

# Part I: Medicare Part A and Part B

## Part I:

### Medicare Part A and Part B

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## 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](#)

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# 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

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

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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](#)

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

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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.

**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.

**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](#)



- 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](#)