Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE REIMBURSEMENT FOR END STAGE RENAL DISEASE DRUGS: THIRD QUARTER 2006

Daniel R. Levinson
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EXECUTIVE SUMMARY

OBJECTIVE

To compare the Medicare reimbursement amounts for selected separately billable end stage renal disease (ESRD) drugs to the average acquisition costs of these drugs for ESRD dialysis facilities in the third quarter of 2006.

BACKGROUND

ESRD facilities (i.e., dialysis facilities) are approved to furnish at least one specific ESRD service and are either independent or hospital based. The Centers for Medicare & Medicaid Services (CMS) reimburses both facility types for most items related to dialysis services based on a prospective payment system known as the composite rate. However, some drugs incident to dialysis treatment are not covered under this rate and are instead billed separately. A recent report by the Government Accountability Office (GAO) recommended that Congress consider establishing a new bundled payment system creating one fixed rate for all ESRD-related drugs and services.

Prior to January 1, 2006, Medicare reimbursed independent and hospital-based dialysis facilities for separately billable ESRD drugs using different methods. In 2005, independent dialysis facilities generally were reimbursed for separately billable drugs at either their acquisition cost or 106 percent of their published average sales price (ASP). Hospital-based dialysis facilities generally were reimbursed for drugs on a reasonable cost basis. Effective January 1, 2006, CMS enacted several significant changes to the drug reimbursement methods used for dialysis facilities. One revision included paying all dialysis facilities 106 percent of the ASP for all separately billable ESRD drugs and biologicals, with certain exceptions, making payment methods for independent and hospital-based dialysis facilities the same.

We sent surveys to a random sample of independent and hospital-based dialysis facilities to collect third-quarter 2006 data on the total amount paid, discounts and rebates received, and total units purchased for 11 high-expenditure, separately billable ESRD drugs. We determined the volume-weighted average acquisition cost per drug and compared it to the drugs' third-quarter 2006 Medicare reimbursement amount. For each drug, we calculated the percentage of facilities that had average acquisition costs below the third-quarter 2006 ASP-based reimbursement amount.

FINDINGS

Among responding independent dialysis facilities, the average acquisition cost was less than the Medicare reimbursement amount for 9 of the 11 ESRD drugs under review. In the third quarter of 2006, the average acquisition cost among the responding independent dialysis facilities for 9 of the 11 ESRD drugs under review was between 7 and 32 percent below the Medicare reimbursement amount. For the remaining two drugs, average acquisition costs ranged from 3 to 9 percent above the Medicare reimbursement amount. Reimbursement for these two drugs combined accounted for less than 1 percent of total Medicare reimbursement for separately billable drugs in independent dialysis facilities in 2005. When weighted by 2005 total Medicare reimbursement for each of the 11 drugs, overall drug acquisition costs for responding independent dialysis facilities were, on average, 10 percent below the Medicare reimbursement amount in the third quarter of 2006.

Overall, responding independent chain dialysis facilities paid less for the drugs under review than nonchain facilities. On average, independent chain facilities could purchase 8 of the 11 drugs under review for less than independent nonchain facilities in the third quarter of 2006. During that same period, the responding chain facilities were able to purchase 9 of the 11 drugs for less than the Medicare reimbursement amount, compared to 7 of the 11 drugs among nonchain facilities. On average, the four drugs that nonchain facilities could not purchase for less than the Medicare reimbursement amount accounted for less than 10 percent of total Medicare payments for separately billable drugs in 2005.

Among responding hospitals, the average acquisition cost was less than the Medicare reimbursement amount for 6 of the 11 ESRD drugs under review. In the third quarter of 2006, the average acquisition cost among the responding hospital-based dialysis facilities for 6 of the 11 ESRD drugs under review was between 4 and 29 percent below the Medicare reimbursement amount. For the remaining five drugs, average acquisition costs ranged from 1 to 8 percent above Medicare reimbursement. Reimbursement for these five drugs accounted for 29 percent of reimbursement to hospital-based dialysis facilities for separately billable drugs in 2005. This indicates that, when compared to independent facilities, hospital-based facilities could potentially face larger gaps between acquisition costs and Medicare reimbursement when purchasing a number of highly utilized drugs.

When weighted by 2005 total Medicare reimbursement for each of the 11 drugs, overall drug acquisition costs for hospital-based dialysis facilities were, on average, 7 percent below the Medicare reimbursement amount in the third quarter of 2006.

CONCLUSION

As the findings in this report show, on average, responding independent dialysis facilities could acquire the majority of the selected separately billable ESRD drugs for less than the Medicare reimbursement amount. Drug acquisition costs among different types of independent dialysis facilities did vary, with overall drug costs to chain facilities being somewhat less than costs to nonchains. However, among both chain and nonchain independent dialysis facilities, reimbursement for the drugs with average acquisition costs above the Medicare reimbursement amount accounted for a small percentage of overall drug expenditures. In contrast, average acquisition costs among hospital-based dialysis facilities for 5 of 11 drugs under review exceeded the Medicare reimbursement amount. Expenditures for these drugs represented almost one-third of overall expenditures in hospital-based dialysis facilities for separately billable drugs.

In conclusion, acquisition costs for the same drug may vary based on the type and chain affiliation of the facility, causing some facilities (especially hospital-based facilities) to potentially experience greater gaps in reimbursement for certain drugs than others. CMS should continue to monitor the situation closely to ensure that all facilities are reimbursed appropriately. In addition, we suggest that CMS consider the cost data presented in this report in its discussions about the merits of separately billable drugs under the composite rate, as recommended by the Government Accountability Office.

AGENCY COMMENTS

CMS reiterated that it would continue to monitor ESRD payments in relation to the drug acquisition costs of dialysis providers. CMS also stated that this report provides useful information that will be helpful in these monitoring efforts, and that the agency looks forward to continuing to work with OIG on ESRD issues in the future.

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INTRODUCTION

OBJECTIVE

To compare the Medicare reimbursement amounts for selected separately billable end stage renal disease (ESRD) drugs to the average acquisition costs of these drugs for ESRD dialysis facilities in the third quarter of 2006.

BACKGROUND

In 2005, Medicare reimbursed separately billable ESRD drugs and biologicals[1] administered in independent dialysis facilities based either on 106 percent of their published average sales price (ASP) or, for certain specified drugs, their acquisition cost.[2] At that time, Medicare generally reimbursed hospital-based dialysis facilities for separately billable drugs on a reasonable cost basis.[3] Effective January 1, 2006, the Centers for Medicare & Medicaid Services (CMS) enacted several significant changes to the drug reimbursement methods used for ESRD facilities. One revision included paying all dialysis facilities (independent and hospital-based) 106 percent of ASP for all separately billable ESRD drugs, making payment methods for independent and hospital-based dialysis facilities the same.[4] However, the ASP methodology is not used for vaccines, blood, and blood products.[5]

This review is the third in a series of Office of Inspector General (OIG) reports on Medicare reimbursement for separately billable ESRD drugs. Staff from CMS, the Medicare Payment Advisory Commission, and a number of dialysis facilities previously expressed their interest in OIG's conducting future reviews on the topic. This current study compares third-quarter 2006 average acquisition costs to Medicare reimbursement amounts for selected separately billable ESRD drugs in both independent and hospital-based dialysis facilities.

ESRD Treatment in Dialysis Facilities

ESRD facilities (i.e., dialysis facilities) are approved to furnish at least one specific ESRD service and are either independent or hospital based.[6]

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[1] Hereinafter, references to separately billable drugs refer to both drugs and biologicals.

[2] 42 CFR § 414.904 (d)(2).

[3] CMS, "Medicare Claims Processing Manual," Chapter 8, § 60.2.2.

[4] Ibid.

[5] 42 CFR § 414.906 (e).

[6] 42 CFR § 405.2102.

Both types of dialysis facilities provide outpatient services directly to ESRD patients as well as home dialysis (i.e., dialysis performed by an appropriately trained patient in his/her home).[7] Independent dialysis facilities are freestanding, whereas hospital-based dialysis facilities must be either attached to or located in a hospital.[8] As of October 2006, 4,050 independent dialysis facilities and 310 hospital-based dialysis facilities were listed on Medicare's Dialysis Facility Compare database.[9]

Medicare Payments to Dialysis Facilities

CMS reimburses dialysis facilities based on a prospective payment system known as the composite rate. Facilities receive a fixed composite rate payment for each dialysis treatment they provide. Independent dialysis facilities receive a lower rate than hospital-based facilities.[10] The composite rate includes most items related to dialysis services, such as labor costs, related supplies, routine tests, and certain drugs.[11] However, the composite rate does not include some drugs, such as epoetin alfa and darbepoetin alfa, which are incident to dialysis treatment. Drugs not covered under the composite rate must be billed separately and thus are referred to as separately billable drugs.[12]

A recent report by the Government Accountability Office (GAO) recommended that Congress consider establishing a new bundled payment system creating one fixed rate, adjusted for differences across facilities, for the services paid for under the composite rate and the drugs that facilities currently bill separately. Such a change would result in one payment rate for all ESRD services and drugs. CMS generally agreed but noted that more research and development were necessary to fully support its implementation.[13]

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[7] 42 CFR § 405.2102.

[8] "2005 United States Renal Disease Researcher's Guide," p. 345.

[9] Dialysis Facility Compare database. Available online at: http://medicare.gov/Dialysis/Home.asp. Accessed in October 2006. This database provides information on all dialysis facilities regarding their services, quality measures, and resources.

[10] CMS, "Medicare Claims Processing Manual," Chapter 8, § 10.1.

[11] Ibid., Chapter 11, § 30.

[12] Ibid., Chapter 11, § 30.4.2.

[13] GAO-07-77, "Bundling Medicare's Payment for Drugs With Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility." Available online at: http://www.gao.gov/cgo-bin/getrpt?GAO-07-77. Accessed on January 24, 2007.

Medicare Payments for Separately Billable ESRD Drugs

In general, Medicare coverage of separately billable drugs in dialysis facilities is limited to products that cannot be self-administered, i.e., drugs that are administered by a health care professional. The exceptions to this requirement are epoetin alfa and darbepoetin alfa, which, if furnished by the dialysis facility, will be covered even if the patient self-administers the drug.[14] Both drugs stimulate the production of red blood cells in patients with anemia; darbepoetin alfa contains two additional carbohydrate chains that lengthen its biological half-life.[15]

According to CMS's National Claims History File, Medicare reimbursed $2 billion for separately billable drugs furnished by independent dialysis facilities and $200 million for separately billable drugs furnished by hospital-based dialysis facilities in 2005.

Independent Dialysis Facilities. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, (MMA), required that CMS base calendar year (CY) 2005 reimbursement to independent dialysis facilities for separately billable drugs on acquisition costs as determined by OIG.[16] In response to this requirement, OIG calculated CY 2003 average acquisition costs (AAC) for 10 high-expenditure drugs (including epoetin alfa)[17] used in independent dialysis facilities as part of a May 2004 report, "Medicare Reimbursement for Existing End Stage Renal Disease Drugs" (OEI-03-04-00120). CMS then determined CY 2005 reimbursement amounts using two methods:

- For the 10 high-expenditure, separately billable drugs included in OIG's report, CMS based reimbursement on AACs as calculated by OIG.
- For all other drugs billed by independent dialysis facilities (with the exception of certain vaccines, blood, and blood products), CMS reimbursed independent dialysis facilities at 106 percent of the drugs' ASP.[18]

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[14] CMS, "Medicare Benefit Policy Manual," Chapter 11, § 90.

[15] 68 Fed. Reg. 63398, 63456 (November 7, 2003).

[16] MMA § 623 (d)(1).

[17] At the time of that review, these 10 drugs accounted for 98.4 percent of Medicare reimbursement to independent dialysis facilities for separately billable drugs.

[18] 42 CFR § 414.904 (d)(2).

Beginning January 1, 2006, CMS no longer reimbursed high-expenditure drugs (including epoetin alfa) based on AACs calculated by OIG but instead began to reimburse all separately billable drugs furnished by independent dialysis facilities (with the exception of certain vaccines, blood, and blood products) at 106 percent of the ASP.[19] This is the same method used to reimburse other drugs under Medicare Part B. CMS implemented this change because the agency believed that it was inappropriate to use older AAC data provided by OIG (updated for inflation) as a basis for reimbursement. In addition, CMS also questioned the feasibility of continually obtaining acquisition cost data over the long term.[20]

Hospital-Based Dialysis Facilities. Prior to January 1, 2006, CMS reimbursed hospital-based dialysis facilities for separately billable drugs based on reasonable cost. The exception to this rule was epoetin alfa, which CMS paid for based on a statutory reimbursement allowance of $10 per 1,000 units prior to January 1, 2005, and based on AAC in 2005.[21, 22] Beginning January 1, 2006, all separately billable drugs (with the exception of certain vaccines, blood, and blood products) furnished by hospital-based dialysis facilities became subject to a new payment methodology and now are reimbursed using the same rate as that of independent dialysis facilities, i.e., 106 percent of the ASP.[23] This change produced a consistent drug payment methodology among independent dialysis facilities and hospital-based dialysis facilities.

Related Work by the Office of Inspector General

OIG has completed two reviews analyzing the differences between acquisition costs for separately billable ESRD drugs and Medicare reimbursement amounts in independent dialysis facilities. Both of these reviews were conducted pursuant to mandates in the MMA.[24]

In our May 2004 report, "Medicare Reimbursement for Existing End Stage Renal Disease Drugs" (OEI-03-04-00120), we found that the four largest corporate dialysis providers and a random sample of unaffiliated independent dialysis facilities were able to acquire 10 high-expenditure

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[19] CMS, "Medicare Claims Processing Manual," Chapter 8, § 60.2.2.

[20] 70 Fed. Reg. 45764, 45845 (August 8, 2005).

[21] The Social Security Act, Section 1881, (11)(B)(ii)(I).

[22] 70 Fed. Reg. 45764, 45845 (August 8, 2005).

[23] CMS, "Medicare Claims Processing Manual," Chapter 8, § 60.2.2.

[24] MMA § 623 (c).

drugs at costs averaging 14 to 22 percent below the Medicare reimbursement amount. We also estimated that there would be an 11 percent increase in Medicare expenditures for separately billable ESRD drugs between 2003 and 2005. CMS used the data presented in this report to set CY 2005 reimbursement rates for the 10 drugs under review.

A second report, completed in March 2006, "Medicare Reimbursement for New End Stage Renal Disease Drugs" (OEI-03-06-00200), sought to examine new separately billable ESRD drugs (i.e., drugs not available prior to January 1, 2004). Darbepoetin alfa 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 responding independent dialysis facilities were able to acquire darbepoetin alfa for less (sometimes substantially less) than the 2005 Medicare reimbursement amount.

METHODOLOGY

Scope

We obtained the average acquisition cost of 11 high-expenditure, separately billable drugs from a random sample of independent and hospital-based dialysis facilities for the third quarter of 2006. The 11 drugs selected for review account for approximately 99 percent of Medicare reimbursement for separately billable drugs in independent dialysis facilities and 98 percent in hospital-based dialysis facilities. We did not include vaccines, blood, or blood products in our analysis because they are not reimbursed under the ASP methodology.

Selection of Drugs Under Review

At the time of sample selection, complete 2005 National Claims History File data were not available. Instead, we used a 1-percent sample of this file to rank separately billable ESRD drugs by their total Medicare reimbursement in both independent dialysis facilities and hospital-based dialysis facilities. The top drugs from the 1-percent sample were nearly identical in both facility types, with 9 of the 10 highest expenditure drugs being the same. The differing drugs were the hepatitis B vaccine (ranked 9th in independent dialysis facilities and 15th in hospital-based dialysis facilities) and albumin (ranked 17th in independent dialysis facilities and 10th in hospital-based dialysis facilities). In selecting drugs for our sample, we removed the hepatitis B vaccine and the blood product albumin because they are both exempted from the ASP methodology.

After removing these two products, our sample of drugs in both facility types was identical. Based on a follow-up analysis, the nine high-expenditure drugs selected for review remain as high-expenditure drugs in the complete 2005 and the preliminary 2006 National Claims History File.

We also included two additional drugs in our review (vancomycin and iron dextran) at the request of CMS staff. Among the 11 selected drugs, 1 drug, epoetin alfa, accounted for 74 percent of drug reimbursement among independent dialysis facilities. Two drugs, epoetin alfa and darbepoetin alfa, combined to account for 61 percent of drug reimbursement among hospital-based dialysis facilities.

Data Collection

Independent Dialysis Facilities. In previous ESRD reviews, we determined that four corporations owned the majority of independent dialysis facilities and accounted for 73 percent of Medicare reimbursement for separately billable ESRD drugs. Since our last review, consolidations among these four corporations have created two large, independent dialysis companies. These two companies own 2,868, or 71 percent, of all independent dialysis facilities. In November 2006, we sent a survey requesting third-quarter 2006 cost information for each of the 11 drugs under review to representatives of the two large companies. We requested information about the total amount paid by each company for each of the 11 drugs, the amount of discounts and rebates received, the net amount paid, the number of units purchased, and the average acquisition cost per drug. We defined average acquisition cost as the total amount paid (net of all rebates and discounts) divided by the total number of units purchased. We also asked the companies to report any additional costs associated with the drugs' acquisition. Both companies responded with the requested information.

In November 2006, we also sent surveys requesting identical third-quarter 2006 cost information to a random sample of 200 independent dialysis facilities not affiliated with the two largest companies.[25] Between December 2006 and February 2007, we received data from 158 facilities (79 percent).[26] Six of the responding facilities owned multiple dialysis units and provided cost data for 358 additional

[25] We randomly selected these facilities from Medicare's Dialysis Facility Compare database.

[26] We received responses from 161 facilities, but 3 were unable to provide the requested data. One provided peritoneal services, one was closed, and one was acquired by a large corporation.

facilities (for a total of 516 respondents not affiliated with the two large independent dialysis companies).

After we combined cost data from the 2,868 facilities owned or managed by the two large companies and the 516 responding unaffiliated independent facilities, our results represent acquisition cost information for 84 percent of all independent dialysis facilities.

Hospital-Based Dialysis Facilities. We selected a random sample of 200 hospital-based dialysis facilities from the 310 identified in Medicare's Dialysis Facility Compare database and in November 2006 sent them surveys requesting third-quarter 2006 cost information. Between December 2006 and February 2007, we received data from 96 hospital-based dialysis facilities (48 percent of facilities sampled and 31 percent of all hospital-based dialysis facilities).[27]

Data Analysis

CMS Data. We obtained the ASP-based reimbursement amounts for the 11 selected separately billable ESRD drugs in the third quarter of 2006 from CMS's Web site.

Acquisition Cost Data. For both facility types, we calculated volume-weighted average acquisition costs by totaling the amount paid net any discounts and rebates for each drug and dividing it by the total units purchased among all facilities for each drug. In calculating these figures, we identified any outliers among the costs reported by facilities and removed them from our analysis. We defined an outlier as an average acquisition cost reported by a facility that was not within three standard deviations of the mean.[28] We determined the percentage difference between the volume-weighted average acquisition cost and CMS's third-quarter 2006 ASP-based reimbursement amount per drug for both facility types. We then calculated the overall percentage difference between facility average acquisition costs and Medicare reimbursement by weighting the percentage differences by total 2005 Medicare expenditures for the individual drugs. For each drug, we also calculated

[27] We received 116 responses, but 23 of these respondents were unable to provide data for reasons including participating in the 340B program, providing inpatient services only, and not being able to itemize dialysis costs. One of the responding hospitals provided data on three additional hospitals, making our total number of responses 96.

[28] Among independent dialysis facilities, an average of 1.4 data points per drug were considered outliers and removed. Among hospital-based ESRD facilities, this number was 1.5. No more than four outliers were removed for any single drug in both types of facilities.

the percentage of facilities that had average acquisition costs below the third-quarter 2006 ASP-based reimbursement amount.

Independent Chain and Nonchain Facilities. For the purpose of this review, we defined a chain facility as one owned by a company that operates four or more independent dialysis units. In total, 3,301 independent dialysis facilities were part of various chains (2,868 owned by the two largest companies and 433 owned by the six respondents that reported data for multiple facilities). To determine whether independent dialysis chain facilities had average acquisition costs different from those of nonchain facilities, we compared cost data from the 3,301 chain facilities to cost data from the 83 nonchain facilities by repeating the analysis described in the above paragraphs.

Limitations

We did not verify the validity of the cost information submitted by the dialysis facilities. This cost information applies only to the 84 percent of all independent dialysis facilities and the 31 percent of all hospital-based dialysis facilities that responded to our request. We do not assume that the findings are representative of the entire population of independent dialysis and hospital-based dialysis facilities.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

FINDINGS

Among responding independent dialysis facilities, the average acquisition cost was less than the Medicare reimbursement amount for 9 of the 11 ESRD drugs under review

In the third quarter of 2006, the average acquisition cost among responding independent dialysis facilities for 9 of the 11 drugs under review was between 7 and 32 percent below the Medicare reimbursement amount. The average acquisition cost for epoetin alfa (a drug that accounts for three-quarters of Medicare expenditures in independent facilities) was 10 percent less than the Medicare reimbursement amount. In total, 99 percent of responding independent dialysis facilities could purchase epoetin alfa for less than the Medicare reimbursement amount.

For 2 of the 11 drugs, average acquisition costs ranged from 3 to 9 percent above the Medicare reimbursement amount. Reimbursement for these two drugs combined accounted for less than 1 percent of total Medicare expenditures for separately billable drugs in independent dialysis facilities in 2005. Table 1 illustrates the percentage difference between average acquisition costs reported by independent dialysis facilities and the third-quarter 2006 Medicare reimbursement amounts.

When weighted by 2005 total expenditures for each of the 11 drugs, overall drug acquisition costs for responding independent dialysis facilities were, on average, 10 percent below the Medicare reimbursement amount.

Table 1: Medicare Reimbursement and Average Acquisition Cost for Independent Dialysis Facilities

Drug	Third-Quarter 2006 Medicare Reimbursement Amount	Third-Quarter 2006 Average Acquisition Cost	Reimbursement and Average Cost Difference
Doxercalciferol, 1 μg*	$3.16	$2.16	-31.63%
Calcitriol, 0.1 μg	$0.51	$0.37	-26.88%
Vancomycin HCl, 500 mg*	$3.23	$2.46	-23.91%
Levocarnitine, 1 g*	$9.08	$7.00	-22.99%
Iron sucrose, 1 mg	$0.37	$0.32	-13.49%
Paricalcitol, 1 μg	$3.81	$3.40	-10.74%
Epoetin alfa, per 1,000 units	$9.48	$8.56	-9.66%
Sodium ferric gluconate, 12.5 mg	$4.75	$4.34	-8.72%
Darbepoetin alfa, 1 μg	$3.03	$2.82	-6.67%
Alteplase recombinant, 1 mg	$31.67	$32.48	2.55%
Iron dextran, 50 mg	$10.34	$11.29	9.16%

Source: OIG analysis of third-quarter 2006 average acquisition costs among responding independent facilities, February 2007. Third-quarter 2006 Medicare reimbursement amounts were downloaded from: http://cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp. Accessed on February 14, 2007.

* mg = milligrams, μg = microgram, g = gram.

Overall, responding independent chain dialysis facilities paid less for the drugs under review than did nonchain facilities. On average, independent chain facilities could purchase 8 of the 11 drugs under review for less than independent nonchain facilities in the third quarter of 2006. During that same period, the responding chain facilities were able to purchase 9 of the 11 drugs for less than the Medicare reimbursement amount, compared to 7 of the 11 drugs among nonchain facilities. On average, the four drugs that nonchain facilities could not purchase for less than the Medicare reimbursement amount accounted for less than 10 percent of total Medicare payments for separately billable drugs in 2005.

When weighted by 2005 total reimbursement for each of the 11 drugs, overall drug acquisition costs for responding chain facilities were 12 percent below the Medicare reimbursement amount, compared to 7 percent below for nonchain facilities. This difference can be attributed, in large part, to the pricing of epoetin alfa. Although chain facilities initially paid more than nonchain facilities for 1,000 units of epoetin alfa ($11.66 compared to $9.47), the chain facilities received an average discount/rebate of $3.11, compared to $0.48 for nonchain facilities. As a result, the final price for epoetin alfa for chain facilities was 5 percent below the final price of the drug for nonchain facilities ($8.55 per 1,000 units compared to $8.99). The average acquisition costs in chain and nonchain facilities for all 11 drugs are presented in Table 2.

Table 2: Average Acquisition Costs of Chain and Nonchain Independent Dialysis Facilities

Drug	Third-Quarter 2006 Medicare Reimbursement Amount	Third-Quarter 2006 Average Acquisition Cost in Chains	Third-Quarter 2006 Average Acquisition Cost in Nonchains
Alteplase recombinant, 1 mg	$31.67	**$32.45**	**$33.66**
Calcitriol, 0.1 μg	$0.51	$0.37	**$0.73**
Darbepoetin alfa, 1 μg	$3.03	$2.72	$2.96
Doxercalciferol, 1 μg	$3.16	$2.33	$0.72
Epoetin alfa, per 1,000 units	$9.48	$8.55	$8.99
Iron dextran, 50 mg	$10.34	**$11.33**	$10.08
Iron sucrose, 1 mg**	$0.37	$0.32	**$0.37**
Levocarnitine, 1 g	$9.08	$7.14	$5.40
Paricalcitol, 1 μg	$3.81	$3.40	$3.70
Sodium ferric gluconate, 12.5 mg	$4.75	$4.32	**$4.84**
Vancomycin HCl, 500 mg	$3.23	$2.41	$2.51

Source: OIG analysis of third-quarter 2006 average acquisition costs among responding independent facilities, February 2007. Third-quarter 2006 Medicare reimbursement amounts were downloaded from: http://cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp. Accessed on February 14, 2007.

* Costs for drugs above the Medicare reimbursement amount are in bold type.

** The average acquisition cost for iron sucrose in nonchain facilities is slightly higher ($0.368) than the third-quarter 2006 Medicare reimbursement amount ($0.366).

Among responding hospitals, the average acquisition cost was less than the Medicare reimbursement amount for 6 of the 11 drugs under review

In the third quarter of 2006, the average acquisition cost among responding hospital-based dialysis facilities for 6 of the 11 ESRD drugs under review was between 4 and 29 percent below the Medicare reimbursement amount. Average acquisition costs for darbepoetin alfa and epoetin alfa (the two drugs that account for the majority of Medicare spending in hospital-based facilities) were 10 and 9 percent below the Medicare reimbursement amount, respectively.

For 5 of the 11 drugs, average acquisition costs ranged from 1 to 8 percent above the Medicare reimbursement amount. Reimbursement for these five drugs accounted for 29 percent of reimbursement to hospital-based dialysis facilities for the selected separately billable ESRD drugs in 2005. This indicates that when compared to independent facilities, hospital-based dialysis facilities could potentially face larger gaps between acquisition costs and Medicare reimbursement when purchasing a number of highly utilized drugs. Table 3 illustrates the percentage difference between average acquisition costs reported by hospital-based dialysis facilities and the third-quarter 2006 Medicare reimbursement amounts.

When weighted by 2005 total reimbursement for each of the 11 drugs, overall drug acquisition costs for responding hospital-based dialysis facilities were, on average, 7 percent below the Medicare reimbursement amount—an amount identical to that for nonchain independent facilities.

Table 3: Medicare Reimbursement and Average Acquisition Cost in Hospital-Based Dialysis Facilities

Drug	Third-Quarter 2006 Medicare Reimbursement Amount	Third-Quarter 2006 Average Acquisition Cost	Reimbursement and Average Cost Difference
Doxercalciferol, 1 μg	$3.16	$2.26	-28.53%
Calcitriol, 0.1 μg	$0.51	$0.37	-27.15%
Alteplase recombinant, 1 mg	$31.67	$27.20	-14.12%
Darbepoetin alfa, 1 μg	$3.03	$2.71	-10.39%
Epoetin alfa, per 1,000 units	$9.48	$8.66	-8.67%
Vancomycin HCl, 500 mg	$3.23	$3.12	-3.54%
Sodium ferric gluconate, 12.5 mg	$4.75	$4.78	0.59%
Levocarnitine, 1 g	$9.08	$9.19	1.19%
Iron sucrose, 1 mg	$0.37	$0.38	3.95%
Paricalcitol, 1 μg	$3.81	$3.99	4.78%
Iron dextran, 50 mg	$10.34	$11.15	7.81%

Source: OIG analysis of third-quarter 2006 average acquisition costs among responding hospital-based dialysis facilities, February 2007. Third-quarter 2006 Medicare reimbursement amounts were downloaded from: http://cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp. Accessed on February 14, 2007.

CONCLUSION

In 2005, CMS reimbursed independent dialysis facilities for most separately billable ESRD drugs based on either their acquisition cost (as determined by OIG) or 106 percent of their ASP. At the same time, CMS reimbursed hospital-based dialysis facilities for most separately billable ESRD drugs on a reasonable cost basis. As of January 1, 2006, CMS enacted several changes to the drug reimbursement methods used for dialysis facilities. One revision included paying all dialysis facilities 106 percent of the ASP for all separately billable ESRD drugs (with the exception of certain vaccines, blood, and blood products), making payment methods for independent and hospital-based dialysis facilities the same.

As the findings in this report show, on average, responding independent dialysis facilities could acquire the majority of the selected separately billable ESRD drugs for less than the Medicare reimbursement amount. Drug acquisition costs among different types of independent dialysis facilities did vary, with overall drug costs among chain facilities being somewhat less than those of nonchains. However, among both chain and nonchain independent dialysis facilities, reimbursement for the drugs with average acquisition costs above the Medicare reimbursement amount accounted for a small percentage of overall drug expenditures. In contrast, average acquisition costs among hospital-based dialysis facilities for 5 of 11 drugs under review exceeded the Medicare reimbursement amount. Expenditures for these drugs represented almost one-third of overall expenditures in hospital-based dialysis facilities for separately billable drugs.

In conclusion, acquisition costs for the same drug may vary based on the type and chain affiliation of the facility, causing some facilities (especially hospital-based facilities) to potentially experience greater gaps in reimbursement than others. CMS should continue to monitor the situation closely to ensure that all facilities are reimbursed appropriately. In addition, we suggest that CMS consider the cost data presented in this report in its discussions about the merits of separately billable drugs under the composite rate, as recommended by the Government Accountability Office.

AGENCY COMMENTS

CMS reiterated that it would continue to monitor ESRD payments in relation to the drug acquisition costs of dialysis providers. CMS also stated that this report provides useful information that will be helpful in these monitoring efforts, and that the agency looks forward to continuing to work with OIG on ESRD issues in the future.

APPENDIX ~ A

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUN 22 2007

TO: Daniel R. Levinson
Inspector General

FROM: Leslie V. Norwalk, Esq.
Acting Administrator

SUBJECT: Office of Inspector General's (OIG) Draft Report: "Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter 2006" (OEI-03-06-00590)

Thank you for the opportunity to review and comment on the OIG's draft report entitled, "Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter 2006." We appreciate the OIG's continuing efforts to examine this important issue.

In accordance with section 1881(b)(13)(A)(iii) of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the payment amount for separately billable end stage renal disease (ESRD) drugs for 2006 and subsequent years is based on the acquisition costs of the drug as determined by the OIG pursuant to section 623(c) of the MMA or the amount determined under section 1847A, as specified by the Secretary. After considering the feasibility of using the acquisition costs from the OIG study, we established the payment amount for separately billable ESRD drugs using the methodology established in section 1847A. Beginning on January 1, 2006, for both freestanding and hospital-based facilities, the payment amount for separately billable ESRD drugs is generally 106 percent of the average sales price, updated quarterly, as reported to the Centers for Medicare & Medicaid Services by manufacturers. As we stated in the December 1, 2006, physician fee schedule final rule (71 FR 69681), we continue to monitor these payments in relation to the drug acquisition costs of dialysis providers.

The OIG report presents findings from a comparison of the Medicare payment amounts for selected separately billable ESRD drugs to the average acquisition costs of these drugs for certain independent and hospital-based dialysis facilities in the third quarter of 2006. The OIG study found that acquisition costs for the same drug may vary based on the type and chain affiliation of the dialysis facility. The overall drug acquisition costs for responding independent dialysis facilities, weighted by 2005 total expenditures, were, on average, 10 percent below the Medicare payment amount. Drug costs for chain facilities were somewhat less (12 percent below the Medicare payment amount) than for non-chain facilities (7 percent below the Medicare payment amount).

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In comparison, the overall drug acquisition costs for responding hospital-based dialysis facilities, weighted by 2005 total expenditures, were on average 7 percent below Medicare payment amount. For these facilities, erythropoiesis-stimulating agents (epoetin alfa and darbepoetin alfa) comprise the majority of the overall drug utilization; therefore the overall findings are significantly influenced by these two drugs.

These findings provide us with useful information that will assist us in our continuing evaluations of Medicare payments associated with providing ESRD services.

We look forward to continuing to work with the OIG on these issues in the future.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director of the Medicare and Medicaid Prescription Drug Unit.

Stephanie Yeager served as the lead analyst. Other regional and central office staff who contributed include Linda B. Abbott, Scott Horning, and Barbara Tedesco.