Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE REIMBURSEMENT FOR NEW END STAGE RENAL DISEASE DRUGS

Daniel R. Levinson
Inspector General

March 2006
OEI-03-06-00200

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts management and program evaluations (called inspections) that focus on issues of concern to HHS, Congress, and the public. The findings and recommendations contained in the inspections generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs. OEI also oversees State Medicaid Fraud Control Units which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

EXECUTIVE SUMMARY

OBJECTIVE

To determine the difference between the Medicare reimbursement amount for a new separately billable end stage renal disease (ESRD) drug and the acquisition cost of this drug for ESRD facilities in 2005, as mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) reimburses all ESRD 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. The composite rate does not include many drugs (i.e., separately billable drugs) that may be part of dialysis treatment.

In 2005, independent dialysis facilities (i.e., freestanding, nonhospital dialysis facilities) were reimbursed for separately billable drugs using two methods. For 10 high-dollar separately billable drugs, reimbursement was based on the average acquisition cost of independent facilities as calculated by CMS using 2003 cost data presented in the Office of Inspector General's (OIG) May 2004 report, "Medicare Reimbursement for Existing End Stage Renal Disease Drugs" (OEI-03-04-00120). All other separately billable drugs furnished by independent dialysis facilities (with certain exceptions, such as vaccines) were reimbursed at 106 percent of the drugs' average sales prices (ASP) as reported by manufacturers. In calendar year (CY) 2005, Medicare reimbursed a total of $1.8 billion for separately billable drugs furnished by independent dialysis facilities.

As of January 1, 2006, CMS began to reimburse all separately billable drugs (again, with certain exceptions) at 106 percent of their ASP, the same method used to reimburse for most other outpatient drugs under Medicare Part B. According to the preamble to a proposed rule published in the August 8, 2005, "Federal Register," CMS stated that it was inappropriate to use the older acquisition cost data provided by OIG (updated by inflation) as a basis for reimbursement. In the proposed rule, CMS also questioned the feasibility of continually acquiring acquisition cost data over the long term.

We conducted this study based on a mandate set forth in section 623(c) of the MMA. Pursuant to section 623(c), this study is to determine the

difference between the Medicare reimbursement amount for any new separately billable ESRD drugs and the acquisition costs of these new drugs for facilities. Section 623(c) of the MMA also directs OIG to estimate the rate of growth of facilities' expenditures for separately billable ESRD drugs.

CMS has the authority to set CY 2007 reimbursement rates for ESRD drugs billed by independent dialysis facilities. Section 1881(b)(12) of the Social Security Act provides for payment neutrality based on increases in the composite rate and reductions in drug reimbursement amounts due to the OIG studies.

Section 623(c)(2)(B) of the MMA defines a "new drug" as a drug "for which a billing code does not exist prior to January 1, 2004." According to our analysis, darbepoetin alfa accounted for 99.9 percent of the Medicare reimbursement for all new ESRD drugs. We sought acquisition cost data for darbepoetin alfa from the 55 facilities responsible for 94 percent of Medicare reimbursement for the drug in 2005. Forty-six facilities (84 percent) responded to our request. We compared CY 2005 acquisition costs for each of these facilities to the Medicare reimbursement amounts in each quarter of that year. We also calculated an average acquisition cost among all the responding facilities, weighted by the number of units of darbepoetin alfa purchased by each facility.

In our May 2004 study, we projected the future growth rate of expenditures for separately billable ESRD drugs, as required by the MMA. In calculating the future growth rate, we looked at past monthly growth rates of expenditures for separately billable drugs over a 3-year period. We could not and did not account for the potential effects of changes to the drug reimbursement methodology. At the time of the earlier study, most separately billable drugs were reimbursed by Medicare using a completely different methodology (based on average wholesale price) than the acquisition-cost based methods used by CMS in 2005 and the ASP-based methods enacted by CMS in 2006. Because of these recent major changes in the reimbursement methodology and the resulting lack of comparable historical data, we determined it would not be possible for us to accurately estimate future growth rates at this time. Once complete data on 2005 and 2006 expenditures become available, the effect of the changes to the reimbursement methodology should be more evident. Any estimates made at that time would therefore be more accurate.

FINDING

In 2005, independent dialysis facilities were able to acquire darbepoetin alfa at prices below the Medicare reimbursement amount. In 2005, net acquisition costs for darbepoetin alfa among the 46 responding facilities were between $2.24 per microgram (mcg) and $2.94 per mcg. On average, facilities paid $2.59 per mcg for darbepoetin alfa in 2005, after all discounts and rebates were taken into account. During this same time period, the Medicare reimbursement amount ranged from a high of $3.54 per mcg in the first quarter of 2005 to a low of $3.01 per mcg in the fourth quarter.

CONCLUSION

Section 623(c) of the MMA mandated that OIG complete a report that determined the difference between the Medicare reimbursement amounts for new separately billable ESRD drugs and the acquisition costs of these drugs for facilities. CMS has the authority to use the data presented in this report to set CY 2007 reimbursement amounts for the new ESRD drugs under review.

This report presents the OIG's findings about acquisition costs to independent dialysis facilities for one new drug, darbepoetin alfa, in 2005. As described in the finding, the responding facilities acquired darbepoetin alfa for less, and sometimes substantially less, than the Medicare reimbursement amount in 2005.

We hope that this data is useful to CMS in its continued efforts to pay appropriately for prescription drugs.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVE

To determine the difference between the Medicare reimbursement amount for a new separately billable end stage renal disease (ESRD) drug and the acquisition cost of this drug for ESRD facilities in 2005, as mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

BACKGROUND

Medicare Reimbursement for Dialysis Services

The Medicare program currently covers kidney dialysis for more than 300,000 enrollees under its ESRD benefit. In accordance with section 1881 of the Social Security Act, the Centers for Medicare & Medicaid Services (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. The composite rate includes most items related to dialysis services, including labor costs, related supplies, routine tests, and some drugs. However, the composite rate does not include many drugs (i.e., separately billable drugs) that may be part of dialysis treatment.

Medicare Reimbursement for Separately Billable ESRD Drugs

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.[1] The exceptions to this requirement are epoetin alfa and darbepoetin alfa, two drugs that stimulate the production of red blood cells in patients with anemia. Epoetin alfa and darbepoetin alfa furnished by dialysis facilities may be covered even when they are self-administered by the patient.[2]

Independent Dialysis Facilities. In 2005, independent dialysis facilities (i.e., freestanding, nonhospital dialysis facilities) were reimbursed for separately billable drugs using two methods.[3] For 10 high-dollar separately billable drugs, reimbursement was based on the average acquisition cost of independent facilities as calculated by CMS based on 2003 cost data presented in the Office of Inspector General's (OIG) May

[1] CMS "Provider Reimbursement Manual," section 2711.2.

[2] CMS "Medicare Benefit Policy Manual," chapter 11, section 90.

[3] 42 CFR § 414.904(d)(2).

2004 report, "Medicare Reimbursement for Existing End Stage Renal Disease Drugs" (OEI-03-04-00120). All other drugs billed by independent dialysis facilities were reimbursed at 106 percent of the drugs' average sales prices (ASP) as reported by manufacturers.[4] In calendar year (CY) 2005, Medicare reimbursed a total of $1.8 billion for separately billable drugs furnished by independent dialysis facilities.

As of January 1, 2006, CMS began to reimburse all separately billable ESRD drugs[5] at 106 percent of their ASP, the same method used to reimburse for other drugs under Medicare Part B.[6,7] CMS stated that it was inappropriate to use the older acquisition cost data provided by OIG (updated by inflation) as a basis for reimbursement, and questioned the feasibility of continually acquiring acquisition cost data over the long term.[8]

Studies Mandated By the MMA

OIG conducted this study and the May 2004 study based on a mandate set forth in the MMA. Section 623(c)(1) of the MMA states:

> The Inspector General of the Department of Health and Human Services shall conduct two studies with respect to drugs and biologicals (including erythropoietin) furnished to end-stage renal disease patients under the Medicare program which are separately billable by end-stage renal disease facilities.

Pursuant to section 623(c)(3) of the MMA, the studies are to determine the difference between the Medicare reimbursement amount for separately billable ESRD drugs and the acquisition costs of these drugs for facilities. The studies must also estimate the growth rate of facilities' expenditures for these drugs. The first study, which focused

---

[4] Exceptions to this payment methodology include certain vaccines, infusion drugs administered through durable medical equipment, and blood products.

[5] Exceptions to this payment methodology include certain vaccines, infusion drugs administered through durable medical equipment, and blood products.

[6] CMS Final Rule 1502-FC, as published in 70 Fed. Reg. 70,116, 70,224 (Nov. 21, 2005).

[7] In 2005, hospital-based dialysis facilities were reimbursed for separately billable drugs (with the exception of erythropoietin) at their cost. In 2006, separately billable drugs furnished by hospital-based facilities are reimbursed at the same rate as independent dialysis facilities, i.e., 106 percent of the ASP. Hospital-based facilities were not included in this study because our review is based on acquisition costs and Medicare reimbursement in 2005.

[8] 70 Fed. Reg. 45,764, 45,845 (Aug. 8, 2005).

on existing ESRD drugs, was completed in May 2004. This second study, which focuses on new ESRD drugs, is to be completed by April 1, 2006. For the purposes of this study, section 623(c)(2)(B) of the MMA defines a "new drug" as a drug "for which a billing code does not exist prior to January 1, 2004."

CMS used data from the first study to set CY 2005 reimbursement rates for ESRD drugs billed by independent dialysis facilities and has the authority do the same in CY 2007 for new drugs identified in this second study. Section 1881(b)(12) of the Social Security Act provides for payment neutrality based on increases in the composite rate to offset any reductions in drug reimbursement amounts due to the OIG studies.

METHODOLOGY

Determining Drugs Under Review

We obtained from CMS a master list of billing codes, and then created a subset of all new billing codes for prescription drugs that became effective on or after January 1, 2004. We then obtained drug reimbursement data for independent dialysis facilities in 2004 and 2005 from CMS's National Claims History File. We determined that codes for six new drugs furnished by independent dialysis facilities had been reimbursed by Medicare in 2004 and 2005.

One drug, darbepoetin alfa, accounted for 99.9 percent of all reimbursement for these six drug codes. Therefore, we limited our data collection to this drug. Among all drugs billed by independent dialysis facilities, darbepoetin alfa ranked in the top seven in terms of total Medicare dollars during the previous 2 years, with reimbursement exceeding $20 million in 2004 and $26 million in 2005.[9] The other five new drugs accounted for less than $20,000 each in reimbursement during both years.

Medicare Reimbursement Amounts

We obtained the Medicare reimbursement amount for darbepoetin alfa from CMS during each quarter of 2005.

[9] Although the $26 million in reimbursement for darbepoetin alfa in 2005 is relatively high, it accounts for less than 2 percent of total Medicare reimbursement for all ESRD drugs billed by independent dialysis facilities. In comparison, Medicare Part B reimbursed almost $800 million in 2005 for darbepoetin alfa provided in physician's offices.

Facility Acquisition Costs

Based on data from CMS's National Claims History File, we determined that only 157 of the approximately 3,900 independent dialysis facilities were reimbursed by Medicare for darbepoetin alfa in 2005. Of these 157, 55 facilities accounted for 94 percent of Medicare reimbursement, with each being reimbursed more than $100,000 for the drug that year.[10] These 55 facilities formed the basis of our sample.

We sent a request to the 55 sampled facilities asking them to provide CY 2005 acquisition cost data for darbepoetin alfa. The requested information was to include the total cost of the purchases, the number of units purchased, and the amount of discounts and rebates received. Forty-six facilities (84 percent) responded to our request. The 46 responding facilities accounted for 86 percent of the Medicare reimbursement for darbepoetin alfa to the 55 facilities in the sample.[11]

We calculated a weighted annual average acquisition cost for darbepoetin alfa among the 46 facilities by adding the total cost of facility purchases (net of all rebates and discounts) in 2005 and dividing the total by the number of units purchased that year. We also obtained a list of any additional costs associated with acquiring separately billable drugs. For this report, we did not verify any of the cost information given by the providers.

Growth Rate of Expenditures

In our May 2004 study, we projected the future growth rate of expenditures for separately billable ESRD drugs, as required by the MMA. In calculating the future growth rate, we looked at past monthly growth rates of expenditures for separately billable drugs over a 3-year period. We could not and did not account for the potential effects of changes to the drug reimbursement methodology. At the time of the earlier study, most separately billable drugs were reimbursed by Medicare using a completely different methodology (based on average

[10] In our 2004 study, we had identified a small number of national chains that accounted for a large majority of Medicare reimbursement for ESRD drugs. However, no facilities owned by these large national chains were among the 55 with the most Medicare reimbursement for darbepoetin alfa in 2005.

[11] The nine facilities that did not respond to our request seemed similar to the facilities that did. There were no distinguishing characteristics (e.g., membership in a chain, amount of Medicare reimbursement, physical location) that would lead to the conclusion that the nonrespondents would have different acquisition costs than the respondents.

wholesale price) than the acquisition-cost based methods used by CMS in 2005 and the ASP-based methods enacted by CMS in 2006. Because of these recent major changes in the reimbursement methodology and the resulting lack of comparable historical data, we determined it would not be possible for us to accurately estimate future growth rates at this time. Once complete data on 2005 and 2006 expenditures become available, the effect of the changes to the reimbursement methodology should be more evident. Any estimates made at that time would therefore be more accurate.

FINDING

In 2005, independent dialysis facilities were able to acquire darbepoetin alfa at prices below the Medicare reimbursement amount

In 2005, net acquisition costs for darbepoetin alfa among the 46 responding facilities were between $2.24 per microgram (mcg) and $2.94 per mcg. On average, facilities paid $2.59 per mcg for darbepoetin alfa in 2005, after all discounts and rebates were taken into account. During this same time period, the Medicare reimbursement amount ranged from a high of $3.54 per mcg in the first quarter of 2005 to a low of $3.01 per mcg in the fourth quarter.[12]

According to the data provided by the facilities, the average discount/ rebate offered for darbepoetin alfa was 17.5 percent. Facility costs before discounts or rebates were taken into account ranged from $2.24 to $4.36, with an average cost of $3.14 per mcg.

Only 10 of the 46 responding facilities estimated any additional costs related to the acquisition of darbepoetin alfa. These additional costs included patient response monitoring, storage, and waste, and were between 0.4 percent and 2.5 percent of total costs for the drug.

[12] In 2005, darbepoetin alfa was not one of the 10 ESRD drugs reimbursed based on the OIG-reported average acquisition cost, and was therefore paid at 106 percent of the ASP. The ASP is reported to CMS by manufacturers on a quarterly basis, and reimbursement amounts may change each quarter based on any increases or decreases in the ASP.

CONCLUSION

Section 623(c) of the MMA mandated that OIG complete a report that determined the difference between the Medicare reimbursement amounts for new separately billable ESRD drugs and the acquisition costs of these drugs for facilities. CMS has the authority to use the data presented in this report to set CY 2007 reimbursement amounts for the new ESRD drugs under review.

This report presents the OIG's findings about acquisition costs to independent dialysis facilities for one new drug, darbepoetin alfa, in 2005. As described in the finding, the responding facilities acquired darbepoetin alfa for less, and sometimes substantially less, than the Medicare reimbursement amount in 2005.

We hope that this data is useful to CMS in its continued efforts to pay appropriately for prescription drugs.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office. Other principal Office of Evaluation and Inspections staff who contributed include:

Dave Tawes, *Director, Prescription Drug Pricing Unit*

Scott Hutchison, *Program Analyst*

Linda Moscoe, *Technical Support Staff*

Linda Boone Abbott, *Program Specialist*