

Good morning, Mr. Chairman and Members of the Subcommittee. I am Robert Vito, Regional Inspector General for Evaluation and Inspections in Philadelphia at the U.S. Department of Health and Human Services' Office of Inspector General (OIG). For nearly 20 years, OIG has devoted considerable attention to end stage renal disease (ESRD)-related services. Our work has involved monitoring the oversight of the quality of care for dialysis patients enrolled in Medicare, conducting criminal and civil investigations of dialysis providers, and examining the pricing and utilization of dialysis-related drugs and services. I appreciate the opportunity to appear before you today to discuss OIG's work in this area and, in particular, summarize the findings of our recent review related to the pricing of separately billable ESRD drugs.

In short, our most recent report, released to you today, which is available on our Web site at <http://oig.hhs.gov/>, found that, on average, dialysis facilities could acquire the majority of ESRD drugs at prices 4 to 32 percent less than the Medicare reimbursement amount during the third quarter of 2006.¹ Acquisition costs for some ESRD drugs ranged from 1 to 9 percent above Medicare reimbursement amounts; however, on average, aggregate drug acquisition costs ranged from 7 to 12 percent below aggregate Medicare reimbursement amounts. This can be attributed, in part, to the average acquisition costs for the two most widely used ESRD drugs, epoetin alfa (Epogen) and darbepoetin alfa (Aranesp), for which acquisition costs were as much as 10 percent below Medicare reimbursement levels. Finally, acquisition costs varied substantially, with chain-owned freestanding facilities often paying less for ESRD drugs than nonchain freestanding and hospital-based facilities.

BACKGROUND

The Medicare program currently covers dialysis services for close to 400,000 patients under its ESRD benefit. Medicare covers all treatment methods for patients, including various methods of maintenance dialysis as well as renal transplants. ESRD facilities are paid based on a prospective payment system known as the composite rate, which covers most items related to dialysis services, such as labor costs, related supplies, routine tests, and certain drugs. Facilities receive a fixed composite rate payment for each dialysis treatment they provide to Medicare beneficiaries. However, the composite rate does not include many drugs that may be part of dialysis treatment and certain laboratory tests. These items are referred to as "separately billable." For example, the drugs Epogen and Aranesep, which stimulate the production of red blood cells in patients with anemia, are billed separately from the composite rate.

¹ "Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter 2006." (OEI-03-06-00590). June 2007.

In 2005, Medicare spent close to \$8 billion for the care of ESRD beneficiaries—approximately 60 percent of that amount was associated with dialysis services covered under the composite rate, with the remaining 40 percent attributable to separately billable items. Beneficiaries are responsible for 20-percent copayments for both composite rate services and separately billable items.

OIG work on ESRD services has identified vulnerabilities and inefficiencies related to quality of care and to the utilization, payment, and pricing of drugs and services.

MEDICARE REIMBURSEMENT FOR ESRD DRUGS: THIRD QUARTER 2006

Beginning January 1, 2006, the Centers for Medicare & Medicaid Services (CMS) instituted a new reimbursement methodology for both freestanding and hospital-based facilities. As of that date, all ESRD drugs—with the exception of certain vaccines, blood, and blood products—were reimbursed at 106 percent of the manufacturer-reported average sales price (ASP). CMS implemented this change because in 2005, as mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the agency had based reimbursement to freestanding facilities for 10 separately billable ESRD drugs on OIG's estimates of acquisition costs for those drugs. However, the agency believed it was inappropriate to continue to use older acquisition cost data provided by OIG (updated for inflation) as a basis for reimbursement and questioned the feasibility of continually obtaining acquisition cost data over the long term. This change also produced a consistent drug payment methodology among freestanding dialysis facilities and hospital-based dialysis facilities.

In our most recent review, OIG compared the Medicare reimbursement amounts for selected separately billable ESRD drugs to average acquisition costs of these drugs in freestanding and hospital-based dialysis facilities. We obtained third-quarter 2006 average acquisition costs for 11 high-expenditure ESRD drugs from a sample of dialysis facilities and calculated the percentage of facilities that had average acquisition costs below the ASP-based reimbursement amounts. We sent surveys to a random sample of freestanding and hospital-based dialysis facilities to collect data on the total amounts paid, discounts and rebates received, and total units purchased for these 11 drugs. We did not verify or validate the information provided by the responding facilities.

The 11 high-expenditure drugs accounted for nearly all of the \$2 billion in Medicare reimbursement for ESRD drugs furnished by freestanding facilities and the \$200 million for ESRD drugs furnished by hospital-based facilities in 2005. At the time of our review, 4,050 freestanding dialysis facilities and 310 hospital-based dialysis facilities were listed on Medicare's database of dialysis facilities. Approximately 71 percent of freestanding facilities are part of two large chain corporations, and another 11 percent are owned by smaller national or regional chains.

Acquisition Costs for Freestanding Facilities

We found that among responding freestanding facilities, third-quarter 2006 average acquisition costs for 9 of the 11 drugs under review were between 7 and 32 percent below the Medicare reimbursement amounts. For the remaining two drugs, acquisition costs ranged from 3 to 9 percent above the Medicare reimbursement amounts. However, reimbursement for these two drugs combined accounted for less than 1 percent of total Medicare expenditures for ESRD drugs in freestanding dialysis facilities in 2005. The average acquisition cost for Epogen, a drug that accounts for three-quarters of Medicare expenditures in freestanding facilities, was 10 percent less than the Medicare reimbursement amount (\$8.56 per 1,000 units compared to \$9.48). In total, 99 percent of freestanding dialysis facilities could purchase Epogen for less than the Medicare reimbursement amount.

Our analysis also showed that chain freestanding facilities paid less for the drugs under review than did nonchain freestanding facilities. On average, drug acquisition costs for chain facilities were 12 percent below the Medicare reimbursement amounts, compared to 7 percent below for nonchain facilities. This difference can be attributed, in large part, to the pricing of Epogen. Although chain facilities initially paid more than nonchain facilities for Epogen, the chain facilities received a much larger discount/rebate (27 percent, on average) than the nonchain facilities (5 percent, on average). As a result, the final price for Epogen among chain facilities was 5 percent less than the final price of the drug among nonchain facilities (\$8.55 per 1,000 units compared to \$8.99).

Acquisition Costs for Hospital-Based Facilities

Among responding hospital-based dialysis facilities, average acquisition costs for 6 of the 11 ESRD drugs under review were between 4 and 29 percent below the Medicare reimbursement amounts. For the remaining five drugs, acquisition costs ranged from 1 to 8 percent above the Medicare reimbursement amounts. These five drugs accounted for 29 percent of reimbursement to hospital-based dialysis facilities for ESRD drugs in 2005. This indicates that when compared to freestanding facilities, hospital-based dialysis facilities could potentially face larger gaps between acquisition costs and Medicare reimbursement when purchasing a number of highly utilized drugs. Average acquisition costs for Aranesp and Epogen (the two drugs that account for the majority of Medicare spending in hospital-based facilities) were 10 and 9 percent below the Medicare reimbursement amounts, respectively (\$2.71 compared to \$3.03 for Aranesp, and \$8.66 compared to \$9.48 for Epogen). On average, overall drug acquisition costs for responding hospital-based dialysis facilities were 7 percent below the Medicare reimbursement amounts—amounts identical to those of nonchain freestanding facilities.

Summary

We concluded that responding facilities, on average, could acquire the majority of ESRD drugs at prices below Medicare reimbursement amounts and that aggregate acquisition costs were below aggregate Medicare reimbursement amounts. However, acquisition costs for the same drug may vary based on the type and chain affiliation of the facility,

causing some dialysis facilities to potentially experience greater gaps in reimbursement than others. Therefore, we concluded that CMS should continue to monitor the situation closely to ensure that all facilities are reimbursed appropriately.

PREVIOUS OIG WORK RELATED TO ESRD SERVICES AND PAYMENTS

Prior Reviews of Medicare Reimbursement of ESRD Drugs

OIG's most recent report on ESRD reimbursement builds upon a body of work regarding the appropriateness of payments for ESRD drugs. Based on a 1990 audit in which we found that Medicare overpaid for ESRD services for nonroutine drugs, we recommended that the Medicare reimbursement rates reflect the cost of dialysis treatment in efficiently operated facilities.² In a 1992 audit, we further suggested that CMS consider folding all separately billable drugs into the composite rate to achieve savings on administrative costs and reduce payment errors.³ A 1993 audit indicated that dialysis providers were being overpaid for Epogen and we suggested a reduction in the reimbursement rate.⁴ In 1997, OIG conducted a follow-up review of Medicare reimbursement for Epogen and found that the reimbursement rate, which at that time was \$10 per 1,000 units administered, exceeded the cost of purchasing Epogen by approximately \$1 per 1,000 units.⁵ In June of 2000, OIG issued another report specifically focusing on ESRD drugs.⁶ This report found that the Department of Veterans Affairs paid between 37 percent and 56 percent less than Medicare for five high-expenditure ESRD drugs.

Based in part on OIG work, Congress included provisions to reform drug reimbursement in the MMA. These provisions created a new methodology for Part B drug reimbursement that is based on manufacturer-reported ASPs rather than problematic average wholesale prices (AWP). In addition, the MMA required that Medicare base payments for certain ESRD drugs on their acquisition costs as determined by OIG.⁷ The MMA also mandated that OIG conduct two studies related to Medicare reimbursement for ESRD drugs.⁸

In the first MMA-mandated OIG report, which was issued in May 2004, "Medicare Reimbursement for Existing End Stage Renal Disease Drugs" (OEI-03-04-00120), OIG found that the four largest freestanding corporate dialysis providers and a random sample of freestanding nonchain dialysis facilities were able to acquire 10 high-expenditure drugs at costs averaging 14 to 22 percent below the Medicare reimbursement amounts.

² "Management Advisory Report - Reductions Continue To Be Needed in Medicare's End Stage Renal Dialysis Rates," (A-14-90-00215). July 1990.

³ "Cost of Dialysis-Related Drugs," (A-01-91-00526). October 1992.

⁴ "Review of Epogen Reimbursement," (A-01-92-00506). February 1993.

⁵ "Review of Epogen Reimbursement," (A-01-97-00509). November 1997.

⁶ "Medicare Reimbursement of End Stage Renal Disease Drugs," (OEI-03-00-00020). June 2000.

⁷ Prior to 2005, the Medicare reimbursement amount for Epogen in both freestanding and hospital-based facilities was set by statute at \$10 per 1,000 units.

⁸ "Medicare Prescription Drug, Improvement, and Modernization Act of 2003." Public Law 108-173. § 623(c)(2)(A)-(B).

As required by the MMA, CMS used the data presented in this report to set calendar year 2005 reimbursement rates for the 10 drugs at the average acquisition costs as calculated by OIG. For all other drugs billed by freestanding dialysis facilities—with the exception of certain vaccines, blood, and blood products—CMS reimbursed freestanding dialysis facilities at 106 percent of the drugs' ASPs. During this same time period, hospital-based facilities were reimbursed at cost for most ESRD drugs.

For the second report, issued in March 2006, "Medicare Reimbursement for New End Stage Renal Disease Drugs" (OEI-03-06-00200), Aranesp was selected as the only drug for review because it accounted for 99.9 percent of Medicare reimbursement for new ESRD drugs. We found that, on average, responding freestanding dialysis facilities were able to acquire Aranesp for between 14 and 27 percent below the Medicare reimbursement amounts in 2005.

Improper Billing and Utilization

Through audits and investigations, OIG has also identified instances of improper billing and utilization of services in ESRD facilities, including inappropriate billing for services outside the composite rate and the provision of medically unnecessary services.

For example, in a 2004 audit of Medicare payments to DaVita, Incorporated, for Epogen services provided at one of its Philadelphia dialysis centers, we found that 44 of the 143 claims reviewed did not meet Medicare payment requirements for Epogen.⁹ In some cases, we identified inconsistencies between the number of units of Epogen prescribed in the written physician order and the number administered by the facility and billed to Medicare. We also identified instances in which Epogen was still administered to the patient after the physician had ordered its discontinuation.

In another example, in 2005, as part of a global settlement with the Government, Gambro Healthcare, Inc. (GHI), owner and operator of over 500 renal dialysis centers, agreed to pay over \$350 million to resolve civil and criminal fraud allegations in the Medicare, Medicaid, and TRICARE programs. To resolve its civil liability, GHI paid \$310.5 million for allegedly submitting false Medicare claims and paying physicians improper remuneration related to their medical director services. In addition, Gambro Supply Corporation (GSC), a wholly owned subsidiary of GHI, agreed to plead guilty to health care fraud, pay a \$25 million criminal fine, and be permanently excluded from Medicare and other Federal health care programs. To circumvent prohibitions applicable to durable medical supply companies, GSC made false statements to Medicare, allegedly enabling GHI to bill for ESRD-related services and equipment at a higher amount. GHI also agreed to pay the Government \$328,286 to resolve its liability under the False Claims Act (FCA) for allegedly causing local laboratories to improperly bill separately for laboratory services that should have been covered under the facilities' composite rate. GHI also agreed to enter into a 5-year corporate integrity agreement with OIG.

⁹ "Review of Medicare Payments to DaVita, Incorporated for Epogen Services Provided at Franklin Dialysis Center, Philadelphia, Pennsylvania," (A-03-03-00003). April 2004.

More recently, in 2007, Dialysis Clinic, Inc. (DCI), which provides health care services to Medicare beneficiaries with ESRD at its clinics located in more than 30 States, agreed to pay \$1.8 million to resolve its liability under the FCA. The majority of the settlement was associated with DCI's administration and billing of Epogen when it was medically unnecessary. CMS authorizes the administration of Epogen to keep a patient's hematocrit blood level in the 33- to 36-percent range. The investigation revealed that DCI allegedly administered Epogen to patients whose hematocrit levels were in excess of 40 percent. Furthermore, DCI allegedly allowed hospital laboratories to bill Medicare separately for tests for DCI patients even though DCI was paid for the lab services as part of Medicare's composite rate payment. As part of the settlement agreement, DCI entered into a 3-year corporate integrity agreement with OIG.

Quality of Care Oversight

In addition to performing work on appropriate payment rates and billing, OIG has also identified concerns regarding CMS's oversight of the quality of care provided by ESRD facilities. In June 2000, OIG issued a report documenting problems with the oversight of these facilities.¹⁰ OIG found that although CMS oversight using standardized performance measures encouraged improvements in quality of care, CMS did not use these measures to hold individual facilities accountable. OIG also found that Medicare certification surveys played a limited role in ensuring that ESRD facilities met minimum standards.

In January 2002, OIG issued a series of reports concerning the lessons learned by the five largest dialysis corporations in using clinical performance measures.¹¹ In those reports, we identified a number of methods the Medicare program could use to improve the quality of care in dialysis facilities. These included examining ways to foster a commitment to performance measures among attending physicians and developing more effective intervention strategies for facilities.

In 2003, GAO reported that problems with quality of care were prevalent at dialysis facilities, putting patients' health at risk and that limitations in the ESRD survey process inadequately addressed or failed to detect quality problems.¹² More recently, in a November 2006 report, OIG found that current sources of data have limitations in assisting CMS and its contactors in identifying quality improvement needs at ESRD facilities.¹³ These limitations include lack of current, comprehensive, and facility-

¹⁰ "External Quality Review of Dialysis Facilities: A Call for Greater Accountability," (OEI-01-99-00050). June 2000; and "Oversight of Kidney Dialysis Facilities Needs Improvement," (GAO/HEHS-00-114). June 2000.

¹¹ "Clinical Performance Measures for Dialysis Facilities: Building on the Experience of the Dialysis Corporations," (OEI-01-99-00052). January 2002; "Clinical Performance Measures for Dialysis Facilities: Practices of the Major Dialysis Corporations *Supplemental Report # 1*," (OEI-01-99-00053). January 2002; and "Clinical Performance Measures for Dialysis Facilities: Lessons Learned by the Major Dialysis Corporations and Implications for Medicare, *Supplemental Report # 2*," (OEI-01-99-00054). January 2002.

¹² "Dialysis Facilities: Problems Remain in Ensuring Compliance With Medicare Quality Standards," (GAO-04-63). October 2003.

¹³ "Availability of Quality of Care Data in the Medicare End Stage Renal Disease Program," (OEI-05-05-00300). November 2006.

specific performance data. We recommended that CMS increase its efforts towards regularly collecting clinical performance data from patients and facilities. CMS has begun to develop a streamlined source of data that could assist contractors in identifying facilities with improvement needs, but this database has yet to be implemented.

CONCLUSION

Through a substantial body of work, OIG has examined the oversight of quality of care at ESRD facilities, appropriateness of payment systems, and improper billing and utilization of ESRD drugs. Our most recent work compared Medicare reimbursement amounts for ESRD drugs in third quarter 2006 to dialysis facilities' acquisition costs. We found that responding freestanding dialysis facilities could typically acquire the majority of the selected separately billable ESRD drugs for less than the Medicare reimbursement amounts. Drug acquisition costs varied among different types of freestanding dialysis facilities, with overall drug costs among chain facilities being somewhat less than those among nonchain facilities. In contrast, average acquisition costs among hospital-based dialysis facilities for almost half of the drugs under review exceeded the Medicare reimbursement amounts. We concluded that CMS should continue to monitor the situation closely to ensure that all facilities are reimbursed appropriately.

OIG remains committed to ensuring that Medicare ESRD beneficiaries receive quality services and that this care is being reimbursed at appropriate levels. Therefore, we will continue to conduct audits, evaluations, and investigations, as warranted, to oversee payment and quality of care at ESRD facilities. Currently, we are conducting audit work at individual dialysis facilities to review the appropriateness of Medicare claims submitted by dialysis facilities for Epogen administration, as well as identifying instances in which laboratory tests that should be included in the composite rate are being billed separately.

This concludes my testimony, and I welcome your questions.