWP States used to estimate acquisition costs overstated the prices retail pharmacies paid to purchase drugs, resulting in inflated reimbursement rates and leading to excessive Medicaid expenditures for prescription drugs. OIG reports concluded that reliance on AWP as a basis for drug reimbursement was fundamentally flawed and that AWP exceeded other available pricing points.

**Findings:** In August 2001, OIG reported a significant difference between pharmacy acquisition costs for brand-name drugs and the AWP for those drugs. We estimated that based on invoice prices, pharmacies' calendar year (CY) 1999 actual acquisition costs averaged 21.84 percent below AWP nationally. We calculated that Medicaid could have saved as much as \$1.08 billion for the 200 brand-name drugs with the greatest amount of Medicaid reimbursements for CY 1999. The savings amount was determined by multiplying the nationwide utilization for each drug by 11.53 percent of AWP, which represented the difference between the average pharmacy acquisition costs (AWP minus a 21.84 percent) and previous findings of average reimbursements (AWP minus 10.31 percent) for the drugs. Using a reduction in AWP of 21.84 percent rather than

10.31 percent for reimbursements would have resulted in savings of as much as \$1.08 billion in CY 1999.

An additional analysis in 2002 included both brand-name and generic drug data. We found that Medicaid could achieve more accurate alignments between reimbursements and pharmacy acquisition costs by separately evaluating reimbursement levels for four tiers of drugs: single-source brand-name drugs (innovators), innovator multiple-source drugs without Federal upper limits (FUL), non-innovator multiple-source drugs without FULs, and multiple-source drugs with FULs.

A single-source innovator drug is under patent protection and is produced by only one manufacturer. Upon expiration of the patent's exclusivity, generic versions of an innovator drug can be produced by other manufacturers, resulting in the original drug being categorized as an innovator multiple-source drug. FULs are maximum amounts that federally funded programs may pay for certain multiple-source drugs. Although our analysis compared pharmacy acquisition cost data with AWP, the four tier approach could be used in better aligning reimbursement rates using other benchmark prices as well.

**Recommendation:** CMS should encourage States to align pharmacy reimbursement more closely with the actual acquisition cost of brand-name drugs paid by pharmacies in their States, e.g., by implementing a four-tier approach to reimbursement consistent with our September 2002 additional analysis report).

**Savings: \$1.08 billion\***

*\*Estimated savings are based on a 21.84-percent average discount below AWP for the 200 brand-name drugs with the highest Medicaid reimbursement for CY 1999. Potential savings would depend on current pharmacy acquisition costs and the pricing benchmarks that States use for reimbursements.*

**Management Response Summary:** In its comments on our 2001 draft report, CMS concurred with our recommendation, stating that it was working with States to review their estimates of acquisition costs in light of our findings. The President's FY 2006 budget proposed requiring States to reimburse the Average Sales Price (ASP) of a drug to pharmacies for Medicaid drugs, plus a 6-percent fee for storage, dispensing, and counseling. ASP is the weighted average of all non-Federal sales from manufacturers, and is therefore a sound proxy for pharmacy acquisition cost. This reimbursement scenario would align pharmacy reimbursement with pharmacy acquisition cost and would create a more sustainable system. Reimbursing ASP plus 6 percent is consistent with Medicare reimbursement for Part B-covered drugs as established by the Medicare

Modernization Act. The HHS *Budget in Brief* estimated the proposal to save \$542 million in FY 2006 and \$5.4 billion over five years. The proposed legislative change was not enacted and was not included in subsequent Presidents' budgets.

We note that although little progress has been made at the Federal level to better align Medicaid drug reimbursements with actual acquisition costs, First DataBank's decision to no longer publish AWP data offers an opportunity for States to implement alternatives.

**Status:** We continue to monitor CMS's efforts to encourage States to improve Medicaid reimbursements for brand-name drugs. We plan to conduct an audit in FY 2011 that will compare pharmacies' actual acquisition costs with other benchmark prices such as wholesale acquisition costs and average manufacturer prices (AMP). We are also conducting a review to assess States' plans for selecting new pricing benchmarks, evaluate the advantages and disadvantages of replacing AWP with alternative approaches, and determine what guidance CMS has provided or anticipates providing to States related to these issues.

### Related Reports:

- 2002 SEP *Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products.* A-06-02-00041 [Report](#)
- 2001 AUG *Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products.* A-06-00-00023 [Report](#)

### See Also:

- 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 MAR *Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products.* A-06-01-00053 [Report](#)
- 2001 SEP *Medicaid's Use of Revised Average Wholesale Prices.* OEI-03-01-00010 [Report](#)

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Medicaid > Prescription Drugs > Pharmacy Reimbursement for Generic Drugs

## Encourage States To Align Medicaid Generic Drug Pharmacy Reimbursements With Pharmacies' Acquisition Costs

**Background:** CMS sets FUL amounts (maximum amounts that federally funded programs may pay) for certain generic drugs or brand-name drugs with generic equivalents. Federal regulations cap aggregate Medicaid reimbursement for drugs with FULs at the FUL amounts plus a reasonable dispensing fee. Historically, FUL amounts have been set at 150 percent of the lowest published price (typically AWP or wholesaler acquisition cost) for the least costly, therapeutically equivalent products. The Affordable Care Act requires CMS to set FUL amounts at 175 percent of the volume-weighted AMP beginning October 1, 2010.

For drugs without FULs, Medicaid reimbursement is typically set at the lower of the estimated pharmacy acquisition cost plus a reasonable dispensing fee or the pharmacy's usual and customary charge. Most States estimate pharmacy acquisition cost using AWP minus a percentage discount, which varies by State. AWP is a published price that is not defined in law or regulation.

The majority of States have used the pricing compendium published by First DataBank as their source to obtain AWP data. In connection with a legal settlement, First DataBank announced that it will discontinue publishing the AWP no later than September 26, 2011. We are conducting a review to assess States' plans for selecting alternative data sources or pricing benchmarks, evaluate the advantages and disadvantages of replacing AWP with alternative approaches, and determine what guidance CMS has provided or anticipates providing to States related to these issues. The change presents an opportunity for States to implement alternative pricing benchmarks for drugs without FULs.

**Findings:** A March 2002 OIG report on State pharmacy reimbursement formulas and pharmacy acquisition costs estimated that pharmacies' actual acquisition costs for generic drugs averaged 65.93 percent below the AWP in CY 1999. We estimated that changing the reimbursement policy to more accurately reflect pharmacies' actual acquisition costs could have saved the Medicaid program as much as \$470 million for the 200 generic drugs with the highest Medicaid reimbursement for CY 1999.

An additional analysis in 2002 included both brand-name and generic drug data. We found that Medicaid could achieve more accurate alignments between reimbursements and pharmacy acquisition costs by separately evaluating reimbursement levels for four specific tiers of drugs.

A 2005 report compared Medicaid FUL amounts to AMPs for the third quarter of 2004. AMPs are statutorily defined prices based on drug sales to the retail class of trade. We found that overall, FUL amounts for generic drug products were five times higher than the average AMP amounts for the same products in the third quarter of 2004. During the same period, the FUL amount was, on average, 22 times higher than the lowest reported AMP.

In 2007, we reported that FUL amounts set under the existing calculation method were more than double the average pharmacy acquisition costs in the second quarter of 2006.

In 2009, we found that existing FULs in the fourth quarter of 2007 were more than four times higher than average pharmacy acquisition costs for 50 high-expenditure FUL drugs, almost three times higher than average Part D payment amounts for 572 FUL drugs, and twice as high as retail prices for 291 drugs available through discount generic programs.

**Recommendations:** CMS should (1) encourage the States to align Medicaid generic drug pharmacy reimbursements more closely with the actual acquisition costs paid by pharmacies in their States (e.g., by implementing a four-tier approach to setting reimbursements consistent with our September 2002 additional analysis report).

**Savings:** TBD\*

*\*Savings not estimated. Reimbursements for generic drugs without FULs may be affected by implementing alternative pricing benchmarks beginning in October 2011, and reimbursement for drugs with FULs will change by implementation of the Affordable Care Act.*

**Management Response Summary:** In its comments on our March 2002 report, CMS concurred with our recommendation, indicating that it would work with States to strongly encourage them to review their estimates. CMS also concurred with the findings of the 2005 report stating that Congress should take action to ensure that Medicaid reimbursement amounts more closely relate to actual transaction prices.

The Deficit Reduction Act of 2005 (DRA) changed the FUL calculation for generic drugs, capping Medicaid drug reimbursement at 250 percent of the lowest AMP for a therapeutically equivalent version of a drug. CMS promulgated a final rule pursuant to this change at [72 Fed. Reg. 39142](#) (July 17, 2007), 42 CFR Part 447. This rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing the provisions of the rule.

In April 2008, CMS told us that it would follow up to ensure that States take OIG's findings into account. Our 2009 report recommended that CMS should continue to work with Congress to identify strategies that would lower inflated Medicaid payments for generic drugs. CMS concurred with our recommendation and stated that our findings supported the agency's belief that AMP-based FULs more accurately reflect acquisition costs and prices used in other programs.

Effective October 1, 2010, section 2503(a)(1) of the Affordable Care Act modified the previous statutory provisions for FULs under the DRA by revising the Social Security Act, § 1927(e)(5), to establish FULs as no less than 175 percent of the weighted average of the most recently reported monthly AMPs. CMS published a final rule at [75 Fed. Reg. 69591](#) (November 15, 2010) to withdraw those parts of the 2007 final rule that established upper limits for multiple-source drugs and revised the definition of AMP.

**Status:** We will continue to monitor reimbursements of Medicaid generic drugs that have (or do not have) FULs to determine whether the calculation methods lead to reimbursement amounts that more accurately reflect pharmacy acquisition costs.

#### **Related Reports:**

- 2009 AUG *A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices.* OEI-03-08-00490 [Report](#)
- 2007 JUN *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program.* OEI-03-06-00400 [Report](#)
- 2005 JUN *Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices.* OEI-03-05-00110 [Report](#)
- 2002 SEP *Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products.* A-06-02-00041 [Report](#)
- 2002 MAR *Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products.* A-06-01-00053 [Report](#)

**See Also:**

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](#)

2001 SEP     *Medicaid’s Use of Revised Average Wholesale Prices.* OEI-03-01-00010  
[Report](#)

Medicaid > Prescription Drugs > Rebate Program

## Establish a Connection Between the Calculations of Medicaid Drug Rebates and Drug Reimbursements

**Background:** The Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) authorized States to collect rebates from drug manufacturers for drug purchases made under the Medicaid program. Medicaid overspending occurs because of an inconsistency between the key values used for calculating rebates and reimbursements.

Medicaid requires that rebates be based on a specifically designated value, AMP, while, at the same time, allowing reimbursements to be calculated using other values (usually a discounted 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 overspending for drugs. When a State increases its payments 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. Legislation would be needed to establish the connection.

**Findings:** Our 1998 review of this matter considered the fact that most States calculate reimbursement for drugs without FULs on EACs based on AWP. Therefore, we explored the effect of basing rebates on AWP instead of AMP. We concluded that requiring manufacturers to pay Medicaid drug rebates using the same basis as Medicaid's reimbursements to pharmacies would establish a much-needed connection between the calculation of Medicaid drug rebates and the calculation of Medicaid reimbursement for drugs at the pharmacy level. Although the 1998 review analyzed an AWP/AWP scenario, other matching alignments (e.g., AMP/AMP) could also be considered.

**Recommendations:** CMS should (1) seek legislation that would require Medicaid drug rebates and reimbursements to be developed using the same basis or (2) review viable alternatives to the current program.

**Savings:** TBD\*

*\*We estimated that if rebates had been based on AWP (instead of on the statutorily required AMP) for CY 1994 through CY 1996, Medicaid would have achieved more than \$1 billion in added rebates for only the top 100 Medicaid-reimbursed brand-name drugs.*

**Management Response Summary:** At the time of our report in 1998, CMS did not concur with our recommendation, stating that it did not believe that a legislative proposal was feasible

In 2005, Section 6001 of the DRA amended the Social Security Act to require that CMS provide States with AMP data. We note that although the DRA did not require States to use AMP data in determining reimbursement, the dissemination of AMP data would have provided States with a new pricing source for establishing EAC. Making AMP available would have enabled States to use monthly AMP data when setting Medicaid reimbursement rates for prescription drugs. The DRA, in effect, provided States an opportunity to establish the critical connection between the calculation of rebates and reimbursements. CMS promulgated a corresponding final rule; however, a Federal injunction prohibited its implementation.

Subsequently, section 2503 of the Affordable Care Act modified the DRA requirement in a way that will limit the availability of AMP information to the States for reimbursement or other purposes. The Affordable Care Act requires CMS to publish weighted AMPs for certain multiple-source drugs, instead of publishing AMPs for all drugs.

**Status:** We are concerned that until States use the same basis in their rebate and reimbursement formulas, fluctuations in reimbursements will not result in a corresponding adjustment in the associated rebates. We continue to monitor this issue.

#### **Related Report:**

1998 May     *Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs.*  
A-06-97-00052 [Report](#)

#### **See Also:**

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 > Prescription Drugs > Rebate Program

## Clarify and Improve Program Guidance to Drug Manufacturers on Average Manufacture Price Issues

**Background:** The Social Security Act, § 1927, requires drug manufacturers to enter into and comply with rebate agreements with the Secretary of HHS for States to receive Federal funds for a manufacturer's covered outpatient prescription drugs. The Secretary may also authorize States to enter into direct agreements with drug manufacturers.

Pursuant to section 1927, manufacturers are required to report their AMPs to CMS for each covered outpatient drug for a base period. The manufacturer is required to report on a quarterly basis the AMP and the best price for each covered outpatient drug. Section 6001 of the DRA required OIG to review the requirements for and the manner in which AMPs are determined under section 1927 and to recommend appropriate changes.

**Findings:** Requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. OIG focused primarily on how manufacturers calculate AMP and found that interpretations of AMP requirements differ among manufacturers. Our findings demonstrated the need to clarify the definition of "retail class of trade" and the treatment of pharmacy benefit manager rebates and Medicaid sales in AMP calculations. Many of our AMP-related reports contain proprietary information and are therefore not available to the public.

Our work related to the use of the AMP by CMS and other agencies highlights the need to consider the timeliness and accuracy of manufacturer-reported AMPs. Consistent with our findings, industry groups also emphasized the need to clarify certain AMP requirements.

**Recommendations:** CMS should (1) clarify requirements with regard to the definition of "retail class of trade" and the treatment of pharmacy benefit manager rebates and Medicaid sales; (2) consider addressing issues raised by industry groups, such as administrative and service fees, lagged price concessions and returned goods, the frequency of AMP reporting, AMP restatements, and baseline AMPs; and (3) encourage States to analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for EACs.

**Management Response Summary:** CMS concurred with our recommendations. Pursuant to AMP-related provisions of the DRA, CMS promulgated a final rule at

[72 Fed. Reg. 39142](#) (July 17, 2007), 42 CFR Part 447. This rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing the provisions of the rule. Subsequently, CMS published a final rule at [75 Fed. Reg. 69591](#) (November 15, 2010) to withdraw those parts of the 2007 final rule that established upper limits for multiple-source drugs and revised the definition of AMP.

**Status:** OIG audits continue to identify variations among calculation methods, and we continue to recommend that CMS provide oversight to ensure that methods used to calculate AMPs are consistent among manufacturers. We plan additional reviews in FY 2011 of selected drug manufacturers to evaluate methodologies they use to calculate the AMP and best price for rebate and reimbursement purposes.

**Related Reports:**

- 2006 MAY *Determining Average Manufacturers Prices for Prescription Drugs Under the Deficit Reduction Act of 2005.* A-06-06-00063 [Report](#)
- 1992 NOV *Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program.* A-06-91-00092 [Report](#)

**See Also:**

- 2005 JUL Multistate Review of Medicaid Drug Rebate Programs. A-06-03-00048 [Report](#)
- 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 > Prescription Drugs > Rebate Program

## Implement an Indexed Best-Price Calculation in the Medicaid Drug Rebate Program

**Background:** OBRA 1990 authorized States to collect rebates from drug manufacturers for drug purchases made under the Medicaid program. Rebates are calculated using the AMP, the manufacturer's best price, and other factors. To discourage drug manufacturers from raising prices, the basic rebate amount for brand-name drugs is increased by the amount that the AMP increases over and above the Consumer Price Index (CPI) for all urban consumers. However, no similar indexing of best price is made, even though best price is part of the basic rebate calculation for brand-name drugs.

**Findings:** Since the inception of the Medicaid drug rebate program, drug manufacturers have consistently increased best prices in excess of the CPI for all urban consumers. To determine the potential effect of increases in best price (beyond the rate of inflation) on rebates, we calculated the difference in rebates that would have resulted from using an indexed best price. We estimated that in 1993, drug rebates would have increased by about \$123 million for the 406 drugs included in our review.

**Recommendation:** CMS should pursue legislation to index the best-price calculation in the Medicaid drug rebate program to the CPI-urban.

**Savings: \$123 million\***

*\*This savings estimate is based on the best-price indexing in 1993 of the 406 drugs included in our review.*

**Management Response Summary:** CMS did not concur with our recommendation. In its comments on our 2002 *Red Book*, CMS said that it believed that savings would be achieved through a President's budget proposal for a legislative change that would have based the Medicaid drug rebate on the difference between AWP and the best price of the drug. However, the proposal was not enacted. In November 2008, CMS noted that the Administration's position, as reflected in the FY 2008 President's budget, was to eliminate the best price; however, this proposal also was not enacted.

**Status:** We plan to continue monitoring the drug rebate program through audits focusing on enhancing the collection of rebates and providing potential savings to the rebate program. The main issue has not been addressed. Brand-name drugs are indexed, and we have suggested a similar calculation for generic drugs.

**Related Report:**

1995 OCT *Special Report for the Ranking Member of the Senate Special Committee on Aging: Potential Impact on the Use of an Indexed Best Price Calculation in the Medicaid Drug Rebate Program.* A-06-94-00039 [Report](#)

**See Also:**

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 > Prescription Drugs > Rebate Program

## Extend Additional Rebate Payment Provisions to Generic Drugs

**Background:** For covered outpatient drugs to be eligible for Federal Medicaid funding, the manufacturers must enter into rebate agreements that are administered by CMS and pay quarterly rebates to the States. The Social Security Act, § 1927(b)(3), requires participating manufacturers to report quarterly to CMS the AMP for covered outpatient drugs. The Social Security Act requires the payment of additional rebates for single-source and innovator multiple-source drugs (collectively, “brand-name drugs”) under certain situations. For these brand-name drugs, section 1927(c)(2) requires manufacturers to pay an additional rebate when the AMP for a drug increases more than a specified inflation factor. Generally, the amount of the additional rebate is based on the amount by which the drug’s reported AMP exceeds its inflation-adjusted baseline AMP, and manufacturers pay the additional rebate for each unit of the drug reimbursed by Medicaid. There is no similar inflation-based rebate provision for noninnovator (generic) drugs.

**Findings:** From 1991 through 2004, we found that generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 percent of the quarterly AMPs we reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. We calculated that by applying the method in the Social Security Act for calculating additional rebates on 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.

**Recommendation:** CMS should consider seeking legislative authority to extend the additional rebate provisions to generic drugs.

**Savings: \$966 million\***

*\*We calculated that 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.*

**Management Response Summary:** CMS said that it could not commit to pursuing the legislative change because at the time of our report, it did not have sufficient time to assess the impact of recent changes to the Medicaid prescription drug program required by the DRA. However, CMS indicated that it would consider our recommendation as it considers future legislative proposals. In December 2009, CMS told us that it continues to consider all improvements to the Medicaid drug rebate program, including seeking legislative change when CMS believes it is appropriate.

**Status:** We will continue to monitor CMS's progress in seeking legislation and other improvements toward implementing the recommendation.

**Related Report:**

2007 OCT *Review of Generic Drug Price Increases.* A-06-07-00042 [Report](#)

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Medicaid > Prescription Drugs > Rebate Program

## Identify Drugs That Are Ineligible for Federal Payments Under Medicaid

**Background:** For Federal payments to be available for covered outpatient drugs provided under Medicaid, the Social Security Act, §§ 1927(a)(1) and (b)(1), requires drug manufacturers to (1) enter into rebate agreements with the Secretary of HHS and (2) pay quarterly rebates to State Medicaid agencies. Covered outpatient drugs must be approved by the Food and Drug Administration (FDA) for safety and effectiveness, with certain exceptions, to qualify for Federal payments. As set forth in section 1927(b)(3), manufacturers must provide CMS with the AMP,<sup>1</sup> by national drug code (NDC), for each of their covered outpatient drugs. The rebate amount for a drug is based in part on whether it is categorized as an innovator or noninnovator product. Innovator products are generally subject to higher reimbursement. Manufacturers provide CMS with the drug categorization in conjunction with AMP data. We compared drug categorizations in CMS's fourth quarter 2007 AMP file to drug categorizations in two national compendia. A compendium is a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium.

**Findings:** We found that most AMP file drug categorizations matched the categorizations in two national compendia. For 90 percent of NDCs in our comparison, the drug categorizations in the fourth-quarter 2007 AMP file were the same as the categorizations in the national compendia. However, drug categorizations did not match for 10 percent of NDCs. Overall, these nonmatching NDCs were associated with 3 percent of total fourth-quarter 2007 Medicaid expenditures for the NDCs under review. A manual review of 75 high-expenditure nonmatching NDCs revealed that 32 NDCs were for drugs that had not been approved by FDA. Medicaid paid \$20 million for these drugs in the fourth quarter of 2007.

In addition, a substantial number of NDCs were excluded from the drug categorization comparison, primarily because of missing data. We were unable to compare drug categorizations for 42 percent of NDCs with fourth-quarter 2007 Medicaid utilization for several reasons: (1) the NDCs were not listed in the AMP file, (2) the NDCs were not listed in one or both of the two national drug compendia, or (3) the NDCs had drug categorizations that differed in the two national compendia.

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<sup>1</sup> In December 2007, the U.S. District Court for the District of Columbia preliminarily enjoined the implementation of AMP-based FULs.

**Recommendation:** CMS should work closely with FDA to identify any potentially problematic Medicaid payments for drugs that have not been approved by FDA.

**Savings: \$20 million\***

*\*Based on OIG analysis of 2007 fourth-quarter Medicaid expenditures.*

**Management Response Summary:** In its response to our recommendation, CMS said that it has worked and will continue to work closely 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 explained 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.

**Status:** We continue to encourage CMS to work closely with FDA to identify potentially problematic Medicaid payments for drugs that have not been approved by FDA. We will continue to monitor CMS's progress through current work.

**Related Report:**

2009 JUL     *Accuracy of Drug Categorizations for Medicaid Rebates.*  
OEI-03-08-00300 [Report](#)

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# Medicaid Administration

Medicaid > Managed Care Encounter Data

## Enforce Federal Requirements for Submitting Medicaid Managed Care Encounter Data

**Background:** Encounter data are the primary records of Medicaid services provided to beneficiaries enrolled in capitated Medicaid managed care. As of 2006, 65 percent of the 45.6 million Medicaid beneficiaries were receiving all or part of their health care services through Medicaid managed care. 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 Medicaid Statistical Information System (MSIS).” As the only national database of Medicaid claims and beneficiary eligibility information, the MSIS is used by CMS to manage, analyze, and disseminate information on Medicaid beneficiaries, services, and payments. The MSIS is also widely used for research and policy analysis by public and private organizations and may also be used for detecting fraud, waste, and abuse. The MSIS must include encounter data to be representative of Medicaid beneficiaries and services.

**Findings:** We found that the 40 States with capitated Medicaid managed care collect encounter data from managed care organizations (MCO); however, the usefulness of the MSIS is limited because CMS does not enforce encounter data requirements.

**Recommendation:** CMS should enforce Federal requirements that States include encounter data in MSIS submissions.

**Management Response Summary:** CMS concurred with our recommendation. CMS’s 2011 update of its response to our recommendation stated 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 this data.

**Status:** Section 6402(c) of the Affordable Care Act authorizes the Secretary to withhold the Federal matching payment for States that fail to report enrollee encounter data in the MSIS. We will monitor CMS's efforts in the implementation of its planned actions and promulgation of Federal regulations regarding section 6402(c).

**Related Report:**

2009 MAY *Medicaid Managed Care Encounter Data: Collection and Use.*  
OEI-07-06-00540 [Report](#)

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Medicaid > Administration > Credit Balances

## Establish a National Medicaid Credit Balance Reporting Mechanism

**Background:** CMS does not require State agencies to routinely monitor providers' efforts to identify and refund Medicaid credit balances in 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.

**Findings:** Two of our reports have indicated that significant outstanding Medicaid credit balances exist nationwide. Between May 1992 and March 1993, we reported that many State agencies' efforts were inadequate to ensure that, nationwide, providers were identifying the majority of Medicaid credit balances and remitting overpayments in a timely manner.

**Recommendations:** CMS should (1) establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A and (2) require its regional offices to actively monitor the reporting mechanism that is established.

**Savings:** TBD\*

*\*Savings not estimated.*

**Management Response Summary:** When commenting on our 1995 report, CMS concurred with our recommendation to establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A. However, CMS decided not to do so, citing the uncertain and minimal savings potential; the Administration's commitment to enhancing States' flexibility; and, specifically, 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 expenditure reports. However, CMS has not implemented a credit balance reporting mechanism, citing cost-effectiveness issues.

**Status:** We continue to recommend that CMS establish a national Medicaid credit balance reporting mechanism and require its regional offices to monitor reporting. We

are conducting audit work in the Medicaid credit balance area to update our work. Based on our audit results, we will update or delete this item accordingly.

**Related Reports:**

1995 MAY *Quarterly Credit Balance Reporting Requirements for Medicaid.*  
A-05-93-00107 [Report](#)

1993 MAR *Nationwide Audit of Medicaid Credit Balances.* A-04-92-01023 [Report](#)

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Medicaid > Administration > Third-Party Liability

## **Advise States of Their Authority To Collect From Noncustodial Parents With the Ability To Contribute Toward Their Children’s Medicaid or Children’s Health Insurance Program Costs**

**Background:** 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, unless the custodial parent and children have satisfactory health insurance other than Medicaid, 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 the Children’s Health Insurance program (CHIP), is silent with regard to collecting CHIP costs from noncustodial parents who have medical support orders.

**Findings:** States can reduce State and Federal Medicaid costs by increasing the number of noncustodial parents who provide medical support for their children. Although Federal regulations authorize States to recover Medicaid costs from third-party payers, Title IV-D regulations do not provide specific guidance for collecting Medicaid costs from noncustodial parents who have the financial ability to pay and who do not have affordable employer-sponsored health coverage available. Medicaid regulations do not address how State Medicaid agencies should coordinate with State Title IV-D agencies or how the States should establish and administer Medicaid fee-for-service (FFS) recoveries.

States also have an opportunity to enroll uninsured Title IV-D children in CHIP and provide a means for noncustodial parents to fulfill their medical support obligations. Unlike Federal Medicaid laws, CHIP laws are silent with regard to an “assignment of rights” that would allow States to recover children’s medical expenses from their 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.

**Recommendations:** CMS should (1) clarify third-party liability regulations to help State Medicaid agencies coordinate with State Title IV-D agencies to collect Medicaid costs from noncustodial parents with medical support orders; (2) seek legislation that would allow States to accumulate medical support payments to offset Medicaid FFS costs for a reasonable period; (3) determine whether more Federal funds are needed to help States interface their Title IV-D and CHIP databases; (4) implement a process to collect CHIP costs from noncustodial parents; and (5) as appropriate, provide funds for this purpose.

**Savings:      \$99 million – Medicaid\***  
**\$14 million –CHIP\*\***

*\*Based on an eight-State review, we estimated that Title IV-D children who were enrolled in Medicaid had noncustodial parents who were financially able to contribute \$99 million based on the most recent data available from each State in 2001 or 2002.*

*\*\*Based on an eight-State review, we estimated that Title IV-D children who received CHIP benefits had noncustodial parents who could potentially contribute \$14 million toward the CHIP premiums based on the most recent data available from each State in 2001 or 2002.*

**Management Response Summary:** CMS did not concur with our recommendation to clarify third-party liability regulations; it agreed, however, to work with us to draft legislation to allow States to accumulate medical support payments because Federal laws and regulations prohibit States from accumulating additional medical support payments. CMS did not concur with our recommendations that issuing formal guidance on CHIP costs was necessary but agreed to alert States to their option to pursue the Federal and State shares of these costs. After our reports were issued, CMS told us during a series of Medical Support Collaboration meetings sponsored by the Administration for Children & Families (ACF) in 2005 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 also noted that States had the authority to fund the administrative costs of building an infrastructure with the State Title IV-D 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.

**Status:** 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.

### **Related 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 [Report](#)
- 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 [Report](#)

Medicaid > Medicaid Administration > Children's Health Screening

## Improve Medicaid Children's Access to Required Preventive Screening Services (New)

**Background:** Services provided under Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit 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. Our review focused on medical, vision, and hearing screenings. Only medical screenings have components specifically required by the statute. Complete medical screenings under the EPSDT benefit must include the following five age-appropriate components: a comprehensive health and developmental history, a comprehensive unclothed physical examination, appropriate immunizations according to age and health history, appropriate laboratory tests, and health education.

**Findings:** Most Medicaid-covered children in nine selected States are not fully benefiting from Medicaid's EPSDT comprehensive screening services. Seventy-six percent of children, or 2.7 million children, in 9 selected States did not receive all required medical, vision, and hearing screenings. Forty-one percent of children did not receive any required medical screenings. In addition, 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. The component that screenings were most often missing was appropriate laboratory tests.

Two primary factors contributed to this problem: children did not receive the correct number of each type of screening, and when children received medical screenings, the screenings were often incomplete. These two factors taken together indicate that very few children received the correct number of complete screenings required by law. 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.

**Recommendations:** CMS should (1) require States to report vision and hearing screenings, (2) collaborate with States and providers to develop effective strategies to encourage beneficiary participation in EPSDT screenings, (3) collaborate with States and providers to develop education and incentives for providers to encourage complete medical screenings, and (4) identify and

disseminate promising State practices for increasing children's participation in EPSDT screenings and providers' delivery of complete medical screenings.

**Management Response Summary:** CMS concurred with our recommendations and stated that it is undertaking efforts in conjunction with States and national experts to improve the provision of EPSDT services. CMS also stated that a National EPSDT Improvement Workgroup has been formed and is 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 will post these on its Web site.

**Status:** We will continue to monitor CMS's implementation of our recommendations.

### Related Reports:

- 2010 MAY *Most Medicaid Children in Nine States Are Not Receiving All Required Preventive Screening Services.* OEI-05-08-00520 [Report](#)
- 2005 JUL *Children's Use of Health Services While in Foster Care: Common Themes.* OEI-07-00-00645 [Report](#)

### See Also:

- 2005 JUN *Children's Use of Health Services While in Foster Care: New York.* OEI-02-00-00362 [Report](#)
- 2005 JAN *Children's Use of Health Services While in Foster Care: Georgia.* OEI-07-00-00644 [Report](#)
- 2004 AUG *Children's Use of Health Services While in Foster Care: North Dakota.* OEI-07-00-00643 [Report](#)
- 2004 JUN *Foster Care Children's Use of Medicaid Services in Oregon.* OEI-02-00-00363 [Report](#)
- 2004 FEB *Children's Use of Health Services While in Foster Care: Texas.* OEI-07-00-00641 [Report](#)
- 2004 FEB *Children's Use of Health Services While in Foster Care: Illinois.* OEI-07-00-00642 [Report](#)
- 2003 AUG *Children's Use of Health Services While in Foster Care: Kansas.* OEI-07-00-00640 [Report](#)

- 2003 JUL *Foster Care Children's Use of Medicaid Services in New Jersey.*  
OEI-02-00-00360 [Report](#)
- 1997 MAY *Medicaid Managed Care and EPSDT.* OEI-05-93-00290 [Report](#)
- 1992 AUG *Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)—Performance Measurement.* OEI-07-90-00130 [Report](#)

**Part IV:**

**Public Health, Human Services,  
and Departmentwide Issues**

## Part IV: Public Health, Human Services and Departmentwide Issues

### Public Health Programs

Public Health > Assistant Secretary for Preparedness and Response

#### Improve States' and Localities' Medical Surge Preparedness for Pandemics

**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.

We assessed the extent to which selected States and localities have prepared for a medical surge in response to an influenza pandemic and have conducted and documented exercises that test their medical surge preparedness. This review is based on a sample of 5 States and 10 localities and presents a snapshot of these States' and localities' preparedness for an influenza pandemic as of late summer 2008. The review is based on a review of documentation from the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), and the selected States and localities, as well as structured in-person interviews with key officials in each of the selected States and localities.

**Findings:** We found 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. We also found that 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 the 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.

Finally, although the localities conducted medical surge exercises, none consistently documented the lessons learned.

**Recommendation:** We recommend that ASPR, in collaboration with CDC, work with States and localities to improve their efforts within each of the five components of medical surge that we reviewed: 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.

**Management Response Summary:** ASPR concurred with our recommendation. In October 2009, ASPR stated 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 stated 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.

**Status:** We continue to monitor ASPR’s progress in implementing our recommendations.

**Related Report:**

2009 SEP     *State and Local Pandemic Influenza Preparedness: Medical Surge.*  
OEI-02-08-00210 [Report](#)

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Public Health > Centers for Disease Control and Prevention

## Ensure That State Public Health Laboratories Meet Cooperative Agreement Requirements on Biological Threats

**Background:** In 2006, through its Cooperative Agreement, CDC allocated about \$766 million to 62 awardees to meet 9 preparedness goals. Preparedness Goal 3, Detect and Report, is the only one that focuses on public health laboratory testing and reporting biological threats. This goal contains 2 required critical tasks with 11 requirements. These requirements contain multiple elements that State public health laboratories must meet to decrease the time needed to detect and report biological public health threats. For most of the Preparedness Goal 3 requirements, State public health laboratories must coordinate with private clinical laboratories, known as sentinel laboratories, that perform preliminary testing and ship specimens to the State.

**Findings:** We surveyed public health laboratory officials in 50 States and 3 metropolitan areas to assess the extent to which they have made progress toward meeting 9 of the 11 Cooperative Agreement requirements for State public health laboratory testing and reporting. We found that every State reported meeting at least three of the requirements that we reviewed, but no State met all nine. At least 87 percent of States reported meeting all of the elements in four of the nine requirements. Less than 65 percent of States reported meeting all the elements in 5 of the 9 testing and reporting requirements we reviewed, and less than 10 percent of States reported meeting all elements in two of these five requirements.

**Recommendations:** CDC should continue to assist States in meeting Cooperative Agreement requirements intended to decrease the time needed to detect and report biological public health threats. CDC should place special emphasis on improving performance for the 2 requirements met by less than 10 percent of States by (1) determining why less than 10 percent of States conducted tests of their sentinel laboratories' ability to ship outside regular business hours and providing assistance to States on how to increase the number of tests conducted and (2) ensuring that States use a consistent method to identify sentinel laboratories to be included in their databases and that the databases include all the required elements.

**Management Response Summary:** CDC concurred with our overall recommendation that it continue to assist States in meeting the Cooperative Agreement requirements to decrease the time needed to detect and report biological public health threats. CDC concurred that it should determine how sentinel laboratories are identified and noted that States should have flexibility in determining the functional criteria for a

facility to be considered a sentinel laboratory. CDC noted at that time that States had until 2010 to meet all the required critical tasks stipulated.

In October 2010, CDC informed the Office of Inspector General (OIG) that it continues to provide guidance to States on how to decrease the time needed to detect and report biological public health threats. CDC also noted that, due to a 12-month extension granted in 2009 by the Department of Health & Human Services (HHS), awardees now have until August 2011 to complete the critical tasks stipulated under the current Cooperative Agreement and subsequent continuation guidance, including the requirement to decrease the time needed to detect and report biological public health threats.

**Status:** We continue to monitor CDC's progress in implementing our recommendations.

**Related Report:**

2008 OCT     *Public Health Laboratory Testing To Detect and Report Biological Threats.*  
OEI-04-07-00750 [Report](#)

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Public Health > Centers for Disease Control and Prevention

## Improve Oversight of the Ethics Program for Special Government Employees on Federal Advisory Committees at CDC (New)

**Background:** Federal Advisory Committees (committees) play an influential role in decisionmaking for the Federal Government. Special Government employees (SGE) are individuals who are not regularly employed by the Government and typically have other employment. On these committees, SGEs serve as subject-matter experts. To protect the committees' integrity and credibility, SGEs with conflicts of interest must not inappropriately influence their committees' work. Before permitting SGEs to participate in committee meetings, CDC must ensure that SGEs disclose complete financial information on a Confidential Financial Disclosure Report and identify and resolve all SGEs' conflicts of interest. Finally, CDC must provide ethics training to SGEs and monitor their compliance with ethics requirements during committee meetings. We reviewed Confidential Financial Disclosure Reports and related documents for 246 SGEs serving on 17 CDC committees in 2007.

**Findings:** We found that CDC and its SGEs on committees did not comply with a number of ethics requirements in 2007. That is, for almost all SGEs, CDC did not ensure that Confidential Financial Disclosure Reports were complete in 2007, and most of these forms contained multiple omissions. In addition, CDC did not identify or resolve conflicts of interest for 64 percent of SGEs in 2007. Over one-fourth of SGEs had both unidentified and unresolved potential conflicts of interest on file. CDC also did not ensure that 41 percent of SGEs received required ethics training in 2007. Finally, 15 percent of SGEs did not comply with ethics requirements during committee meetings in 2007. These SGEs either participated in meetings without having a current, certified Confidential Financial Disclosure Report on file, or they voted on committee matters in which they were prohibited from participating because of a documented conflict of interest.

**Recommendations:** CDC should (1) ensure SGEs' Confidential Financial Disclosure Reports are complete; (2) require SGEs to disclose their involvement in grants and other relevant interests that could pose conflicts which are not disclosed on the Confidential Financial Disclosure Report; (3) identify and resolve all SGEs' conflicts of interest before permitting them to participate in committee meetings; and (4) track SGE compliance with ethics requirements.

**Management Response Summary:** In its response to our draft report, CDC concurred with all of our recommendations. Since the time of our review, CDC indicated that it has begun or plans to implement improvements that coincide with our recommendations.

**Status:** We will continue to monitor CDC's implementation of our recommendations.

**Related Report:**

2009 DEC     *CDC's Ethics Program for Special Government Employees on Federal Advisory Committees.* OEI-04-07-00260 [Report](#)

Public Health > Food and Drug Administration

## Update and Maintain an Accurate National Drug Code Directory

**Background:** The Drug Listing Act of 1972, § 3, amended the Food, Drug, and Cosmetic Act (FDCA) to require drug firms that are engaged in manufacturing, preparing, propagating, compounding, or processing drugs to report all drug products to the Food and Drug Administration (FDA). Drug products are uniquely identified and reported using a three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs. FDA assigns the first segment, and drug firms assign the other two segments. FDA enters the full NDC number and information submitted as part of the listing process into a database known as the Drug Registration and Listing System. FDA extracts information from the database several times a year and publishes that information in the *NDC Directory* (the directory). When drug firms introduce a new drug product or discontinue a product, they must report the complete NDC and associated information to FDA as part of the drug-product listing process.

**Findings:** We found that the directory was neither complete nor accurate. An estimated 9,187 prescription drug products were missing from the list, while another 5,150 had not cleared the listing process. An estimated 34,257 drug products listed were no longer on the market or were listed in error. Problems with the directory resulted primarily from drug firms' failure to report instances when drugs are placed on or taken off the market and the firms' failure to provide sufficient and accurate information to complete the listing process.

**Recommendations:** FDA should (1) provide greater control over the assignment of NDCs, (2) implement a mechanism to routinely identify drug product omissions and inaccuracies, and (3) identify and take appropriate action against drug firms that consistently fail to list drug products and update information.

**Management Response Summary:** FDA concurred with our recommendations and requested access to our data files to follow up on identified problems. In comments on our draft report, FDA delineated a number of initiatives to improve the directory's completeness and accuracy, such as conversion to an electronic listing system for use by drug firms.

FDA said in its response to the report that it was preparing a proposed rule to clarify listing requirements, enhance control of the drug establishment registration and drug-listing process, and improve data accuracy and completeness. This proposed rule was published on August 29, 2006 (71 Fed. Reg. 51276). Subsequent to the publication of our report, FDA told us that in December 2006, it held a public hearing on this proposed

rule. In its 2011 update of its response to our recommendations, FDA said that it was in the process of finalizing this rule.

In a step toward implementation of our second recommendation, FDA has begun implementing an electronic system for firms to submit drug product listing data using the structured product label submission process. In a step toward implementation of our third recommendation, FDA has collaborated with The Centers for Medicare & Medicaid (CMS) to develop a Non-Matched NDC List that, among other things, helps FDA identify drug products that are not properly listed, as required. The development and posting of this list has prompted firms to address previously incorrect or incomplete listing data, including discontinued products that are no longer marketed.

**Status:** We continue to monitor FDA's progress in implementing our recommendations.

**Related Report:**

2006 AUG *The Food and Drug Administration's National Drug Code Directory.*  
OEI-06-05-00060 [Report](#)

Public Health > Food and Drug Administration

## Improve and Strengthen Food Facilities' Compliance With Records Requirements for Traceability of Food Products

**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. Traceability is the ability to follow the movement of food products through the stages of production, processing, and distribution. Traceability is often needed to identify the sources of food contamination and the recipients of contaminated food in product recalls and seizures. We used two primary data sources for our review: a traceability exercise of 40 selected food products and structured interviews with the managers of the food facilities that handled the selected food products to determine the extent of the information that facilities kept about their sources, recipients, and transporters, which we used to trace the products.

**Findings:** We were able to trace 5 of the 40 products through each stage of the food supply chain. For 31 of the 40 products, we were able to identify facilities that likely handled the products. Most facilities did not maintain lot-specific information in their records and could estimate only a range of deliveries (from one or more facilities) that may have included the products we purchased. Several factors prevented us from tracing the specific products through the food supply chain: facilities did not always maintain lot-specific information; products were not labeled with required information; and products from a number of farms were mixed. We found that 59 percent of the facilities did not meet FDA's record requirements about sources, recipients, and transporters. This meant that 70 of the 118 facilities in our sample did not provide required information. We also found that one-quarter of the food facilities were not aware of FDA's records requirements. Others described practices designed to improve traceability.

**Recommendations:** We recommend that FDA (1) work with the food industry to develop additional guidance to strengthen traceability; (2) address issues related to mixing raw food products from a large number of farms; (3) seek statutory authority to ensure that facilities are complying with record requirements; and (4) conduct education and outreach to inform the food industry about its records requirements.

**Management Response Summary:** In its comments on our report, FDA said that it would consider our recommendation regarding seeking statutory authority, and it

described its efforts in response to our recommendation to work with the food industry to conduct education and outreach. FDA did not say whether it concurred with the other recommendations but noted that it continues to work closely with its food-safety partners to strengthen its ability to protect Americans from foodborne illness, which includes determining whether additional statutory authority is needed to better protect public health.

In its February 2011 update of its response to our recommendations, FDA said 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 in response to our recommendation to work with the food industry to conduct education and outreach.

**Status:** We acknowledge the efforts FDA has taken and continue to monitor its progress in implementing our recommendations. Although the FDA Food Safety Modernization Act implemented several of the report's recommendations, we continue to emphasize the need for FDA to seek statutory authority to ensure that facilities are complying with the record requirements related to food traceability. FDA does not have the authority to request facilities' records regarding traceability during routine inspections.

**Related Report:**

2009 MAR *Traceability in the Food Supply Chain*. OEI-02-06-00210 [Report](#)

**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](#)

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Public Health > Food and Drug Administration

## Ensure That Clinical Investigators Disclose All Financial Interests

**Background:** Most new drugs, biological products, and medical devices undergo clinical trials on human subjects before they are marketed in the United States. Sponsors, generally pharmaceutical or device companies, oversee trials conducted by clinical investigators. Sponsors must collect financial information from clinical investigators before the trials. However, sponsors submit financial information to FDA only when they submit their marketing applications after 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.

**Findings:** We found that clinical investigators might not be disclosing all their financial interests. One percent of clinical investigators disclosed a financial interest during the period reviewed. FDA cannot determine whether sponsors have submitted financial interest information for all their clinical investigators. We also found that almost half of marketing applications were missing financial interest 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.

**Recommendations:** FDA should (1) ensure that sponsors submit complete financial information for all their clinical investigators, (2) 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, and (3) require that sponsors submit financial information as part of the pretrial application process.

**Management Response Summary:** FDA generally agreed with our recommendations. However, the agency did not agree with our final recommendation that FDA require 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. FDA also updated the *Compliance Program Guidance Manual* chapter entitled "Clinical Investigator Inspections."

FDA is revising its *Guidance for Industry: Financial Disclosure by Clinical Investigators*. The proposed revisions are aimed at ensuring that all required information is included in the application to FDA. FDA plans to issue the revised guidance in draft; as of January 2011, the document was in agency clearance.

**Status:** We continue to monitor FDA's implementation of our recommendations.

**Related Report:**

2009 JAN     *The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information*. OEI-05-07-00730 [Report](#)

Public Health > Food and Drug Administration

## Minimize Financial Risk in the Food and Drug Administration's Information Technology Contracts

**Background:** Pursuant to the Federal Acquisition Regulation (FAR), agencies must establish procedures to select qualified contractors while protecting the Government from unnecessary financial risk. Agencies must perform acquisition planning, clearly define what they are buying in the requirements section of a statement of work (SOW), and select an appropriate contract type and method. Agencies must also monitor contractors to ensure quality results.

**Findings:** We found that FDA's Center for Drug Evaluation and Research (CDER) relied primarily on acquisition methods that emphasize speed and flexibility over planning. CDER also relied on time-and-materials contract actions that increase risk for the Government. Because CDER did not clearly define its requirements or performance measures, it also did not apply quality assurance (QA) plans consistently.

**Recommendations:** We recommend that FDA minimize its contract risk by (1) defining information technology (IT) requirements more clearly, (2) converting ongoing time-and-materials contract actions to fixed-price contract actions when appropriate, (3) using performance incentive plans when appropriate, and (4) using documented QA plans.

**Management Response Summary:** FDA neither agreed nor disagreed with our recommendation to define its IT requirements more clearly. However, it did identify actions that it is taking that support that recommendation, such as implementing a formal business process model. FDA agreed with our other recommendations to convert time-and-materials contracts to fixed-price contracts when appropriate and to use performance incentives and QA plans, saying that it will use these methods in future contracts when applicable. In its January 2011 update to its response to our recommendations, FDA stated that it has developed and initiated standard operating procedures as part of its IT information management process.

**Status:** We continue to monitor FDA's implementation of our recommendations.

### Related Report:

2009 JAN *Management of Information Technology Contracts at the Food and Drug Administration's Center for Drug Evaluation and Research.*  
OEI-01-07-00450 [Report](#)

Public Health > Food and Drug Administration

## Use Adverse Event Reports to Detect and Address Safety Concerns About Medical Devices (New)

**Background:** The adverse event reporting system provides the Center for Devices and Radiological Health (CDRH) and manufacturers with a means to identify and monitor significant adverse events involving 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. Regulations require that manufacturers of medical devices and facilities that use these devices (hereinafter referred to as user facilities) submit reports to FDA within specific timeframes ranging from 5 days to 1 year following the occurrence of an adverse event.

**Findings:** We found that CDRH 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, CDRH rarely acts when manufacturers and user facilities submit reports late. We also found that the inability to obtain complete and usable information in adverse event reports hinders analysts' review of the reports, and that CDRH 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. We also found that although manufacturers submitted most adverse event reports on time, many 5-day manufacturer reports and 5-day user facility reports were late.

**Recommendations:** FDA should (1) develop a clear protocol for reviewing adverse event reports that specifically addresses the following needs: (a) documenting followup on adverse events, (b) ensuring and documenting that CDRH is meeting its own guidelines for reviewing high-priority adverse event reports, (c) following up with manufacturers who routinely submit reports late or with incomplete information, and (d) enhancing outreach strategies to reduce user facility underreporting; and (2) seek legislative authority to eliminate the regulation for user facilities to submit annual reports.

**Management Response Summary:** FDA agreed with both of our recommendations. In its comments, FDA said that CDRH would develop a clear review protocol that addresses the needs that our report identified. FDA stated that it is developing a new database that should allow for more extensive documentation and followup on adverse events and permit FDA to more readily identify late and incomplete reports. FDA also stated that CDRH has developed a tracking system that facilitates referrals to its Office of Compliance and follows up on them.

**Status:** We will continue to monitor FDA's progress in addressing our recommendations.

**Related Report:**

2009 OCT *Adverse Event Reporting for Medical Devices.* OEI-01-08-00110 [Report](#)

Public Health > Food and Drug Administration

## Ensure That Food Facility Registry Provides Complete and Accurate Information (New)

**Background:** Section 305(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires certain food facilities to register with FDA. 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. The purpose of this registration is to provide FDA with sufficient and reliable information about food facilities so that it can quickly locate facilities during an outbreak of foodborne illness. It also allows FDA to locate these facilities for inspection. Our review was based on a purposive sample of 130 selected domestic food facilities. Our analysis compared information about the selected facilities in the registry with information obtained during structured interviews with the facility managers.

**Findings:** Our review raised questions about the accuracy and utility of the registry. We found that 7 percent of selected facilities either failed to register or failed to cancel their registrations with FDA, as required. Additionally, we found that 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. We also found that FDA's regulations do not ensure that the registry contains certain information that may be needed in an emergency. In many cases, we found that because providing certain information in the registry is optional, facilities failed to provide information that may be useful to FDA in an emergency. Finally, we found that 52 percent of the facility managers at the selected facilities reported that they were unaware of FDA's registry requirements.

**Recommendations:** FDA should (1) 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; (2) consider making some of the optional fields within the registry mandatory; and (3) work with the food industry to conduct additional education and outreach activities to inform food facilities about the registry requirements.

**Management Response Summary:** FDA generally agreed with our recommendations. FDA noted that the study confirms problems that the agency has encountered as well as the need for additional statutory authority.

**Status:** We will continue to monitor FDA's progress in addressing our recommendations. 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.

**Related Report:**

2009 DEC *FDA's Food Facility Registry*. OEI-02-08-00060 [Report](#)

Public Health > Food and Drug Administration

## Improve Monitoring of Foreign Clinical Trials (New)

**Background:** The FDCA requires all new investigational drugs and biologics to undergo clinical trials on human subjects to demonstrate the safety and efficacy of these products prior to approval for sale in the United States. FDA ensures the rights, safety, and well-being of subjects who participate in these trials and verifies that the clinical trial data collected are accurate and reliable. Sponsors may submit data from foreign and domestic clinical trials to support marketing applications. For data from foreign clinical trials, often the first time that FDA has the opportunity to review the safety and accuracy of those trials is when the sponsor is seeking permission to market the drug in the United States, which may be years after the clinical trials have concluded.

Sponsors may realize benefits from conducting research abroad, such as lower costs in some countries or the ability to conduct larger trials in less time. However, medical ethicists have raised concerns about the increased prevalence of foreign clinical trials. These concerns include the ability of local regulatory bodies and institutional review boards to adequately monitor clinical trials to protect the rights and welfare of subjects and to ensure data integrity.

**Findings:** We found that in fiscal year (FY) 2008, sponsors relied heavily on data from foreign clinical trials to support their marketing applications for drugs and biologics. We found that 80 percent of approved marketing applications for drugs and biologics contained data from foreign clinical trials. Further, over half of clinical trial subjects and sites were located outside the United States. Although FDA inspected clinical investigators at few clinical trial sites overall, FDA inspected clinical investigators at foreign sites at an even lower rate—less than 1 percent of foreign sites.

Challenges in conducting foreign inspections and data limitations inhibit FDA's ability to monitor foreign clinical trials. For example, if a sponsor has not submitted an Investigational New Drug (IND) application or consulted with FDA in some other way about its foreign clinical trials prior to seeking FDA marketing approval, the agency has no way of knowing whether and where foreign clinical trials are taking place and therefore cannot conduct inspections while the trials are in progress.

Further, despite guidelines in the Good Clinical Practice international quality standard, sponsors generally submitted data that were presented inconsistently, making it difficult to locate clinical trial information, particularly site locations and subject enrollment.

**Recommendations:** FDA should (1) require standardized electronic clinical trial data and create an internal database of clinical trial data; (2) monitor trends in foreign clinical trials not conducted under INDs and, if necessary, take steps to encourage sponsors to file INDs; and (3) continue to explore ways to expand its oversight of foreign clinical trials.

**Management Response Summary:** FDA agreed with all of our recommendations. With regard to the first recommendation, FDA is piloting a site selection tool to standardize clinical trial data and may expand use of the tool within the agency. FDA added that the data captured by the site selection tool represent a partial solution and that it is considering long-term solutions. With regard to the second recommendation, FDA said that it will continue to assess trends in foreign clinical trials through inspection data and will explore whether tracking the number of applications with clinical trial data not collected under INDs is feasible. With regard to the third recommendation, FDA plans to leverage its partnership with the European Medicines Agency to work with other regulatory bodies. FDA is also expanding worldwide outreach and training in concepts of Good Clinical Practice.

**Status:** We will continue to monitor FDA's implementation of our recommendations.

**Related Reports:**

2009 JUN *Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials.*  
OEI-01-08-00510 [Report](#)

2007 SEPT *The Food and Drug Administration's Oversight of Clinical Trials.*  
OEI-01-06-00160 [Report](#)

2001 SEPT *The Globalization of Clinical Trials.* OEI-01-00-00190 [Report](#)

Public Health > Food and Drug Administration

## Strengthen Inspections of Domestic Food Facilities to Ensure Food Safety and Compliance (New)

**Background:** FDA inspects food facilities to ensure food safety and compliance with regulations. According to FDA guidance, when the agency identifies violations that are significant enough to warrant an “official action indicated” (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.

**Findings:** We found that many food facilities went 5 years or longer without an FDA inspection. We also found that 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, we found that for 36 percent of the facilities that received OAI classifications, FDA took no additional steps to ensure that the violations were corrected.

**Recommendations:** To strengthen the significant weaknesses in its inspections and to ensure food safety and compliance with the regulations, FDA should (1) provide additional guidance about when it is appropriate to lower OAI classifications; (2) take appropriate actions against facilities with OAI classifications, particularly those that have histories of violations; (3) ensure that violations are corrected for all facilities that receive OAI classifications; and (4) consider seeking additional statutory authority that would allow FDA to impose civil penalties through administrative proceedings.

**Management Response Summary:** In its comments on our draft report, FDA supported our recommendation to seek additional statutory authority (recommendation 4) and agreed with our recommendation to provide additional guidance about when it is appropriate to lower OAI classifications (recommendation 1). FDA noted several actions it has taken, or plans to take, to address the remaining two recommendations.

**Status:** We will continue to monitor FDA’s implementation of our recommendations.

### Related Report:

2010 APR *FDA Inspections of Domestic Food Facilities*. OEI-02-08-00080 [Report](#)

Public Health > Health Resources and Services Administration

## Eliminate Excessive Costs in the 340B Drug Pricing Program

**Background:** The Public Health Service Act of 1944 (PHS Act), § 340B, created the 340B Drug Pricing program to lower drug prices for more than 12,300 entities, including community health centers, public hospitals, and various Federal grantees. Pharmaceutical manufacturers calculate the 340B discount using a specified formula and must sell their products at or below this ceiling price to continue to have their products covered by the Medicaid program. The Health Resources and Services Administration's (HRSA) Pharmacy Affairs Branch administers the program for the thousands of enrolled entities nationwide, which are estimated to have spent \$3.4 billion on drugs in 2003.

**Findings:** Because of systemic problems with the accuracy and reliability of the Government's record of 340B ceiling prices, we found that HRSA could not adequately oversee the 340B Drug Pricing Program. HRSA lacked the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price. We found that in a single month in 2005, 14 percent of total purchases made by 340B entities exceeded 340B ceiling prices, resulting in total projected overpayments of \$3.9 million for the year.

**Recommendations:** HRSA should (1) improve its oversight of the 340B Drug Pricing Program to ensure that entities are charged at or below the 340B ceiling price; (2) work with CMS to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices; and (3) strengthen its administration of the 340B Drug Pricing Program by (a) establishing detailed standards for the calculation of 340B ceiling prices and (b) providing participating entities with secure access to certain pricing data to help approximate the 340B ceiling prices.

**Savings: \$46.8 million by federally supported covered entities.\***

*\*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. More indirect savings to HHS are likely but have not been calculated.*

**Management Response Summary:** HRSA concurred with our recommendations and said that it had taken steps to monitor more closely prices paid by the 340B program. In its comments on our 2005 report, HRSA said that it anticipated promulgating a price policy in conjunction with formalizing instructions for the calculation of 340B ceiling prices. HRSA indicated that in April 2007, it had implemented a 1-year 340B Drug Pricing Program pilot project requesting

manufacturers to voluntarily submit their prices for comparison with the ceiling prices. To the extent that resources permitted, HRSA would review the data that manufacturers and entities voluntarily submitted. HRSA also indicated that oversight mechanisms to validate 340B price calculations and access to certain pricing data by participating entities will be addressed through the initiatives supported by the appropriation funding.

In March 2009, HRSA informed us that it would consider seeking the authority to establish penalties for violations of the PHS Act, § 340B, and is following CMS's practices concerning detailed standards for the 340B price calculations.

In a September 2009 followup review, HRSA indicated that it was drafting guidelines for 340B pricing publications; however, it lacked the resources to complete the project. In September 2009, HRSA reported that its pilot project revealed that apparent price discrepancies between the manufacturer's price and the 340B ceiling price were primarily because of differences in the package size that were being compared.

Section 7102 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) directs 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 limited access to ceiling prices. On September 20, 2010, HRSA published an advance notice of public rulemaking to solicit comments for the development of such regulations.

**Status:** We continue to monitor HRSA's efforts to develop new regulations on 340B program integrity.

### **Related Reports:**

2006 JUL *Review of 340B Prices.* OEI-05-02-00073 [Report](#)

2005 OCT *Deficiencies in the Oversight of the 340B Drug Pricing Program.*  
OEI-05-02-00072 [Report](#)

### **See Also:**

2005 DEC *OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: "340B Program."*  
[Testimony](#)

Public Health > Health Resources and Services Administration

## Improve Monitoring of Ryan White CARE Act Grantees and Subgrantees

**Background:** The Ryan White Comprehensive AIDS Resources Emergency Act (CARE Act) was passed in 1990 and reauthorized in 1996 and 2000. In FY 2001, Congress provided \$597.3 million under Title I and \$977.4 million under Title II of the CARE Act. In 2006, Congress enacted the Ryan White HIV/AIDS Treatment Modernization Act. Title I of the Ryan White HIV/AIDS Treatment Modernization Act provides emergency relief grants to cities disproportionately affected by human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS), and Title II provides grants to States to improve the organization of HIV/AIDS-related health and support services. States distribute Title II funds to subgrantees.

**Findings:** We found that in 2000, Title I and Title II project officers had not adequately monitored sampled grantees (e.g., progress reports were missing, monitoring visits were not conducted, and grantee applications were not used as management tools). HRSA provided limited support to project officers to systematically monitor grantees (e.g., little guidance and training, lack of corrective action plans, and minimal coordination). Grantees' monitoring of subgrantees was limited (75 percent of the sampled grantees did not have comprehensive documentation to demonstrate that they were monitoring subgrantees).

**Recommendations:** HRSA should (1) specify and enforce standards and policies about how project officers should monitor grantees, (2) address training of project officers, (3) standardize corrective actions, (4) increase the number of site visits, (5) improve project officer continuity and coordination, (6) set standards for grantees' monitoring of subgrantees, and (7) increase efforts to monitor grantees' oversight of subgrantees.

**Management Response Summary:** HRSA concurred with our recommendations and indicated that significant administrative changes had occurred since the studies were conducted. In May 2008, HRSA told OIG that it had taken a variety of steps to implement our recommendations. The steps include enhancing training for project officers, developing a site visit protocol for onsite monitoring, and increasing the number of grantee site visits. HRSA reported that in March 2009, it had consolidated its grants operations and project officers and its monitoring of Part A and Part B (formerly Title I and II) grantees and, through its Office of Performance Review, was receiving more information with regard to grantee performance.

Per congressional request, in June 2009, OIG reviewed HRSA's status in addressing our recommendations related to grantees' monitoring of subgrantees. In December 2010, HRSA stated that it was in the process of developing monitoring standards that may be used by CARE Act Part A and Part B programs in a comprehensive onsite review of programmatic, fiscal, and clinical quality management performance of their subgrantees. A site-visit protocol will also be developed specifically to measure compliance with legislative mandates and HRSA policies, grants management requirements, and program guidance. Full implementation of this effort is anticipated in the FY 2011 grant year.

**Status:** We continue to monitor HRSA's progress in implementing our recommendations.

**Related Reports:**

2004 MAR *Monitoring of Ryan White CARE Act Title I and Title II Grantees.*  
OEI-02-01-00640 [Report](#)

2004 MAR *Ryan White CARE Act Title I and Title II Grantees' Monitoring of Subgrantees.*  
OEI-02-01-00641 [Report](#)

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Public Health > Health Resources and Services Administration

## Increase Reporting of Medical Malpractice Cases to the National Practitioner Data Bank

**Background:** 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 National Practitioner Data Bank (NPDB).

**Findings:** We found 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: Indian Health Service (IHS), 290 cases; HRSA, 179 cases; and the National Institutes of Health (NIH), 5 cases.

This underreporting was caused by a number of factors, including (1) lost medical malpractice files; (2) incomplete information in medical malpractice files; (3) 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 (4) the failure to replace a key Program Support Center claims official or to reassign the person's reporting duties.

**Recommendations:** IHS, HRSA, and NIH should each (1) implement corrective action to address unreported cases, (2) improve internal controls involving file management, and (3) assign staff members to assume responsibility for addressing practitioner questions/complaints and data entry of reports to NPDB.

**Management Response Summary:** There was partial concurrence with our recommendations. Before OIG issued its October 2005 report, IHS started reporting cases in which standards of care were not met. HRSA started reporting such cases soon thereafter. In comments on our draft report, 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, IHS had submitted 205 more reports of practitioners to NPDB, and HRSA had submitted 297 reports. 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. For the same period, IHS reported to OIG that it had submitted 33 malpractice payment reports and assigned a specific risk-management team to address complaints and questions and perform data entry of NPDB reports. IHS also told us that it had a risk management and medical liability manual and had established file management controls.

In December 2010, IHS reported that it submitted 37 medical malpractice payment reports to the NPDB in FYs 2009 and 2010, and that the agency is up to date on reporting. HRSA stated that it submitted 22 medical malpractice payment reports to NPDB in FY 2010. NIH stated that it will not submit reports to NPDB until a revised departmental policy is issued.

**Status:** We continue to monitor implementation of our recommendations by IHS, HRSA, and NIH.

**Related Report:**

2005 OCT *HHS Agencies' Compliance With the National Practitioner Data Bank Malpractice Reporting Policy.* OEI-12-04-00310 [Report](#)

Public Health > Health Resources and Services Administration

## Collect Health Education Assistance Loan Debts (New)

**Background:** The Health Education Assistance Loan (HEAL) program began in 1978 to help eligible graduate students in health professions finance their education. Although no new HEAL loans have been issued since September 30, 1998, HRSA continues to oversee prior loans made by participating lenders, such as banks and credit unions. HHS's Program Support Center provides HRSA with debt management services that include many of the activities involved in trying to obtain payments when individuals default on HEAL loans. HHS reimburses lenders for any HEAL loans that are not repaid because of borrowers' default, bankruptcy, death, or total and permanent disability.

**Findings:** We found that of the 486 HEAL defaulters who earned income in FY 2008, 312 made no payments on their loans during that time. These 312 HEAL defaulters earned \$13.4 million and owed \$47.5 million on their loans in FY 2008. Ninety-eight of these defaulters (31 percent) earned \$50,000 or more and were responsible for nearly \$15 million of the \$47.5 million owed.

We also found that of the 174 HEAL defaulters who earned income and made loan payments in FY 2008, nearly half (45 percent) paid less than \$2,000 each during that time. The median income for these defaulters was \$47,331. The 174 HEAL defaulters earned \$9.6 million and owed \$22.5 million on their loans in FY 2008. The amount these defaulters paid totaled \$659,135 in FY 2008, or just 3 percent of their total loan balance during that time.

**Recommendation:** HRSA should work with the Program Support Center to consider obtaining wage data from Federal or State sources to enable HRSA and the Program Support Center to target future collection efforts on defaulters with income.

**Management Response Summary:** HRSA concurred with our recommendation. In September 2010, HRSA stated that the HEAL program might be transferred to the Department of Education (ED). However, there is no further information as to when this transfer might take place or how this transfer would affect the debt collection process.

**Status:** We will continue to monitor HRSA's implementation of our recommendations.

### Related Report:

2010 FEB *Health Education Assistance Loan Defaulters With Income in Fiscal Year 2008.*  
OEI-03-09-00100 [Report](#)

Public Health > Indian Health Service

## Reduce Overpayments for Contract Health Services Hospital Claims and Cap Payments for Nonhospital Services at the Medicare Rate for Those Services

**Background:** Contract Health Services (CHS) contracts with private providers, such as hospitals and physicians, to deliver emergency or specialty services to eligible Indians when an IHS or tribal facility is unable to provide the necessary care. 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. 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.

**Findings:** We found 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.

**Recommendation:** IHS should seek legislative authority to cap payments for CHS nonhospital services at the Medicare rate for those services.

**Savings:** TBD\*

*\*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 between January and March 2008.*

**Management Response Summary:** In its comments on our draft report, IHS concurred with our recommendation. IHS stated that it will continue to meet with tribes and tribal organizations to develop a plan to cap payments for CHS nonhospital services.

**Status:** We will continue to monitor IHS's implementation of our recommendations.

**Related Report:**

2009 SEP     *IHS Contract Health Services Program: Overpayments and Potential Savings.*  
OEI-05-08-00410 [Report](#)

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Public Health > National Institutes of Health

## Increase Oversight of Grantees' Management of Financial Conflicts of Interest in Research (New)

**Background:** NIH is the primary Federal agency responsible for conducting and supporting medical research. Organized into 27 Institutes and Centers, NIH receives billions of dollars annually to support its mission. In FY 2008, the total appropriation was \$29.5 billion, 80 percent of which was distributed through almost 50,000 competitive grants to more than 325,000 investigators at over 3,000 universities, medical schools, and other research institutions across the country and around the world. Pursuant to Federal regulation, each grantee institution receiving NIH funds must have a written policy for identifying financial conflicts of interest and ensuring that conflicts are managed, reduced, or eliminated. Each grantee institution must also certify that existing conflicts will be reported to NIH prior to the expenditure of any funds under that award; that these conflicts have been managed, reduced, or eliminated; and that any subsequently identified conflicts will be reported and will be managed, reduced, or eliminated, at least on an interim basis, within 60 days of identification.

**Findings:** The most common type of financial conflict of interest among NIH-funded researchers is equity ownership. To manage financial conflicts of interest, grantee institutions often require researchers to disclose their conflicts in research publications; however, grantee institutions rarely reduce or eliminate financial conflicts of interest. There are a number of vulnerabilities in grantee institutions' identification, management, and oversight of financial conflicts of interest. We found that because nearly half of the grantee institutions do not require researchers to provide specific amounts of equity or compensation on their financial disclosure forms, specific financial interests of NIH-funded researchers are often unknown. In addition, when researchers submit information regarding their financial interests, grantee institutions do not routinely verify it.

**Recommendations:** NIH should (1) require grantee institutions to provide it with details regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated at the time grant funds are issued; (2) require grantee institutions to collect all information on significant financial interests held by researchers and not just those deemed by researchers to be reasonably affected by the research; (3) require grantee institutions to collect information on specific amounts of equity and compensation from researchers; (4) develop and disseminate guidance on methods to verify researchers' financial interests; (5) ensure that grantee institutions are providing adequate oversight of subgrantee compliance with the Federal financial conflict-of-interest regulations;

(6) ensure that grantee institutions are maintaining proper documentation as outlined in the Federal financial conflict-of-interest regulations, (7) ensure that grantee institutions are taking appropriate actions against researchers who do not follow grantee institutions' financial conflict-of-interest policies and procedures; (8) increase oversight of grantee institutions to ensure that financial conflicts of interest are reported and managed appropriately; and (9) develop regulations that address financial conflicts of interest at grantee institutions.

**Management Response Summary:** NIH did not state in its response to our final report whether it concurs or does not concur with our recommendations. NIH stated that many of the report findings were not made within the context of the current regulation on financial conflicts of interest and therefore, many of the recommendations are difficult to assess and/or cannot be implemented because NIH is bound by the requirements of the current regulation. The current regulation permits NIH to rely on grantee institutions to monitor and enforce researcher compliance with the regulation.

Based on the public comments received in response to the advance notice of proposed rulemaking (ANPRM), and taking into consideration observations made by OIG in its reports and other related information, NIH published a notice of proposed rulemaking on May 21, 2010 (75 Fed. Reg. 28688), and a Supplemental Notice (specifically encouraging comment on whether the proposed enforcement authorities should be further revised and clarified) on July 21, 2010 (75 Fed. Reg. 42362), extending the public comment period until August 19, 2010. NIH is currently in the process of drafting a final rule that NIH believes will increase institutional and NIH oversight and broaden the scope of clinical investigator disclosure.

NIH notes that many of the observations made by the OIG in the report were included in the ANPRM and NPRM and are currently under consideration as the final rule is developed. Because the final rule has not been issued, NIH believes it is premature to take a position on the OIG recommendations at this time.

In addition to the pending regulation, NIH also reported initiating a compliance review to determine if selected NIH-supported institutions have policies and/or procedures that are consistent with the conflict-of-interest requirements set forth in 42 CFR part 50, subpart F. The program targets a review of the top 100 NIH-supported institutions that received grant funding under the American Reinvestment and Recovery Act of 2009 (Recovery Act) in FY 2009 and have not submitted a financial conflict of interest report to the NIH over the past 5 years.

**Status:** OIG maintains its position that increased oversight of grantee institutions is needed to ensure that conflicts of interest are reported and managed appropriately. We will continue to monitor NIH's implementation of our recommendations.

**Related Report:**

2009 NOV *Review of How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health.* OEI-03-07-00700 [Report](#)

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Public Health > National Institutes of Health

## Increase Oversight of Grantee Institutions To Ensure Compliance With Federal Financial Conflict-of-Interest Regulations

**Background:** 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. The regulations require each institution that receives NIH funds to have a written policy for identifying 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. NIH's Office of Extramural Research (OER) develops and implements policies and regulations governing NIH grants and develops and maintains information systems related to extramural research grants administration. 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, via conflict-of-interest reports, to the institutes within 60 days. Institutes are asked but not required to forward reports of grantee conflicts of interest to OER. We examined the extent to which NIH oversees grantee institutions' financial conflicts of interest for FY 2004 through FY 2006.

**Findings:** Our examination of financial conflict-of-interest reports and related documentation revealed that NIH institutes and OER could not provide an accurate count of the financial conflict-of-interest reports received from grantees because the regulations did not explicitly require reporting of the nature of the conflicts or other details; grants officials did not know what types of conflicts existed and had little information on which to follow up; and the institutes' primary method of oversight was to rely on grantees' assurances that financial conflict-of-interest regulations were being followed.

**Recommendations:** NIH should (1) increase oversight of grantee institutions to ensure their compliance with Federal financial conflict-of-interest regulations; (2) require grantee institutions to provide details of the nature of financial conflicts of interest and how they are managed, reduced, or eliminated, and (3) work with the Secretary of HHS to amend the regulation to require submission of such details.

**Management Response Summary:** NIH concurred with the first recommendation but did not concur with the second or third recommendations, saying that grantee institutions are responsible for identifying and managing financial conflicts of interest.

NIH issued an advance notice of proposed rulemaking at 74 Fed. Reg. 21610, May 8, 2009, to gain public input on whether modifications are needed to 42 CFR part 50, subpart F. NIH invited public comments on the potential regulation of this area, particularly on (1) expanding the scope of the regulation and disclosure of interests, (2) defining “significant financial interest,” (3) identifying and managing conflicts by grantee institutions, (4) ensuring grantee institution compliance, (5) requiring grantee institutions to provide more information to NIH, and (6) broadening the regulation to address institutional conflicts of interest. In response to public comments, NIH issued a notice at 75 Fed. Reg. 28688, May 21, 2010, with revisions to the ANPRM. If enacted as proposed, this regulation would implement several of OIG’s recommendations, such as requiring grantee institutions to provide detailed information on financial conflicts and how they are managed. NIH is developing a final regulation.

In addition to the pending regulation, NIH also reported initiating a compliance review to determine if selected NIH-supported institutions have policies and/or procedures that are consistent with the conflict-of-interest requirements set forth in 42 CFR part 50, subpart F. The program targets a review of the top 100 NIH-supported institutions that received grant funding under the Recovery Act in FY 2009 and have not submitted a financial conflict-of-interest report to NIH over the past 5 years.

**Status:** We continue to recommend that NIH collect details of the nature and management of financial conflicts of interest as part of its oversight responsibility of grantee institutions. We will continue to monitor the progress of the rulemaking. In the interim, OIG recommends that NIH use its authority pursuant to 42 CFR § 50.604(g)(3) to request details on the nature and management of financial conflicts of interest at grantee institutions.

### **Related 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 [Report](#)
- 2008 JAN *National Institutes of Health: Conflicts of Interest in Extramural Research.* OEI-03-06-00460 [Report](#)

## Human Services Programs

Human Services > Administration on Aging

### Use Voluntary Contributions To Expand Services for the Elderly

**Background:** Administration on Aging (AoA) regulations permit States to use voluntary contributions to meet cost-sharing or matching grant requirements. However, during the audit period, this use of contributions was contrary to the Older Americans Act of 1965 (OAA), which requires that voluntary contributions be used to increase services for the elderly.

**Findings:** According to their financial status reports, 28 States and the District of Columbia erroneously used \$90.8 million in voluntary contributions in FY 1996 to meet cost-sharing or matching grant requirements.

**Recommendations:** AoA should revise its regulations in accordance with the OAA.

**Savings:** \$90.8 million\*

*\*Estimated savings are based on information in FY 1996 financial status reports for all States, the District of Columbia, and Puerto Rico.*

**Management Response Summary:** AoA concurred with the recommendation. AoA subsequently told us that because the OAA Amendments of 2006 (OAAA) changed provisions relating to voluntary contributions, it was determining the kinds of regulatory changes needed as a result. As of October 2010, no regulatory changes had been made.

**Status:** We continue to monitor any regulatory changes in relation to AoA's progress on implementation of this recommendation.

#### Related Report:

2001 FEB *States' Use of Voluntary Contributions Under Title III of the Older Americans Act.* A-12-00-00002 [Report](#)

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Human Services > Administration on Aging

## Ensure That States' Cost-Sharing Practices Comply With Requirements and Improve Data Quality

**Background:** In 2000, amendments to the OAA allowed States to implement cost sharing for certain OAA services. The AoA defines "cost sharing" as a method of requiring a recipient to share in the cost of the service received. The amendments include a number of requirements to protect low-income older individuals' access to services.

**Findings:** We found that as of March 2005, States' implementation of cost sharing had been limited. Twelve States had implemented cost sharing for at least one OAA service in at least one part of the State. None of these States had implemented cost sharing for all allowed OAA services. AoA had provided limited guidance to States about implementing cost sharing. States had not implemented cost sharing in accordance with the OAA requirements designed to protect low-income older individuals' access to services. Also, AoA's participation data could not be used to determine the impact of cost sharing on participation, primarily because States reported participation data in the National Aging Program Information System/State Program Reports (NAPIS/SPR) differently.

**Recommendations:** AoA should (1) ensure that States' cost-sharing practices comply with OAA requirements, (2) provide more guidance to States about cost sharing, and (3) improve the quality of its data so that any effects of cost sharing can be determined.

**Management Response Summary:** AoA partially concurred with our recommendations. 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 guidance for State Units on Aging. AoA did not concur with the recommendation to improve the NAPIS/SPR data, noting that it had made several improvements to these data, such as developing a software reporting structure and training manual. Despite these improvements, our work indicated that States varied in their reporting of data. These data are essential for cost-sharing and AoA performance measurements.

**Status:** We will continue to monitor AoA's progress in implementing our recommendations.

**Related Report:**

2006 SEP     *Cost Sharing for Older Americans Act Services.* OEI-02-04-00290 [Report](#)

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Human Services > Administration for Children and Families

## Delineate Roles and Enforce Unaccompanied Children's Services Requirements

**Background:** An unaccompanied alien child is defined in 6 U.S.C. § 279(g)(2) as 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, the Department of Homeland Security (DHS) apprehends and detains the child and contacts the Administration for Children & Families (ACF) Office of Refugee Resettlement (ORR), which contacts a facility funded by the Division of Unaccompanied Children's Services (DUCS). Pursuant to the Homeland Security Act of 2002 (HSA), the Director of ORR is responsible for the care and custody of unaccompanied alien children, and DHS is responsible for immigration benefits and enforcement. The Flores Agreement (so named for a class-action lawsuit challenging detention policies and procedures for children in Federal custody) includes minimum standards for placement, care, and release to sponsors of alien children in Federal custody.

**Findings:** In our case file reviews of unaccompanied children apprehended by DHS who were in DUCS-funded facilities 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, DUCS program oversight, and the delineation of responsibilities between DHS and HHS.

**Recommendations:** ACF should establish a memorandum of understanding (MOU) between HHS and DHS to clearly delineate the roles and responsibilities of each Department.

**Management Response Summary:** ACF did not indicate whether it concurred with our recommendation. It said that ORR was drafting a *Joint Operations Manual* (JOM) with DHS, with the ultimate goal of drafting an MOU. In December 2010, ACF informed us that ORR and DHS were updating the draft version of the JOM to conform to the new statutory requirements in the Trafficking Victims Protection Reauthorization Act of 2008. DUCS and DHS are also in the process of drafting regulations outlining responsibilities that have changed due to the passage of the act.

**Status:** While we acknowledge the actions ACF has taken to address the other recommendations in this report, we continue to recommend that an MOU between HHS and DHS be implemented.

**Related Report:**

2008 MAR *Division of Unaccompanied Children's Services: Efforts To Serve Children.*  
OEI-07-06-00290 [Report](#)

## Departmentwide Issues

Departmentwide Issues > Interagency Coordination

### Strengthen State Protections for Persons With Disabilities in Residential Settings

**Background:** Several HHS operating divisions fund programs or services that play a role in protecting persons with disabilities from abuse or neglect. For facilities receiving Medicare or Medicaid funds—including nursing homes, psychiatric facilities, and intermediate care facilities for persons with mental retardation—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.

**Findings:** We found that between 1999 and 2000, about 90 percent of persons with disabilities in residential facilities were in facilities that are not subject to CMS oversight 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.

**Recommendations:** CMS, ACF, SAMHSA, and FDA should work cooperatively to provide information and technical assistance to States to (1) improve the reporting of potential abuse or neglect of persons with disabilities across all residential settings, (2) strengthen investigation and resolution processes, (3) assist in analyzing incident data to identify trends that indicate systemic problems, and (4) identify the nature and causes of incidents to prevent future abuse.

**Management Response Summary:** CMS, ACF, SAMHSA, and FDA concurred with our recommendation to work cooperatively and 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. Currently, SAMHSA is establishing a national technical assistance center for seclusion and restraint and trauma-informed care. The contract was awarded in September 2010 and the center is expected to be fully operational in January 2011. 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.

**Status:** We continue to monitor the progress made on these recommendations.

**Related Report:**

2001 MAY *Reporting Abuses of Persons with Disabilities.* A-01-00-02502 [Report](#)

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Departmentwide > Financial Management

## Improve Financial Analysis and Reporting Processes

**Background:** The Government Management Reform Act of 1994 (GMRA) requires that many Federal agencies, including HHS, prepare annual financial statements. 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 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.

**Findings:** The FY 2010 financial statement audit noted that internal control weaknesses continued in HHS's financial management systems and financial analyses and oversight. HHS's lack of an integrated financial management system impaired its ability to support and analyze account balances. Manual intervention was required to correct transactions that did not post in accordance with standards and to transfer information between systems that did not interface electronically.

In addition, certain reconciliations and account analyses were not adequately or promptly performed to ensure that differences were identified and resolved and that invalid or old transactions were identified and closed. Also, management has not implemented corrective action for some longstanding deficiencies in internal control. HHS's financial management systems did not substantially comply with Federal financial management systems requirements or the U.S. Government Standard General Ledger at the transaction level.

Furthermore, general control issues related to the design and operation of key controls related to security management, access controls, configuration management, segregation of duties, and contingency planning were noted. In addition, weaknesses were noted in general controls, business process controls, interface controls, and data management system controls for specific financial applications.

**Recommendations:** HHS should (1) continue to develop and refine its financial management systems and processes to improve its accounting, analysis, and oversight of financial management activity and (2) provide a secure computing environment for critical applications throughout all the operating divisions.

**Management Response Summary:** In the *FY 2010 Agency Financial Report*, issued in November 2010, HHS generally concurred with the findings in the audit report. HHS will prepare corrective action plans to address the findings.

**Status:** 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.

**Related Report:**

2010 NOV *Department of Health and Human Services Fiscal Year 2010 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 2010*. A-17-10-00001 (pp. II-7, II-53) [Report](#)

## Appendix: Acronyms and Abbreviations

The appendix includes a list of selected acronyms and abbreviations related to terms and organizations, followed by a second list for public laws.

### Terms and Organizations

ACF	Administration for Children & Families
ACR	adjusted community rate proposals
AFR	Agency Financial Report
AHRQ	Agency for Healthcare Research and Quality
AIDS	acquired immune deficiency syndrome
AMA RUC	American Medical Association Relative Value Scale Update Committee
AMP	average manufacturer price
AoA	Administration on Aging
APC	Advanced Primary Care
ASC	Accredited Standards Committee
ASC	ambulatory surgical center
ASP	average sales price
ASPR	Assistant Secretary for Preparedness and Response
ASR	annual status report
AWP	average wholesale price
BLS	Bureau of Labor Statistics
CBO	Congressional Budget Office
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CERT	Comprehensive Error Rate Testing (program)
CFC	Conditions for Coverage
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance program (AKA SCHIP)
CHS	Contract Health Services
CLAS	Culturally and Linguistically Appropriate Services in Health Care
CMP	civil monetary penalty
CMS	Centers for Medicare & Medicaid Services
CMS-ARTS	CMS Analysis, Reporting, and Tracking System
CoP	Conditions of Participation
CPI	Consumer Price Index
CPM	clinical performance measure
CR	change request
CY	calendar year
DEA	Drug Enforcement Administration
DHS	Department of Homeland Security
DME	durable medical equipment
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DOJ	Department of Justice
DPNA	denial of payment for new admissions
DRG	diagnosis-related group
DSH	disproportionate share hospital

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DUCS	Division of Unaccompanied Children's Services
E&M	evaluation and management
ED	Department of Education
EBDP	Entitlement Benefits Due and Payable
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment
ESRD	end stage renal disease
FACS	Financial Accounting Control System
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FFS	fee for service
FI	fiscal intermediary
FMO	field marketing organization
FPEA	Fraud Prevention and Early Abatement
FUL	Federal upper limit
FY	fiscal year
GAO	Government Accountability Office
GME	graduate medical education
HAC	hospital-acquired condition
HEAT	Health Care Fraud Prevention and Enforcement Action Team
HEAL	Health Education Assistance Loan
HHA	home health agency
HHS	Department of Health & Human Services
HIGLAS	Healthcare Integrated General Ledger Accounting System
HIPDB	Healthcare Integrity and Protection Data Bank
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IND	investigational new drug
IOM	Institute of Medicine
IT	information technology
JOM	Joint Operations Manual
JSM/TDL	joint signature memorandum/technical direction letter
LCD	local coverage determination
LEP	limited English proficient
LTC	long term care
M+C	Medicare+Choice
MA	Medicare Advantage
MAC	Medicare administrative contractor
MAO	Medicare Advantage organization
MCO	managed care organization
MED	Medicare Exclusions Database
Medi-Medi	Medicare and Medicaid data matches
MEDIC	Medicare prescription drug integrity contractor
MDS	minimum data set
MOU	memorandum of understanding
MLN	Medicare Learning Network
MSIS	Medicaid Statistical Information System
NAPIS/SPR	National Aging Program Information System/State Program Reports
NCCI	National Correct Coding Initiative
NDC	National Drug Code
NF	nursing facility

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NLA	National Limit Amount
NIH	National Institutes of Health
NIST	National Institutes of Standards and Technology
NPDB	National Practitioner Data Bank
NPI	national provider identifiers
NPRM	notice of proposed rulemaking
NSC	National Supplier Clearinghouse
OACT	Office of the Actuary
OAI	official action indicated
OCR	Office for Civil Rights
OER	Office of Extramural Research (NIH)
OFM	Office of Financial Management
OIG	Office of Inspector General
OMB	Office of Management and Budget
OMH	Office of Minority Health
OPPS	Outpatient Prospective Payment System
ORR	Office of Refugee Resettlement (ACF)
PCS	personal care services
PDE	prescription drug event
PDP	prescription drug plan
PECOS	Provider Enrollment, Chain, and Ownership System
PERM	Payment Error Rate Measurement (program)
PHS	Public Health Service
PMD	power mobility device
POA	present on admission
POS FE	Point-of-Sale Facilitated Enrollment
PPI	Producer Price Index
PPS	prospective payment system
PSC	program safeguard contractor
PSO	patient safety organization
QA	quality assurance
QAPI	Quality Assurance and Performance Improvement
QIO	quality improvement organization
RAC	Recovery Audit Contractor
RHC	rural health clinic
RUC	Relative Value Scale Update Committee
RVU	relative value unit
SAMHSA	Substance Abuse and Mental Health Services Administration
S&C	survey & certification letter
SGE	special Government employee
SNF	skilled nursing facility
SOSI	statement of social insurance
SOW	statement of work
TBD	to be determined
TrOOP	True out-of-pocket costs for Part D
UPIN	unique physician identification number
UPL	Upper Payment Limit
VA	Department of Veterans Affairs
ZPIC	Zone Program Integrity Contractor

## Public Laws

The *Compendium* refers to the following acronyms and abbreviations for Public Laws (P.L.).

Affordable Care Act	Patient Protection and Affordable Care Act of 2010, P.L. No. 111-148.
BBA	Balanced Budget Act of 1997, P.L. No. 105-33.
BBRA	Balanced Budget Refinement Act of 1999, P.L. No. 106-113.
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, P.L. No. 106-554.
CARE Act	Ryan White Comprehensive AIDS Resources Emergency Act of 1990, P.L. No. 101-381.
COBRA	Consolidated Omnibus Budget Reconciliation Act of 1985, P.L. No. 99-272.
DRA	Deficit Reduction Act of 2005, P.L. No. 109-171.
FDAA	FDA Amendment Act of 2007, P.L. No. 110-85.
FDAMA	Food and Drug Administration Modernization Act of 1997, P.L. No. 105-115.
FDCA	Food, Drug, and Cosmetic Act of 1938, P.L. No. 75-717.
FFMIA	Federal Financial Management Improvement Act of 1996, P.L. No. 104-208.
FMFIA	Federal Managers' Financial Integrity Act of 1982, P.L. No. 97-255.
GMRA	Government Management Reform Act of 1994, P.L. No. 103-356.
HCQIA	Health Care Quality Improvement Act of 1986, P.L. No. 99-660.
HIPAA	Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191.
HSA	Homeland Security Act of 2002, P.L. No. 107-296.
IDEA	Individuals With Disabilities Education Act, so named by the Education of the Handicapped Act Amendments of 1990, P.L. No. 101-476. Formerly, Education of the Handicapped Act Amendments of 1983, P.L. No. 98-199.
MIPPA	Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275.
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173.
MMSEA	Medicare, Medicaid, and SCHIP Extension Act of 2007, P.L. No. 110-173.
OAA	Older Americans Act of 1965, P.L. No. 89-73.
OAAA	OAA Amendments of 2006, P.L. No. 109-365.
OBRA 1981	Omnibus Budget Reconciliation Act of 1981, P.L. No. 97-35.
OBRA 1986	Omnibus Budget Reconciliation Act of 1986, P.L. No. 99-509.
OBRA 1987	Omnibus Budget Reconciliation Act of 1987, P.L. No. 100-203.
OBRA 1990	Omnibus Budget Reconciliation Act of 1990, P.L. No. 101-508.
OBRA 1993	Omnibus Budget Reconciliation Act of 1993, P.L. No. 103-296.
PHS Act	Public Health Service Act of 1944.
PRIOA	Peer Review Improvement Act of 1982, P.L. No. 97-248.
Recovery Act	American Recovery and Reinvestment Act of 2009, P.L. No. 111-5.
TRHCA	Tax Relief and Health Care Act of 2006, P.L. No. 109-432.