Part I:

Medicare Reviews

Part I: Medicare Reviews

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Medicare Reviews

The Office of Inspector General (OIG) relies on the Department of Health & Human Services (HHS) management, other policymakers in the executive branch, States, and Congress to implement the recommendations that arise from our reviews. Many of our recommendations are directly implemented by organizations within HHS, and some are acted on by States that collaborate with HHS to administer, operate, and/or oversee joint programs, such as Medicaid and Head Start program grants. Congress often incorporates our recommendations into legislative actions, resulting in substantial improvements in HHS programs and operations and in funds being made available for better use.

Medicare Part A and Part B

Hospitals

Medicare > Part A and Part B > Hospitals > Adverse Events

Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries

Of the nearly 1 million Medicare beneficiaries who were discharged from hospitals in October 2008, an estimated one in seven (13.5 percent) experienced adverse events during their hospital stays.

To establish an estimated adverse events incident rate, we included in our review:

- the National Quality Forum's Serious Reportable Events;
- Medicare hospital-acquired conditions (HAC); and
- events resulting in prolonged hospital stays, permanent harm, life-sustaining intervention, or death.

The incidence rate projects to about 134,000 Medicare beneficiaries experiencing at least 1 adverse event in hospitals during a single month, with such events contributing to the deaths of a projected 15,000 beneficiaries. Physician reviewers determined that 44 percent of events were preventable, most commonly because of medical errors, substandard care, and inadequate patient monitoring and assessment.

We recommended that Administration for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) broaden patient safety

efforts to include all types of adverse events and enhance efforts to identify events. We also recommended that CMS provide more incentives for hospitals to reduce adverse events through its payment and oversight functions, including strengthening the Medicare HAC policy and holding hospitals accountable for adopting evidence-based practices. AHRQ and CMS concurred with our recommendations. *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*. OEI-06-09-00090. Full Report

Medicare > Part A and Part B > Hospitals > Hospital-Based Outpatient Services

Payments Exceeding Charges for Outpatient Services Processed by Wisconsin Physicians Service Insurance Corporation for Calendar Years 2004 through 2007

Wisconsin Physicians Service Insurance Corporation (WPS), a Medicare contractor, made incorrect Medicare payments to hospitals in excess of their charges for outpatient services for calendar years (CY) 2004 through 2007. The incorrect payments included overpayments totaling $9.2 million, which hospitals had not refunded by the start of our audit.

Medicare pays hospitals for outpatient services using the hospital outpatient prospective payment system. In this method of reimbursement, the Medicare payment is not based on the amount that the hospital charges. Consequently, the billed charges (the prices that a hospital sets for its services) do not affect the current Medicare payment amounts. Billed charges generally exceed the amount that Medicare pays the hospital. Therefore, a Medicare payment that significantly exceeds the billed charges is at high risk of overpayment. The incorrect payments involved excessive units of service, Healthcare Common Procedure Coding System (HCPCS) codes that did not reflect the procedures performed, unallowable services, and lack of supporting documentation.

We recommended that WPS recover the $9.2 million in identified overpayments and use the results of this audit in its hospital education activities. WPS described actions that it had taken or planned to take to address our recommendations. *Review of Payments Exceeding Charges for Outpatient Services Processed by Wisconsin Physicians Service Insurance Corporation for Calendar Years 2004 Through 2007*. A-07-10-04167. Full Report

Nursing Homes

Medicare > Part A and Part B > Nursing Homes > Part B Payments During Part A Stays

Payments for Ambulatory Surgical Center Services Provided to Beneficiaries in Skilled Nursing Facility Stays Covered Under Medicare Part A

Medicare contractors made at least an estimated $6.6 million in overpayments to ambulatory surgical centers (ASC) for services provided to beneficiaries during Part A skilled nursing facility (SNF) stays in CYs 2006 through 2008.

All 100 services that we reviewed, totaling $103,000, were already included in the SNFs' Part A payments but were nevertheless billed to Medicare Part B. As a result, Medicare paid twice for these services.

We recommended that the CMS instruct its Medicare contractors to: (1) recover the $103,000 in overpayments for the 100 incorrectly billed services that we identified; (2) review the 20,806 services that we did not review and recover overpayments estimated to total at least $6.5 million; and (3) provide guidance to ASCs on consolidated billing requirements and the need for timely and accurate communication between ASCs and SNFs about beneficiaries' Medicare Part A status. We also recommended that CMS establish an edit in the Common Working File (CWF) to prevent Part B payments for ASC services that are subject to consolidated billing. *Payments for Ambulatory Surgical Center Services Provided to Beneficiaries in Skilled Nursing Facility Stays Covered Under Medicare Part A in Calendar Years 2006 through 2008*. A-01-09-00521. Full Report

Medicare > Part A and Part B > Nursing Homes > SNF Payment Rules

Questionable Billing by Skilled Nursing Facilities

From 2006 to 2008, SNFs increasingly billed for higher-paying resource utilization groups, even though beneficiary characteristics remained largely unchanged.

In that period, Medicare payments to SNFs for ultra-high therapy increased by nearly 90 percent, rising from $5.7 billion to $10.7 billion. For billing purposes, SNFs categorize Medicare beneficiaries into resource utilization groups (RUG) based on their care and resource needs at various points during their stays. Payment rates are generally higher for beneficiaries who are in groups that require physical, speech, or occupational therapy. The RUGs for ultra-high therapy apply to those beneficiaries needing higher levels of therapy. Medicare generally pays the most for ultra-high level therapy. This review raised concerns about the potentially inappropriate use of higher-paying RUGs, particularly those for ultra-high therapy.

We recommended that CMS: (1) monitor overall payments to SNFs and adjust rates, if necessary; (2) change the current method for determining how much therapy is needed to ensure appropriate payments; (3) strengthen monitoring of SNFs that are billing for higher-paying RUGs; and (4) follow up on the SNFs identified as having questionable billing. CMS concurred with three of the four recommendations. It did not concur with the recommendation to change the method for determining how much therapy is needed but stated that it is committed to pursuing improvements to the SNF payment system. We remain concerned that the payment system continues to provide incentives to SNFs to bill for more therapy than is needed, and we strongly encourage CMS to pursue the options we recommended to reduce this vulnerability. *Questionable Billing by Skilled Nursing Facilities*. OEI-02-09-00202. Full Report

Medicare > Part A and Part B > Nursing Homes > Background Checks of Employees

Nursing Facilities' Employment of Individuals With Criminal Convictions

Almost all (92 percent) of nursing facilities in our review employed at least one individual with at least one criminal conviction.

We analyzed criminal history records maintained by the Federal Bureau of Investigation (FBI) and found that overall, 5 percent of nursing facility employees had at least one criminal conviction. Forty-four percent of employees with criminal convictions committed crimes against property such as burglary, shoplifting, and writing bad checks. Most convictions occurred prior to employment. We found that the FBI's records do not contain information on whether the victim of a crime was a nursing facility resident and therefore cannot be used by themselves to determine whether a conviction disqualifies an individual from nursing facility employment. We also found that most States required, and/or nursing facilities reported conducting, some type of background check.

The Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) requires the Secretary of HHS to carry out a nationwide program for States to conduct national and statewide criminal background checks for direct patient access employees of nursing facilities and other providers. States may participate in the national background check program by entering into agreements with the Secretary.

In light of the background check program that the Affordable Care Act created, we recommended that CMS develop background check procedures, including (1) clearly defining the employee classifications that are direct patient access employees and (2) working with participating States to develop a list of convictions that disqualify an individual from nursing facility employment under the Federal regulation and timeframes in which each conviction bars the individual from employment. CMS agreed with our recommendation. *Nursing Facilities' Employment of Individuals With Criminal Convictions*. OEI-07-09-00110. Full Report

Other Medicare Services

Medicare > Part A and Part B > Outpatient Therapy Services

Questionable Billing for Medicare Outpatient Therapy Services

Medicare's per-beneficiary spending on outpatient therapy services in Florida's Miami-Dade County was three times the national average in 2009.

We identified 20 high-utilization counties that had, in 2009, (1) the highest average Medicare payment per beneficiary and (2) more than $1 million in total Medicare payments for outpatient therapy. We analyzed Miami-Dade County separately from the other 19 counties because it had the highest average Medicare payments per beneficiary among the high-utilization counties and the highest total Medicare payments for outpatient therapy in 2009. Medicare's per-beneficiary spending on outpatient therapy services to the 19 other high-utilization counties as a group was 72 percent greater than the national average. We found that for five of six questionable billing characteristics that may indicate fraud, Miami-Dade's levels were at least three times the national levels. The other 19 counties also exhibited questionable billing. As a group, the other 19 counties had at least twice the national levels for five of the six questionable billing characteristics.

We recommend that CMS (1) target outpatient therapy claims in high-utilization areas for further review, (2) target outpatient therapy claims with questionable billing characteristics for further review, (3) review geographic areas and providers with questionable billing and take appropriate action based on results, and (4) revise the current therapy cap exception process. CMS concurred with the recommendations. *Questionable Billing for Medicare Outpatient Therapy Services*. OEI-04-09-00540. Full Report

Medicare > Part A and Part B > Medical Equipment and Supplies > Diabetic Testing Strips

Medicare Market Shares of Mail Order Diabetic Testing Strips

We found that suppliers submitted claims for at least 75 types of mail order diabetic testing strips during the 3-month period ending December 2009. We projected that 2 types accounted for approximately 26 percent of the Medicare mail order market share, 7 types accounted for approximately 50 percent, and 19 types accounted for approximately 81 percent.

Section 154(d)(3)(B) of the Medicare Improvements for Patients and Providers Act (MIPPA) requires OIG to complete this review to determine market shares of diabetic testing strips. MIPPA requires that future rounds of Competitive Bidding Program contracts for mail order diabetic testing strips be awarded to suppliers who provide at least 50 percent, by volume, of all types of mail order diabetic testing strips (the MIPPA 50-percent requirement). Our findings may help in determining

whether future rounds of suppliers' mail order diabetic test strip bids comply with the MIPPA 50-percent requirement. Our report provided the data requested by MIPPA but did not make recommendations. *Medicare Market Shares of Mail Order Diabetic Testing Strips*. OEI-04-10-00130. Full Report

Medicare > Part A and Part B > Medical Equipment and Supplies > Blood-Glucose Test Strips and Lancets

Medicare Claims for Home Blood-Glucose Test Strips and Lancets

We estimated that about $169.7 million could have been saved for CY 2007 had controls been in place at four Medicare administrative contractors to ensure that claims for blood-glucose test strips and/or lancets complied with certain Medicare documentation requirements.

Medicare Part B covers test strips and lancets that physicians prescribe for diabetics. Medicare utilization guidelines allow up to 100 test strips and 100 lancets every month for insulin-treated diabetics and every 3 months for non-insulin-treated diabetics. Additional requirements apply for reimbursements of claims for quantities of test strips and lancets that exceed the utilization guidelines (referred to as high-utilization claims).

To help achieve potential savings for the Medicare program in the future, we recommended that the contractors (1) implement system edits to identify high-utilization claims for test strips and/or lancets and work with CMS to develop cost-effective ways of determining which claims should be further reviewed for compliance with Medicare documentation requirements; (2) implement system edits to identify claims for test strips and/or lancets that have overlapping service dates for the same beneficiary; and (3) enforce Medicare documentation requirements for claims for test strips and/or lancets by identifying durable medical equipment (DME) suppliers with a high volume of high utilization claims, performing prepayment reviews of those suppliers, and referring them to the OIG or CMS for further review or investigation when necessary. Following are the contractor names and audit report titles and numbers for our reviews.

- National Government Services, Inc. *Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction B*. A-09-08-00044. Full Report
- CIGNA Government Services, LLC and Palmetto Government Benefits Administrators, LLC. *Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C*. A-09-08-00045. Full Report
- Noridian Administrative Services, LLC. *Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets—Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction D*. A-09-08-00046. Full Report

Part B Prescription Drugs

Medicare > Part A and Part B > Part B Prescription Drugs > Payment Calculations

Medicare Payments for Newly Available Generic Drugs

Medicare and its beneficiaries could have saved an estimated $111 million had payment amounts reflected actual sales prices during the initial period in which 16 generic drugs became available.

The potential savings account for 25 percent of total expenditures for the drugs during the same period. We found that during the period of initial generic availability, generic versions of these drugs were being administered or dispensed to beneficiaries, but Medicare was still paying brand prices. Manufacturers are required to submit average sales price (ASP) data to CMS within 30 days after the close of each quarter, and those data are used to calculate the payment amounts for the following quarter. As a result, there is a two-quarter lag between the point at which drug sales occur and when the payment amounts reflect those sales. This lag is especially problematic when newly available generic drugs enter the market because their ASPs are often substantially lower than their brand counterparts; however, payment amounts remain at the higher brand level for two quarters or more. According to the Food and Drug Administration (FDA), 26 of the 48 brand-only drugs with the highest Part B expenditures in 2008 could have first generic versions approved in the next several years, meaning that the vulnerability posed by the two-quarter lag likely will continue to grow.

We recommended that CMS work with Congress to require manufacturers of first generics to submit monthly ASP data during the period of initial generic availability. This could substantially reduce the two-quarter lag and make Medicare payment amounts more reflective of market prices. If CMS finds this to be an effective means for alleviating the financial impact of the two-quarter lag, it could consider requiring monthly ASP submissions for all Part B-covered drugs. CMS did not concur with our recommendation, citing potential problems with manufacturer price submissions and increased administrative burdens under a proposed monthly ASP reporting requirement. We maintain that the savings from a reduced reimbursement lag may outweigh any issues involved with implementing a monthly ASP reporting system. *Medicare Payments for Newly Available Generic Drugs*. OEI-03-09-00510.
Full Report

Medicare > Part A and Part B > Part B Prescription Drugs > Payment Calculations

Comparison of Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement of Part B Prescription Drugs

The Social Security Act, § 1847A(d), requires OIG to compare ASPs to average manufacturers prices (AMP) and notify the Secretary of HHS if the ASP for a particular drug exceeds the drug's AMP by a threshold of 5 percent. If the 5-percent threshold is met, pursuant to section 1847A(d)(3)(A), the Secretary may disregard the ASP for the drug when setting reimbursement and shall substitute the payment amount with the lesser of either the widely available market price or 103 percent of the AMP. Although CMS has yet to make any changes to Part B drug reimbursement as a result of the reviews, the agency published a proposed rule at 75 Fed. Reg. 40040, 40259 (July 13, 2010) that specified circumstances under which AMP-based price substitutions would occur. However, the agency opted not to finalize the price substitution policy from the proposed rule. Some of OIG's previous reports comparing ASPs and AMPs have contained recommendations, which we continue to support. We did not make additional recommendations in the reports below.

- **First-Quarter 2010: Impact on Third Quarter 2010**. We identified 38 HCPCS codes with ASP that exceeded AMP by at least 5 percent in the first quarter of 2010. Of these, 13 had complete AMP data (i.e., AMP data for every drug product that CMS used to establish reimbursement amounts). If reimbursement amounts for all 13 codes with complete AMP data had been based on 103 percent of the AMPs during the third quarter of 2010, we estimate that Medicare expenditures would have been reduced by about $988,000 in that quarter alone. If CMS's proposed price substitution policy had been in effect, reimbursement amounts for 10 of the 13 drugs with complete AMP data would have been reduced, resulting in estimated savings of $840,000 in the third quarter of 2010. We could not compare ASPs and AMPs for 68 HCPCS codes because AMP data were not submitted for any of the national drug codes (NDC) that CMS used to calculate reimbursement. Manufacturers for 23 percent of these NDCs had Medicaid drug rebate agreements and were therefore generally required to submit AMPs. OIG will continue to work with CMS to evaluate and pursue appropriate actions against those manufacturers that fail to submit required data. *Comparison of First-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2010***.** OEI-03-10-00440. Full Report

- **Second-Quarter 2010: Impact on Fourth Quarter 2010.** We identified 25 HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the second quarter of 2010. Of these, 10 had complete AMP data (i.e., AMP data for every drug product that CMS used to establish reimbursement amounts). If reimbursement amounts for all 10 codes with complete AMP data had been based on 103 percent of the AMPs during the fourth quarter of 2010, we estimate that Medicare

expenditures would have been reduced by $713,000 in that quarter alone. We could not compare ASPs and AMPs for 54 HCPCS codes because AMP data were not submitted for any of the NDCs that CMS used to calculate reimbursement. Manufacturers for 16 percent of these NDCs had Medicaid drug rebate agreements and were therefore generally required to submit AMPs. OIG will continue to work with CMS to evaluate and pursue appropriate actions against those manufacturers that fail to submit required data. *Comparison of Second-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2010*. OEI-03-11-00030.
Full Report

Medicare > Part A and Part B > Part B Prescription Drugs > Inhalation Drugs

Questionable Billing for Brand-Name Inhalation Drugs

Medicare payments to South Florida suppliers for the inhalation drug budesonide were reduced by almost half after Medicare implemented a utilization edit for the drug in September 2008. However, the decreases were offset by payments for the inhalation drug arformoterol (for which there was no edit), which then more than doubled within 6 months. Medicare paid South Florida suppliers for up to 10 times more units of arformoterol than were distributed for sale in the geographic area.

The substantial difference between the sales data provided by arformoterol's manufacturer and the claims data for South Florida suppliers suggests that these suppliers were billing for drugs that may not have been actually purchased.

We recommended that CMS (1) require DME contractors to implement utilization edits in high-fraud areas as soon as Medicare begins paying for a brand-name drug, (2) monitor utilization changes among brand-name inhalation drugs, (3) strengthen initial claim review processes to focus on prevention of improper payments, and (4) perform site visits and request documentation to support budesonide and arformoterol billings from the South Florida suppliers that we will refer for further review. CMS concurred with our recommendations; however, the concurrence with our first recommendation included the caveat that certain procedures, such as developing and issuing a local coverage determination, would need to be followed before implementing edits. *Questionable Billing for Brand-Name Inhalation Drugs in South Florida*. OEI-03-09-00530. Full Report

Medicare > Part A and Part B > Part B Prescription Drugs > Hospital-Based Outpatient Prescription Drugs

Payment for Drugs under the Hospital Outpatient Prospective Payment System

We found that Medicare payments were 31 percent higher than acquisition costs among responding hospitals that participate in the Public Health Service Act section

340B drug pricing program (340B Program) and 1 percent higher than acquisition costs among responding non-340B hospitals for selected separately payable drugs.

The 340B Program, which is overseen by the Health Resources and Services Administration (HRSA), was created to assist entities that provide services to disproportionately low-income, uninsured, and underinsured populations and allow them to purchase drugs at reduced prices. Under the 340B Program, pharmaceutical manufacturers agree to charge at or below statutorily defined prices, known as the 340B ceiling prices, for certain sales to certain covered entities.

The hospital Outpatient Prospective Payment System (OPPS) was implemented to pay hospitals for Part B outpatient services including, but not limited to, certain Part B-covered drugs. The OPPS payment for drugs is generally divided into two categories: separately payable drugs and packaged drugs. For more than half of the selected drugs, Medicare payments exceeded non-340B hospital acquisition costs. For the remaining drugs, Medicare payments were below average non-340B acquisition costs by between 0.6 and 11 percent. This report did not contain recommendations. *Payment for Drugs Under the Hospital Outpatient Prospective Payment System*. OEI-03-09-00420. Full Report

Medicare Part A and Part B Administration

Medicare > Part A and Part B > Administration > Program Integrity > Payment Suspensions

Use of Payment Suspensions to Prevent Inappropriate Medicare Payments

We found that CMS used payment suspensions in 2007 and 2008 almost exclusively as a tool to fight fraud, though the sanction is available in overpayment circumstances short of fraud, and that CMS's guidance on payment suspensions to its contractors has incomplete or inconsistent requirements. In particular, guidance lacks specificity in terms of the types of information that its contractors should submit with a request for a suspension, as well as in describing the circumstances in which an extension is permitted.

After we collected data for this evaluation, the Affordable Care Act established new provisions for payment suspensions. The Affordable Care Act states that a provider's payments may be suspended based on a credible allegation of fraud, unless there is good cause not to suspend such payments. The statute also requires CMS to consult with OIG in determining whether a credible allegation of fraud exists. On September 23, 2010, CMS issued proposed regulations at 75 Fed. Reg. 58204, 58239 (Sept. 23, 2010) for these provisions. In finalizing the regulations and developing related guidance, CMS could also address the inconsistencies that this report identified. The report did not contain recommendations. *The Use of Payment Suspensions To Prevent Inappropriate Medicare Payments*. OEI-01-09-00180. Full Report

Medicare > Part A and Part B > Administration > Program Integrity

Medicare and Medicaid Fraud and Abuse Training in Medical Education

Despite lack of a Federal requirement, 44 percent of medical schools and 68 percent of institutions offering residency and fellowship programs reported providing instruction to students and participants on compliance with Medicare and Medicaid fraud and abuse laws in 2010.

Almost all the medical schools and institutions offering residency and fellowship programs that we reviewed expressed interest in receiving OIG-provided instructional materials relating to Medicare and Medicaid fraud and abuse. Most respondents expressed interest specifically in more information about the civil False Claims Act (FCA), the anti-kickback statute, and the physician self-referral statute.

Accordingly, OIG decided to (1) prepare educational materials appropriate for medical schools and institutions offering residency and fellowship programs, (2) distribute the materials to those medical schools and institutions that sponsor residency and fellowship programs, and (3) seek feedback from the medical schools and institutions offering residency and fellowship programs on ways to improve the materials. *Medicare and Medicaid Fraud and Abuse Training in Medical Education*. OEI-01-10-00140. Full Report

Medicare > Part A and Part B > Administration > Quality Improvement Organizations

Quality Improvement Organizations' Final Responses to Beneficiary Complaints

Our review covering August 1, 2008, through December 31, 2009, showed that most Quality Improvement Organizations' (QIO) responses to beneficiary complaints are meeting applicable standards and CMS's additional criteria that apply when the involved practitioners provide consent for disclosure.

CMS contracts with QIOs, which, among other responsibilities, review written complaints from Medicare beneficiaries about the quality of care the beneficiaries received and, at the conclusion of such reviews, send to the beneficiaries final responses summarizing the findings of the reviews. We found that of the 120 QIO final responses to Medicare beneficiaries' complaints that we reviewed in detail, 116 met requirements. However, we found that QIOs do not obtain consent for disclosure from almost half of the practitioners involved. Medicare regulations allow practitioners to refuse to give consent to the QIOs' release of information in final reports that identify them. We made no recommendations based on this review. *Quality Improvement Organizations' Final Responses to Beneficiary Complaints*. OEI-01-09-00620. Full Report

Medicare > Part A and Part B > Administration > Program Inegrity > Error-Prone Providers

Use of Medicare Fee-for-Service Error Rate Data To Identify and Focus on Error-Prone Providers

Although Medicare payment contractors developed corrective actions based on available error rate data, they typically did not focus on error-prone providers for review and corrective action.

Using the reported error rate data from the Hospital Payment Monitoring Program and the Comprehensive Error Rate Testing (CERT) program for fiscal years (FY) 2005 through 2008, we identified 740 error-prone providers. These providers accounted for a significant portion of the total dollars in error in the sampled years. Focusing on error-prone providers for corrective action and repayment of improper payments could improve the effectiveness of CMS's efforts to reduce improper payments.

We recommended that CMS (1) use available error rate data to identify error-prone providers, (2) require error-prone providers to identify the root causes of claim errors and to develop and implement corrective action plans, (3) monitor provider-specific corrective action plans, and (4) share error rate data with its contractors to assist in identifying improper payments. CMS concurred with our recommendations. *Centers for Medicare & Medicaid Services' Use of Medicare Fee-for-Service Error Rate Data To Identify and Focus on Error-Prone Providers*. A-05-08-00080. Full Report

Medicare > Part A and Part B > Administration > Program Integrity > Hotline

Complaints Received Through the 1-800-HHS-TIPS Hotline

Our review revealed that as of March 2010, CMS had resolved or closed administratively 88 percent of the complaints it received during the first 6 months of 2008 from the 1-800-HHS-TIPS hotline. CMS and contractor staff reported the need for written guidance for processing hotline complaints.

We recommended that CMS (1) issue written guidance to its own staff and contractor staff for processing hotline complaints and (2) upgrade its information system for processing complaints. CMS concurred with our recommendations. *CMS's Processing of Complaints Received Through the 1-800-HHS-TIPS Hotline*. OEI-07-09-00020. Full Report

Medicare > Part A and Part B > Administration > Program Integrity > Information Security

Medicare Contractor Information Security Program Evaluations for Fiscal Year 2008

We found that the PricewaterhouseCoopers LLP (PwC) information security program evaluations for FY 2008 were adequate in scope and sufficiency. However,

we could not determine the scope and sufficiency of work performed by JANUS Associates, Inc. (JANUS) because of several issues with its working papers.

Pursuant to the Social Security Act, § 1874A(e)(2)(C)(ii), we assessed the scope and sufficiency of Medicare contractor information security program evaluations and data center technical assessments. OIG is required to report to Congress annually on the results of these contractor-conducted evaluations.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added information security requirements for Medicare contractors to the Social Security Act. Each Medicare contractor must have its information security program evaluated annually by an independent entity. To comply with this provision, CMS contracted with PwC to evaluate information security programs at the contractors using a set of agreed-upon procedures. The Social Security Act also requires evaluations of the information security controls for a subset of systems. To satisfy this requirement, CMS developed an information security assessment methodology and contracted with JANUS to perform technical assessments at Medicare datacenters using the methodology.

We recommended that CMS review all contractor documentation related to future data center technical assessments and ensure that the work performed complies with CMS contractual requirements. At a minimum, this should include a review of test plans to ensure that the contractor has completed all required testing procedures and a review of contractor working papers to verify that reported gaps have been adequately supported, identified, and included in the technical assessment reports. CMS concurred with our recommendation and stated that it would take the appropriate actions to address the identified issues. *Review of Medicare Contractor Information Security Program Evaluations for Fiscal Year 2008*. A-18-09-30200.
Full Report

Medicare Part C

Medicare > Part C > Prepayments to MA Organizations

Impact on Medicare Program of Investment Income That Medicare Advantage Organizations Earned and Retained From Medicare Funds in 2007

The Medicare program loses potential savings associated with investment income that Medicare Advantage (MA) organizations earn between the time that they receive Medicare prepayments and the time that the MA organizations pay for medical services.

We estimated that in CY 2007 MA organizations held Medicare funds for about 46 days before paying for medical services. The Medicare Part A and Part B trust

funds (which finance the MA program) could have earned approximately $450 million of interest income in CY 2007 had prepayments to MA organizations been delayed until after the beginning of the beneficiary's coverage period by the same number of days that we estimated MA organizations held the Medicare funds.

Alternatively, we estimated that Medicare could have saved about $376 million that 457 MA organizations earned in CY 2007 had Federal requirements been established to require MA organizations to reduce their revenue requirements in bid proposals to account for anticipated investment income. In contrast to the Federal requirements that govern the MA program, the Federal Employees Health Benefits (FEHB) program limits the ability of companies to retain as additional revenue the investment income earned from Federal funds.

We recommended that CMS evaluate the audit results and either (1) pursue legislation to adjust the timing of Medicare's prepayments to MA organizations to account for the time that these organizations invest Medicare funds before paying providers for medical services, or (2) develop and implement regulations that require MA organizations to reduce their revenue requirements in bid proposals to account for anticipated investment income. CMS did not concur with our recommendations because of concern that the implementation of either option would cause most MA organizations to increase their bid proposals to recoup the investment income that they would lose, which would result in a decrease in most or all of the estimated cost savings. CMS noted that it could be asked to pay interest on the additional payments that CMS frequently makes to MA organizations after the completion of the risk adjustment reconciliation each year. *Rollup Review of Impact on Medicare Program for Investment Income That Medicare Advantage Organizations Earned and Retained From Medicare Funds in 2007*. A-07-10-01080. Full Report

Medicare Part D

Medicare > Part D > Pharmacy Discounts

Medicare Part D Pharmacy Discounts for 2008

For five of the six sponsors we reviewed, pharmacy discounts negotiated by pharmacy benefit managers on behalf of Part D sponsors were not always passed on to beneficiaries and to the Government. These discounts directly affect the amount that beneficiaries and the Government pay for drugs.

This report, which does not make recommendations, provides information about how third-party pharmacy benefit managers negotiate with pharmacies on behalf of Part D sponsors for discounts on Part D drug prices.

The Part D sponsors we reviewed relied on pharmacy benefit managers to negotiate the discounts. Pharmacies generally accepted the lower prices negotiated by pharmacy benefit managers because participating in sponsors' networks increased

the number of beneficiaries who used their pharmacies. For brand-name drugs, the pharmacy discounts were based on average wholesale prices and varied by the length of supply, pharmacy type, and geographic location, whereas discounts for generic drugs were based on prices established by the pharmacy benefit managers. *Medicare Part D Pharmacy Discounts for 2008*. OEI-02-10-00120. Full Report

Medicare > Part D > Terminated Drugs

Terminated Drugs in the Medicare Part D Program

Of the approximately $115 billion in gross drug costs included in Medicare Part D sponsors' prescription drug event (PDE) data for CYs 2006 and 2007, CMS accepted PDE data totaling $112.1 million associated with 2,967 terminated drugs.

Terminated drugs are discontinued drugs that have passed their shelf life or drugs that have been pulled from the market for health or safety reasons. Such medications could be weak, ineffective, or detrimental to beneficiaries' health. However, Federal regulations do not specifically prohibit coverage of terminated drugs under the Part D program. After the close of the coverage year, CMS is responsible for reconciling prospective payments made to Part D sponsors with actual costs. This reconciliation is based on final PDE data.

We recommended that CMS issue regulations to prohibit Medicare Part D coverage of terminated drugs and, in the interim, publish a list of these drugs on its Web site. CMS did not concur and questioned our reliance on the termination dates reported by drug manufacturers for use in the Medicaid program. CMS also disagreed that terminated drugs were actually dispensed to Medicare beneficiaries. *Review of Terminated Drugs in the Medicare Part D Program*. A-07-09-03130. Full Report

Medicare > Part D > Drug Categories

Erectile Dysfunction Drugs in the Medicare Part D Program

Of approximately $133 billion in gross drug costs included in private prescription drug plans' and MA plans' (collectively known as sponsors) PDE data for CYs 2007 and 2008, CMS improperly accepted PDE data totaling $3.1 million in gross Medicare Part D drug costs for erectile dysfunction (ED) drugs approved only for the treatment of sexual or erectile dysfunction.

Pursuant to the Social Security Act, § 1860D-2(e)(2)(A), effective January 1, 2007, Part D should not have covered these drugs. According to CMS officials, the software edit in place in CMS's Medicare Drug Data Processing System during our audit period did not prevent CMS from accepting PDE data for some ED drugs in CY 2007 and most of CY 2008 because the Part D program used an incomplete list of excluded drugs as the basis for the edit. Although the officials indicated that CMS

had updated its list of ED drugs in CY 2008, CMS accepted PDE data for some ED drugs during our entire audit period.

We recommended that CMS (1) determine whether it can impose financial adjustments on sponsors that were paid for furnishing ED drugs used for the treatment of sexual or erectile dysfunction and (2) strengthen internal controls to help ensure that drugs covered by Medicare Part D comply with Federal requirements by collaborating with FDA to create and maintain a comprehensive list of ED drugs that have been approved by FDA for the treatment of sexual or erectile dysfunction, regularly disseminating this list to all sponsors, and periodically updating the edit used to reject PDE data for ED drugs used for the treatment of sexual or erectile dysfunction. CMS partly agreed and partly disagreed with our recommendations. *Review of Erectile Dysfunction Drugs in the Medicare Part D Program*. A-07-10-03143. Full Report

Medicare > Part D > Rebates

Concerns With Rebates in the Medicare Part D Program

Part D sponsors underestimated rebates in 69 percent of their bids for plan year 2008, which led to higher beneficiary premiums and caused both beneficiaries and the Government to overpay for the benefit.

Part D is Medicare's optional prescription drug program. Private insurance companies, known as sponsors, provide drug coverage to beneficiaries who choose to enroll. Sponsors' bids to participate in Part D include estimates of the cost to provide the benefit to each beneficiary. CMS uses bids to calculate beneficiary premiums for each plan. Sponsors also negotiate drug manufacturer rebates and other price concessions to reduce the cost of the program to beneficiaries and the Government. Sponsors must include an estimate in their bids of the rebates they expect to receive for the plan year. Underestimating rebates increases beneficiary premiums. Sponsors may pass rebates on to beneficiaries at the point of sale to reduce beneficiaries' drug costs and copayments, but they commonly did not. Our review revealed that Medicare Part D sponsors reported receiving $6.5 billion in drug manufacturer rebates in 2008.

Our review also revealed that some sponsors reported large differences in rebates across their plans and received manufacturer rebates when they encouraged beneficiaries to use certain drugs. Some sponsors had complex contractual relationships with their third-party pharmacy benefit managers that sometimes lacked transparency, and some reported that their pharmacy benefit managers collected fees from drug manufacturers that were not always passed on to the Part D program.

We recommended that CMS: (1) take steps to ensure that sponsors more accurately include their expected rebates in their bids, (2) require sponsors to use methods CMS

deems reasonable to allocate rebates across plans, (3) ensure that sponsors have sufficient audit rights and access to rebate information, and (4) ensure that sponsors appropriately report the fees that pharmacy benefit managers collect from manufacturers. CMS concurred with our first recommendation and partially concurred with our fourth recommendation. *Concerns With Rebates in the Medicare Part D Program*. OEI-02-08-00050. Full Report

Medicare > Part D > Prescription Drug Event Data

Oversight of the Prescriber Identifier Field in Part D Prescription Drug Event Data for Schedule II Drugs

Our audit of PDE records for drugs classified as Schedule II pursuant to the Controlled Substances Act revealed approximately 228,000 PDE records with invalid prescriber identifiers, accounting for about $20.6 million in gross drug costs for CY 2007.

Without valid identifiers from sponsors, CMS and its Part D contractors might not be able to monitor excessive prescribing patterns, determine whether a prescription was written by an excluded or deceased provider, or identify those physicians who illegally prescribe Schedule II drugs. Schedule II drugs have a high potential for abuse, have an accepted medical use with severe restrictions, and may cause severe psychological or physical dependence if abused. With limited guidance and edits in place for the prescriber identifier field, CMS and Medicare Part D sponsors did not identify the invalid prescriber identifiers that we found. In addition, because of invalid prescriber identifiers, we were unable to identify top prescribers for oxycodone, Ritalin, and methadone, which are three Schedule II drugs that are frequently involved in health care investigations.

We recommended that CMS (1) issue specific guidance requiring sponsors to include a valid Drug Enforcement Administration (DEA) number on standard and nonstandard format PDE records involving Schedule II drugs and (2) implement an edit to reject PDE records for Schedule II drugs when the prescriber identifier field contains an invalid prescriber identifier number. CMS did not concur. It believes that the DEA number is not suitable as a single identifer because only a fraction of PDE volume involves Schedule II drugs. *Oversight of the Prescriber Identifier Field in Prescription Drug Event Data for Schedule II Drugs*. A-14-09-00302. Full Report