Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

END STAGE RENAL DISEASE DRUGS: FACILITY ACQUISITION COSTS AND FUTURE MEDICARE PAYMENT CONCERNS

Daniel R. Levinson
Inspector General

September 2010
OEI-03-09-00280

EXECUTIVE SUMMARY

OBJECTIVES

1. To compare Medicare payment amounts for selected separately billable end stage renal disease (ESRD) drugs to average acquisition costs for these drugs at dialysis facilities in the first quarter of 2009.
2. To examine how facility acquisition costs for selected separately billable ESRD drugs have changed over the past several years.
3. To determine whether the method the Centers for Medicare & Medicaid Services (CMS) plans to use to update payments for separately billable ESRD drugs after 2011 is an accurate predictor of changes in facility acquisition costs.

BACKGROUND

Beneficiaries typically receive treatment for ESRD, such as dialysis, from a facility that is approved to furnish specific ESRD services. In 2008, 94 percent of dialysis facilities were independent and 6 percent were hospital based. Medicare currently pays both types of 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. Drugs not covered under the composite rate, such as epoetin alfa and darbepoetin alfa, must be billed separately and are referred to as separately billable drugs. Medicare pays for most separately billable drugs furnished by independent and hospital-based dialysis facilities at 106 percent of their average sales prices (ASP). In 2008, Medicare paid $2.1 billion for separately billable ESRD drugs.

On January 1, 2011, Federal law will require CMS to begin implementation of a new system that combines composite rate payments with payments for items and services that are currently separately billable (including separately billable drugs) to create a single bundled payment. Federal law will require that once the bundled rate takes effect, it be updated annually to reflect the changes over time in the prices of goods and services used to provide ESRD care. CMS has decided to base these price updates on wage and price proxy data from the Bureau of Labor Statistics. For the ESRD drugs portion of the new bundled rate, CMS plans to use the Producer Price Index (PPI) for Prescription Drugs to estimate price changes.

We sent requests for information to the three largest independent dialysis companies, a random sample of independent facilities not

owned by the three largest dialysis companies, and all hospital-based dialysis facilities. These surveys included a request for first-quarter 2009 data on the total amount paid; discounts and rebates received; and total units purchased for 11 high-expenditure separately billable ESRD drugs. In total, we received acquisition cost information for more than three-quarters of all dialysis facilities.

We calculated the volume-weighted average acquisition cost per drug and compared it to each drug's first-quarter 2009 Medicare payment amount. We also performed this comparison in the aggregate (i.e., for the entire group of drugs as a whole). To examine how facility acquisition costs for selected separately billable ESRD drugs have changed over the past several years, we compared average acquisition costs for the first quarter of 2009 to average acquisition costs in 2003, 2005, and the third quarter of 2006, as determined in previous Office of Inspector General (OIG) reports. To determine whether the PPI for Prescription Drugs has been an accurate predictor of changes in acquisition costs for certain separately billable ESRD drugs, we compared the changes in acquisition costs for separately billable drugs in independent facilities to changes in the PPI for Prescription Drugs from 2003 to the first quarter of 2009 (changes for darbepoetin alfa were measured from 2005, as the drug did not yet have a Medicare billing code in 2003).

FINDINGS

In the aggregate, drug acquisition costs at independent dialysis facilities were 10 percent below Medicare payment amounts.
In the first quarter of 2009, aggregate acquisition costs for ESRD drugs among responding independent dialysis facilities averaged 10 percent below Medicare payment amounts. For these facilities, average acquisition costs for all 11 of the drugs under review were between 2 percent and 27 percent below Medicare payment amounts. The average acquisition cost for epoetin alfa (a product that accounted for nearly 70 percent of Medicare drug expenditures in independent facilities in 2008) was 9 percent less than the Medicare payment amount. Overall, responding independent chain dialysis facilities paid less for drugs under review than nonchain facilities.

In the aggregate, drug acquisition costs at hospital-based dialysis facilities were 7 percent below Medicare payment amounts. In the first quarter of 2009, aggregate acquisition costs for ESRD drugs among

responding hospital-based dialysis facilities averaged 7 percent below Medicare payment amounts. For these facilities, average acquisition costs for 5 of the 11 ESRD drugs under review were between 4 percent and 33 percent below Medicare payment amounts. Average acquisition costs for epoetin alfa and darbepoetin alfa (two products that accounted for 73 percent of Medicare drug spending in hospital-based facilities in 2008) were 4 percent and 15 percent below the Medicare payment amounts, respectively. For 6 of the 11 drugs, average acquisition costs among responding hospital-based facilities ranged from 0.4 percent to 12 percent above the Medicare payment amounts (for 3 of these drugs, the difference was 1 percent or less). These six drugs accounted for 23 percent of total Medicare payments to hospital-based facilities in 2008.

Over the past several years, average acquisition costs for 7 of the 11 drugs under review have decreased among responding independent dialysis facilities. Seven of the eleven separately billable ESRD drugs under review have seen a decrease in their average acquisition costs for responding independent dialysis facilities over the last several years. In contrast, only four drugs became more expensive for independent dialysis facilities during this time period. These four drugs accounted for only 3 percent of total Medicare payments to independent facilities for separately billable ESRD drugs in 2008.

During a period when acquisition costs for many ESRD drugs decreased, the index CMS plans to use as the basis for future payment changes increased by 39 percent. Once the new payment methodology takes effect in 2011, CMS plans to use the PPI for Prescription Drugs as the basis for annual adjustments to the prescription drug portion of the bundled rate. According to PPI data, prices for prescription drugs were 39 percent higher in the first quarter of 2009 than in 2003. However, facility acquisition costs for the drugs that account for the majority of Medicare expenditures in independent dialysis facilities actually decreased during this same period.

For example, the average acquisition cost among responding independent dialysis facilities for 1,000 units of epoetin alfa fell from $8.82 in 2003 to $8.37 in the first quarter of 2009 (a decrease of 5 percent). If the PPI for Prescription Drugs had been an accurate predictor for changes in the acquisition cost of epoetin alfa since 2003, dialysis facilities would have paid $12.22 for 1,000 units of the drug in the first quarter of 2009. This amount would be 46 percent higher than epoetin alfa's average

acquisition cost among responding independent dialysis facilities (and 33 percent higher than the ASP-based payment amount). Had the Medicare payment amount for epoetin alfa since 2003 been based on changes in the PPI for Prescription Drugs, total program payments to all independent dialysis facilities for the drug in the first quarter of 2009 alone would have been $113 million higher than actual payments under the current ASP-based system.

RECOMMENDATION

CMS currently pays all dialysis facilities at 106 percent of ASPs for most separately billable ESRD drugs. Under the current system, we found that aggregate acquisition costs for ESRD drugs at both independent and hospital-based dialysis facilities were below Medicare payment amounts. In addition, when we compared acquisition costs among responding independent dialysis facilities to costs from prior OIG reports, we found that 7 out of the 11 separately billable ESRD drugs under review have actually seen a decrease in their average acquisition costs over the last several years. The cost of epoetin alfa, a drug responsible for more than $1.4 billion in annual Medicare spending in dialysis facilities, fell by 5 percent. During this same period, the PPI for Prescription Drugs increased by 39 percent.

If the new bundled system is implemented as planned and acquisition costs for the majority of separately billable ESRD drugs decrease (as they have in the past) while price indexes rise, the existing gap between Medicare payment amounts and dialysis facility acquisition costs will continue to grow each year. As a result, payments under the new bundled system would not accurately reflect facility acquisition costs, potentially costing the program additional hundreds of millions of dollars per year. Therefore, we recommend that CMS:

Develop a more accurate method for estimating changes in the prices of ESRD drugs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS did not concur with our recommendation. In its response to the draft report, CMS stated that the downward trajectory of average acquisition costs documented in OIG's analysis was influenced largely by changes in CMS's payment mechanism for separately billable ESRD drugs, particularly for epoetin alfa. CMS states that, as a result, OIG's

figures are not suitable for inferring future price trends as the market for epoetin alfa becomes more competitive. CMS's view is that it is more appropriate to look at recent quarterly price changes—changes that CMS states have not been distorted by changes in payment policy—that show an increase in the cost of epoetin alfa since the end of 2008. CMS expects that future ESRD drug price growth will more closely reflect market-based price drivers, such as those measured by the PPI for Prescription Drugs.

OIG fully appreciates the difficulty that CMS faces in implementing the new bundled rate payment system, especially in terms of estimating future costs for all items and services related to ESRD care. OIG also realizes that the historical average acquisition cost data presented in this report may not necessarily be predictive of future trends in the costs of separately billable drugs. Nevertheless, based on our findings, we remain concerned that Medicare could end up paying too much for these drugs once the bundled rate is implemented, potentially costing the program and its beneficiaries hundreds of millions of dollars a year. Therefore, OIG intends to work with CMS to carefully monitor the cost of epoetin alfa and other ESRD drugs in the future.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVES

1. To compare Medicare payment amounts for selected separately billable end stage renal disease (ESRD) drugs to average acquisition costs for these drugs at dialysis facilities in the first quarter of 2009.
2. To examine how facility acquisition costs for selected separately billable ESRD drugs have changed over the past several years.
3. To determine whether the method the Centers for Medicare & Medicaid Services (CMS) plans to use to update payments for separately billable ESRD drugs after 2011 is an accurate predictor of changes in facility acquisition costs.

BACKGROUND

Medicare pays dialysis facilities for most items and services based on a prospective payment system, known as the composite rate. However, many ESRD drugs and biologicals used in treating dialysis patients must be billed separately and are therefore referred to as separately billable drugs.[1] Medicare currently bases payment for most separately billable ESRD drugs on 106 percent of their average sales prices (ASP). Prior Office of Inspector General (OIG) reports have found that Medicare payment amounts for the majority of the high-expenditure separately billable ESRD drugs reviewed were consistently higher than average acquisition costs reported by dialysis facilities.[2]

On January 1, 2011, Federal law will require CMS to begin implementation of a new system that combines composite rate payments with payments for items and services that are currently separately billable (including separately billable drugs) to create a single bundled payment.[3] On August 12, 2010, CMS published a notice of final rulemaking that sets forth the payment methodology under the new bundled rate system.[4] According to the preamble to the final rule, once the new system takes effect in 2011, bundled payments in future

[1] Hereinafter, the term "drugs" refers to both drugs and biologicals.

[2] OIG, *Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter 2006* (OEI-03-06-00590), June 2007; *Medicare Reimbursement for New End Stage Renal Disease Drugs* (OEI-03-06-00200), March 2006; *Medicare Reimbursement for Existing End-Stage Renal Disease Drugs* (OEI-03-04-00120), May 2004.

[3] Social Security Act (the Act), § 1881(b)(14).

[4] 75 Fed. Reg. 49030 (Aug. 12, 2010).

years (i.e., 2012 and later) will be annually updated based on an inflationary index developed by CMS. This index will use data published by the Bureau of Labor Statistics (BLS), including the Producer Price Index (PPI) for Prescription Drugs, to estimate yearly changes in the prices of ESRD-related goods and services.[5]

In a letter to OIG, Representative Pete Stark expressed concerns that the bundled payment system in 2011 may not accurately reflect facility acquisition costs and requested that OIG update its analysis of the acquisition costs paid by dialysis facilities for separately billable ESRD drugs. Specifically, OIG was requested to (1) compare recent acquisition costs in dialysis facilities to the Medicare payment amounts and (2) compare recent acquisition costs in dialysis facilities to acquisition costs from prior years as published in earlier OIG reports.

Treatment of End Stage Renal Disease

ESRD is a condition in which the kidneys are no longer able to function at a level necessary for day-to-day life. The loss of kidney function in ESRD patients is usually permanent. Treatment options include kidney transplantation and dialysis. In 2007, Medicare covered approximately 400,000 beneficiaries with ESRD.[6] One of the most common complications of ESRD is anemia, a deficiency in red blood cells. Erythropoietin-stimulating agents, such as epoetin alfa (trade name Epogen) and darbepoetin alfa (trade name Aranesp), treat anemia by increasing the number of red blood cells.

Beneficiaries receive treatment for ESRD, such as dialysis, from a facility that is approved to furnish specific ESRD services. Facilities may be either independent or hospital based. Both types of dialysis facilities provide outpatient services to ESRD patients as well as home maintenance dialysis, which is dialysis performed by appropriately trained patients at their own homes. Independent dialysis facilities are freestanding and the majority are owned or managed by a chain (87 percent of independent dialysis facilities are chain facilities according to CMS's Dialysis Facility Compare database). Hospital-based dialysis facilities must be financially and

[5] 75 Fed. Reg. 49030, 49154–49161 (Aug. 12, 2010).

[6] *Payment, Safety and Quality Issues in Treatment of Patients with ESRD.* Testimony of Leslie V. Norwalk, Esq., Acting Administrator, CMS, June 26, 2007. Accessed at http://waysandmeans.house.gov/media/pdf/110/norwalk.pdf on July 9, 2009.

administratively integrated within a hospital.[7] As of December 2008, independent dialysis facilities accounted for 94 percent of all facilities and hospital-based dialysis facilities represented only 6 percent.[8]

Medicare Payments to Dialysis Facilities

CMS currently pays 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 is composed of a labor and nonlabor portion, with an add-on adjustment for area wage index. The composite rate includes most items and services related to dialysis services, such as labor costs; related supplies; routine tests; and certain drugs, such as antihistamines, glucose, and insulin. Since January 1, 2009, hospital-based facilities receive the same rate as independent dialysis facilities.[9] Drugs not covered under the composite rate, such as epoetin alfa and darbepoetin alfa, must be billed separately and are referred to as separately billable drugs.[10]

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 physician or other health care professional. Exceptions include epoetin alfa and darbepoetin alfa, which are covered even if self-administered by the patient.[11]

According to CMS's National Claims History File, Medicare paid $2.1 billion for separately billable drugs furnished by dialysis facilities in 2008 ($2 billion in independent dialysis facilities and $116 million in hospital-based dialysis facilities).[12] Epoetin alfa and darbepoetin alfa accounted for 72 percent of Medicare payments for separately billable ESRD drugs in independent dialysis facilities and 73 percent of payments in hospital-based dialysis facilities.

---

[7] 42 CFR §§ 413.174(c)(4) and 413.174(c)(5).

[8] Dialysis Facility Compare database. Accessed at http://www.medicare.gov on December 10, 2008.

[9] CMS, *Medicare Benefit Policy Manual*, ch. 11, § 30.5; CMS, *Medicare Claims Processing Manual,* ch. 8, § 10.1.

[10] CMS, *Medicare Benefit Policy Manual*, ch. 11, § 30.4.2; CMS, *Medicare Claims Processing Manual,* ch. 8, § 60.2.1.1.

[11] CMS, *Medicare Benefit Policy Manual*, ch. 11, §§ 30.4 and 90.

[12] As of December 2009, the National Claims History File for 2008 was 95-percent complete.

Independent dialysis facilities. Prior to January 1, 2005, CMS paid independent dialysis facilities for separately billable drugs based on the lower of the billed amount or 95 percent of their average wholesale prices. The exception was epoetin alfa, which was paid for based on a statutory payment allowance of $10 per 1,000 units.[13]

Beginning January 1, 2005, in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), P.L. 108-173, CMS based payment to independent dialysis facilities for the 10 highest expenditure separately billable drugs on acquisition costs determined by OIG.[14] With certain exceptions, including specific vaccines, CMS paid all other drugs administered in independent dialysis facilities in 2005 at 106 percent of their ASPs.[15]

As of January 1, 2006, with certain exceptions, CMS began to pay for all separately billable drugs furnished by independent dialysis facilities at 106 percent of their ASPs.[16] This is the same method used to pay for other drugs under Medicare Part B. In announcing this change, CMS stated that it was inappropriate to use the older acquisition data provided by OIG (updated for inflation) as a basis for payment and questioned the feasibility of continually acquiring acquisition cost data over the long term.[17]

Hospital-based dialysis facilities. Prior to January 1, 2006, CMS paid hospital-based dialysis facilities for separately billable drugs based on reasonable cost.[18] The exception to this rule was epoetin alfa, which was paid in the same manner as in independent facilities, i.e., based on a statutory payment allowance of $10 per 1,000 units prior to January 1, 2005, and based on the OIG-reported average acquisition cost in 2005.[19] Since January 1, 2006, all separately billable drugs

---

[13] The Act, §§ 1881(b)(11)(B)(ii)(I) and 1881(b)(11)(B)(ii)(II). CMS, *Medicare Claims Processing Manual,* ch. 8, §§ 60.2.2 and 60.4.3.

[14] MMA, § 623(d)(1). The Act, § 1881(b)(13)(A)(ii). As required by the MMA, OIG reviewed 2003 acquisition costs for 10 high-dollar ESRD drugs in the study entitled *Medicare Reimbursement for Existing End-Stage Renal Disease Drugs* (OEI-03-04-00120), May 2004. See the discussion of related OIG work on p. 7 for additional information.

[15] 42 CFR §§ 414.904(d)(2) and 414.904(e).

[16] CMS, *Medicare Claims Processing Manual*, ch. 8, § 60.2.2; 42 CFR §§ 414.904(d)(2)(iii) and 414.904(e).

[17] 70 Fed. Reg. 70116, 70222–70223 (Nov. 21, 2005).

[18] CMS, *Medicare Claims Processing Manual*, ch. 8, § 60.2.2.

[19] The Act, §§ 1881(b)(11)(B)(ii)(I) and 1881(b)(11)(B)(ii)(II). CMS, *Medicare Claims Processing Manual,* ch. 8, § 60.4.3.

(with certain exceptions) furnished by hospital-based dialysis facilities have been paid at 106 of their ASPs.[20] This change produced a consistent drug payment methodology among independent dialysis facilities and hospital-based dialysis facilities.

Changes to the ESRD Payment Methodology Under the Medicare Improvements for Patients and Providers Act of 2008

Effective January 1, 2011, section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), P.L. 110-275, will require Medicare payment for all items and services used in the treatment of ESRD, including drugs that are currently separately billable, to be included in a single bundled rate. The new bundled rate is to be implemented over a multiyear phase-in period, with full implementation beginning January 1, 2014.[21] However, prior to January 1, 2011, ESRD facilities may make a one-time election to be excluded from the phase-in and accept payment entirely under the ESRD bundled rate.[22]

This new bundled rate will include a payment adjustment based on patient characteristics, unusual variations in the type or amount of medical care needed, and additional costs incurred at low-volume facilities.[23] On August 12, 2010, CMS published a final rule that would implement the bundled rate for outpatient ESRD facilities.[24]

Base rate in 2011. According to the final rule, CMS will calculate a base rate per treatment (base rate) by adding the projected 2011 composite rate payment to the projected 2011 average payment for separately billable services (including separately billable drugs).[25] In accordance with Federal law, the estimated total payments under the bundled base rate must equal 98 percent of the estimated total amount of payments

---

[20] CMS, *Medicare Claims Processing Manual*, ch. 8, § 60.2.2. 42 CFR §§ 414.904(d)(2)(iii) and 414.904(e).

[21] During the phase-in, ESRD facilities will be paid based on a blend of the ESRD bundled rate and composite rate payment/separately billable systems.

[22] The Act, § 1881(b)(14)(E)(ii).

[23] The Act, § 1881(b)(14)(D). Payment adjustments may also include additional items that the Secretary of Health & Human Services determines appropriate, such as an adjustment for facilities located in rural areas.

[24] 75 Fed. Reg. 49030 (Aug. 12, 2010).

[25] 75 Fed. Reg. 49030, 49200 (Aug. 12, 2010).

that would have been made for 2011 if the bundled rate had not been implemented.[26]

Separately billable drugs component of the base rate in 2011. In the preamble to its final rule, CMS states that total payments for the top 11 separately billable ESRD drugs accounted for 99.8 percent of total spending for all separately billable drugs in 2007.[27, 28] Because total payments under the new system must initially equal 98 percent of the estimated total payments that would have been made if the bundled system were not implemented, CMS must determine what total payments for separately billable drugs would likely be in 2011 under the current system. In doing this, CMS updated the second-quarter 2010 ASP-based payment amounts for separately billable drugs to 2011 levels using the PPI for Prescription Drugs.[29, 30]

Annual payment increases after 2011. Once the base rate for ESRD bundled payments is established, it will be annually updated to reflect changes over time in the prices of goods and services used to provide ESRD care. Federal law requires CMS to develop an all-inclusive ESRD bundled rate (ESRDB) input price index that will reflect annual price increases of the various categories that make up the ESRDB market basket.[31, 32] CMS plans to use wage and price proxies published by BLS to measure the annual rate of price change in each category (e.g., wages and salaries, pharmaceuticals, capital costs).[33] Beginning in 2012, ESRD bundled payment amounts must be annually updated by the increase in the ESRDB price index minus a productivity adjustment.[34]

---

[26] The Act, § 1881(b)(14)(A)(ii).

[27] 75 Fed. Reg. 49030, 49076 (Aug. 12, 2010).

[28] Ten of these drugs were included in this report. The drugs selected for this report were chosen prior to CMS's publishing its final rule for the new ESRD payment system.

[29] 75 Fed. Reg. 49030, 49079 (Aug. 12, 2010).

[30] According to CMS, the term "PPI for Prescription Drugs," as used in its final rule, refers specifically to BLS's price index for *Pharmaceuticals for Human Use (Prescription)*. See 75 Fed. Reg. 49030, 49160 (Aug 12, 2010).

[31] The Act, § 1881(b)(14)(F)(i), as amended by section 3401(h) of the Patient Protection and Affordable Care Act (PPACA), P.L. 111-148. We conducted this study prior to the passage of the PPACA. The changes contained in the PPACA had no effect on our analysis.

[32] In this context, the term "ESRD market basket" refers to the mix of goods and services used to produce ESRD care.

[33] 75 Fed. Reg. 49030, 49158–49160 (Aug. 12, 2010).

[34] The Act, §§ 1881(b)(14)(F)(i)(I) and 1881(b)(14)(F)(i)(II), as amended by section 3401(h) of the PPACA. The productivity adjustment is described in the Act, § 1886(b)(3)(B)(xi)(II).

According to the preamble to CMS's final rule, the pharmaceutical category of the ESRDB will account for approximately 25 percent of the entire ESRDB market basket, with epoetin alfa expenditures making up almost 70 percent of the pharmaceutical category.[35] CMS intends to use the PPI for Prescription Drugs as its price proxy for the pharmaceutical category.[36] According to CMS, the PPI for Prescription Drugs reflects price changes associated with the average mix of all prescription drugs sold in pharmacies. CMS states that it anticipates "… the price changes associated with the assortment of drugs administered in ESRD facilities should, over time, be similar to the average prescription drug price changes observed across the entire economy."[37]

Related Work by the Office of Inspector General

An OIG report completed in May 2004 and a followup report completed in March 2006 compared the average acquisition costs reported by independent dialysis facilities to the Medicare payment amounts for selected ESRD drugs.[38] The May 2004 report found that large independent dialysis facilities could acquire 10 high-expenditure drugs at costs that averaged 22 percent below the Medicare payment amount; smaller independent facilities could acquire these drugs for an average of 14 percent less. Both large and small facilities could obtain epoetin alfa for an average of 12 percent and 5 percent below the Medicare payment amount, respectively. The March 2006 report focused on only darbepoetin alfa, which did not yet have its own Medicare billing code during the period covered by the May 2004 report. Independent dialysis facilities could acquire darbepoetin alfa for less (sometimes substantially less) than the Medicare payment amount.

A June 2007 OIG report provided updated information on payment differences for 11 high-dollar separately billable ESRD drugs (the 10 drugs included in the May 2004 report and the 1 drug from the March 2006 report).[39] In the June 2007 report, we found that independent dialysis facilities could acquire 9 of the 11 ESRD drugs

---

[35] 75 Fed. Reg. 49030, 49156–49158 (Aug. 12, 2010).

[36] Ibid, 49160 (Aug. 12, 2010).

[37] Ibid.

[38] OIG, *Medicare Reimbursement for Existing End-Stage Renal Disease Drugs* (OEI-03-04-00120), May 2004; *Medicare Reimbursement for New End Stage Renal Disease Drugs* (OEI-03-06-00200), March 2006.

[39] OIG, *Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter 2006* (OEI-03-06-00590), June 2007.

under review for costs averaging from 7 percent to 32 percent less than the Medicare payment amounts. For the two remaining drugs, average acquisition costs among independent facilities were 3 percent and 9 percent above the Medicare payment amounts. Hospital-based dialysis facilities could acquire 6 of the 11 drugs under review at prices averaging from 4 percent to 29 percent less than the Medicare payment amounts. For the five remaining drugs, average acquisition costs among hospital-based facilities ranged from 1 percent to 8 percent above the Medicare payment amounts.

METHODOLOGY

Scope

This study focused on the 11 drugs that had been included in OIG's 3 most recent studies of ESRD drug pricing. Since 2003, these 11 drugs have consistently accounted for nearly all of Medicare's spending on separately billable ESRD drugs in dialysis facilities.

Drugs Under Review

We compiled a list of the 11 drugs included in the 3 OIG ESRD drug pricing studies issued since 2003. Using data from CMS's National Claims History File, we then determined Medicare expenditures in 2007 for each of these 11 drugs, as well as for all separately billable ESRD drugs furnished by dialysis facilities.[40] As Table 1 shows, all of the selected drugs were among the 15 drugs (excluding vaccines) with the highest total payments in independent and hospital-based dialysis facilities (and all but 3 were among the top 10 in both settings). In independent and hospital-based dialysis facilities, the 11 selected drugs accounted for 99 percent and 97 percent of total Medicare payments for separately billable drugs in 2007, respectively.

[40] At the time we selected our sample, outpatient data for 2008 were not 100 percent complete. See Appendix A for Medicare payments in 2008 for the drugs under review.

Table 1: Payment in 2007 for Drugs Under Review

Separately Billable Drug	Payment Ranking in Independent Dialysis Facilities	Total Payment in Independent Dialysis Facilities	Payment Ranking in Hospital-Based Dialysis Facilities	Total Payment in Hospital-Based Dialysis Facilities
Epoetin alfa, per 1,000 units	1	$1,457,712,457	2	$44,438,489
Paricalcitol, 1 μg*	2	$243,791,813	3	$9,182,565
Iron sucrose, 1 mg	3	$125,469,448	4	$5,185,761
Doxercalciferol, 1 μg	4	$56,453,718	5	$3,438,602
Sodium ferric gluconate, 12.5 mg	5	$49,201,885	6	$3,400,363
Darbepoetin alfa, 1 μg	6	$47,980,810	1	$57,389,882
Alteplase recomb, 1 mg	7	$16,286,265	7	$3,307,690
Levocarnitine, 1 g	8	$3,561,991	11	$328,083
Vancomycin HCL, 500 mg	9	$2,595,876	12	$194,233
Calcitriol, 0.1 μg	10	$1,931,801	10	$414,817
Iron dextran, 50 mg	15	$474,834	13	$129,437
Total		**$2,005,460,898**		**$127,409,922**

Source: OIG analysis of 2007 National Claims History File.

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

Data Collection

Independent dialysis facilities. As of December 2008, 3 dialysis companies (Davita, Fresenius, and Dialysis Clinic, Inc.) owned 3,181 (71 percent) of the 4,461 independent dialysis facilities.[41] We sent a survey requesting first-quarter 2009 acquisition cost information for the 11 drugs under review to representatives of these 3 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. Between August 2009 and January 2010, all three companies responded with the requested information. In their responses, the 3 large dialysis companies indicated that they had

[41] Dialysis Facility Compare database. Accessed at http://www.medicare.gov on December 10, 2008.

acquired or opened an additional 137 independent dialysis facilities in the first quarter of 2009 (for a revised total of 3,318).

We also sent requests for information for identical first-quarter 2009 cost data to a random sample of 200 independent dialysis facilities not affiliated with the 3 largest companies.[42] We asked each facility if it was part of a chain. Between August and December 2009, we received responses from 165 facilities (83 percent). However, 18 of the responding independent facilities had actually been acquired by Davita or Fresenius, meaning that they were owned by 1 of the 3 large dialysis companies during the review period. Acquisition cost data for these 18 facilities were thus included as part of the larger companies' responses. Another two facilities provided incomplete data that could not be included in the analysis. Therefore, we received complete data from 145 independent dialysis facilities not affiliated with the 3 largest companies. Several of the responding facilities owned multiple dialysis units and provided cost data for 20 additional facilities (for a total of 165 respondents not affiliated with the 3 large independent dialysis companies). According to the responses provided, 106 of these facilities were part of a chain and 59 were nonchains.

After we combined data from the 3,318 facilities owned or managed by the 3 largest dialysis companies and the 165 responding unaffiliated independent dialysis facilities, our results represent acquisition costs for more than three-quarters of all independent dialysis facilities.

Hospital-based dialysis facilities. We selected all of the 276 hospital-based dialysis facilities that were listed in CMS's Dialysis Facility Compare database as of December 2008. In July 2009, we sent surveys to these facilities requesting first-quarter 2009 acquisition cost information for each of the 11 drugs under review. Between August and December 2009, we received responses from 199 hospital-based dialysis facilities (72 percent of all hospital-based dialysis facilities).

We were unable to use data from 57 respondents because of their participation in the 340B program.[43] In addition, one hospital-based facility was excluded from our analysis because it received Department

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

[43] The 340B program requires drug manufacturers to provide drugs to eligible health care centers at or below statutorily defined ceiling prices. Public Health Services Act, § 340B.

of Veterans Affairs pricing, which is heavily discounted compared to the marketplace. Another five facilities were excluded from our analysis for providing incomplete data. Two hospital-based facilities had been acquired by one of the major dialysis companies (and therefore no longer met the definition of "hospital based"). One of the responding hospitals provided data on 3 additional hospitals, resulting in 134 respondents with valid data for 137 hospital-based dialysis facilities.

CMS data. We obtained the ASP-based Medicare payment amounts for the 11 selected separately billable ESRD drugs in the first quarter of 2009 from CMS's Web site.

PPI data. For the purpose of comparing changes in the PPI for Prescription Drugs to changes in facility acquisition costs, we obtained from BLS's Web site annual and monthly values of the PPI for Prescription Drugs for the period beginning in 2003 (i.e., the period covered by OIG's first mandated ESRD pricing study) and ending in March 2009.

Data Analysis

Comparing acquisition costs to Medicare payment amounts. For both facility types (i.e., independent and hospital-based), we calculated volume-weighted average acquisition costs (hereinafter referred to as average acquisition costs) by totaling the amount paid net of 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.[44] We calculated the percentage difference between the average acquisition cost and CMS's first-quarter 2009 ASP-based Medicare payment amount per drug for both facility types.

To calculate the aggregate difference between the average acquisition costs and CMS's first-quarter 2009 ASP-based Medicare payment amounts among all 11 drugs, we:

[44] Among independent dialysis facilities, an average of 1.9 responses per drug were considered outliers and removed. Among hospital-based dialysis facilities, this number was 1.5. No more than four outliers were removed for any single drug in both types of facilities.

- calculated the total amount paid for the 11 drugs among the facilities by summing the data reported by all respondents;
- multiplied the total units purchased for each drug, as reported by facilities, by its Medicare payment amount to calculate the total amount that facilities would have paid for all these drugs if their acquisition costs equaled Medicare payment amounts; and
- calculated the percentage difference between the total amount paid for the 11 drugs, as reported by facilities, and the total that would have been paid had the acquisition cost been equal to Medicare payment amounts.

Independent chain versus nonchain facilities. To determine whether independent dialysis chain facilities had average acquisition costs that differed from those of nonchain facilities, we compared cost data from the 3,424 responding facilities affiliated with chains to cost data from the 59 responding nonchain facilities by repeating the analysis described in the section above. In addition, we compared chain and nonchain acquisition costs to CMS's first-quarter 2009 ASP-based Medicare payment amounts. We also calculated the aggregate difference between chain and nonchain acquisition costs and CMS's first-quarter 2009 ASP-based payment amounts.

Change in PPI for Prescription Drugs versus change in acquisition costs. Using cost data from previous OIG reports, we compared average acquisition costs from the first quarter of 2009 to average acquisition costs in 2003 (for 10 of the 11 drugs), 2005 (for darbepoetin alfa only), and the third quarter of 2006.[45, 46] To determine whether actual drug costs have increased, decreased, or remained the same, we determined

[45] OIG reports entitled *Medicare Reimbursement for Existing End-Stage Renal Disease Drugs* (OEI-03-04-00120), May 2004, and *Medicare Reimbursement for New End Stage Renal Disease Drugs* (OEI-03-06-00200), March 2006, contained acquisition cost data for the entire years (2003 and 2005, respectively). *Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter 2006* (OEI-03-06-00590), June 2007, contained acquisition cost data only for the third quarter of 2006. In addition, the March 2006 report focused only on a single drug (darbepoetin alfa), which did not yet have its own Medicare billing code at the time of our initial report.

[46] In the May 2004 OIG report entitled *Medicare Reimbursement for Existing End-Stage Renal Disease Drugs* (OEI-03-04-00120), we separately calculated average acquisition costs for the four largest independent dialysis companies and smaller independent dialysis facilities (we did not calculate a combined figure). For the purpose of this report, we estimated a combined average acquisition cost for independent facilities in 2003 using a weighting method that approximates how costs for independent facilities were calculated in later reports.

the percentage change in price between each period for each drug. Because two of the earlier OIG reports did not collect acquisition cost data from hospital-based dialysis facilities, we compared acquisition cost changes over time only for independent dialysis facilities.

To determine whether the PPI for Prescription Drugs has been an accurate predictor of changes in prices for separately billable ESRD drugs, we compared the changes in per-drug acquisition costs among independent dialysis facilities for separately billable drugs to changes in the PPI from 2003 to the first quarter of 2009. Using the same data, we also calculated how much epoetin alfa (a drug whose expenditures will account for nearly 70 percent of the pharmaceutical portion of the ESRD market basket under the new bundled rate) would have cost in the first quarter of 2009 if its average acquisition cost from 2003 had changed at the same rate as the PPI for Prescription Drugs. To estimate the amount that total Medicare expenditures would have differed in the first quarter of 2009 had payment for epoetin alfa been based on the PPI for Prescription Drugs since 2003 rather than ASP, we (1) calculated the percentage difference between the drug's first-quarter 2009 Medicare payment amount and the PPI-based cost figure from the same quarter and (2) multiplied this amount by one-quarter of Medicare expenditures for the drug in independent dialysis facilities in 2008.[47]

Limitations

We did not verify the drug cost information submitted by the dialysis facilities. The acquisition cost data provided in this report represent all purchases for the drugs under review made by more than three-quarters of all dialysis facilities during the first quarter of 2009; we did not project these figures to facilities not included in our sample.

Standards

This study was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

[47] This calculation assumes that Medicare expenditures in the first quarter of 2009 were equal to one-quarter of the annual expenditures in 2008.

In the aggregate, drug acquisition costs at independent dialysis facilities were 10 percent below Medicare payment amounts

In the first quarter of 2009, aggregate acquisition costs for ESRD drugs among responding independent dialysis facilities averaged 10 percent below Medicare payment amounts. For these facilities, average acquisition costs for all 11 of the drugs under review were between 2 percent and 27 percent below Medicare payment amounts.

The average acquisition cost for epoetin alfa (a product that accounted for nearly 70 percent of Medicare drug expenditures in independent facilities in 2008) was 9 percent less than the Medicare payment amount. In total, 99 percent of responding independent dialysis facilities could purchase epoetin alfa at prices that were below the Medicare payment amount in that quarter. Table 2 illustrates the percentage difference between Medicare payment amounts and average acquisition costs reported by independent dialysis facilities for the first quarter of 2009.

Table 2: Medicare Payment Amounts and Average Acquisition Costs for Responding Independent Dialysis Facilities

Separately Billable Drug	First-Quarter 2009 Medicare Payment Amount	First-Quarter 2009 Average Acquisition Cost	Percentage Difference	Percentage of Medicare Payments to Independent Facilities for Separately Billable Drugs in 2008
Alteplase recombinant, 1 mg	$34.10	$33.40	-2.1%	0.8%
Iron dextran, 50 mg	$11.78	$11.21	-4.8%	< 0.1%
Sodium ferric gluconate, 12.5 mg	$4.74	$4.40	-7.2%	2.5%
Epoetin alfa, per 1,000 units	$9.20	$8.37	-9.0%	69.5%
Paricalcitol, 1 μg	$3.66	$3.29	-10.1%	14.2%
Doxercalciferol, 1 μg	$3.31	$2.94	-11.2%	2.5%
Vancomycin HCl, 500 mg	$3.08	$2.70	-12.3%	0.1%
Iron sucrose, 1 mg	$0.37	$0.31	-16.2%	6.6%
Darbepoetin alfa, 1 μg	$3.06	$2.54	-17.0%	2.2%
Levocarnitine, 1 g	$6.71	$5.35	-20.3%	0.1%
Calcitriol, 0.1 μg	$0.45	$0.33	-26.7%	0.1%
Aggregate			**-9.7%**	**98.6%**

Source: OIG analysis of first-quarter 2009 average acquisition costs among responding independent facilities, November 2009.

Overall, responding independent chain dialysis facilities paid less for the drugs under review than nonchain facilities

In the aggregate, overall acquisition costs among responding independent chain facilities averaged 10 percent below Medicare payment amounts. Costs among responding independent nonchain facilities averaged 3 percent below Medicare payment amounts.

On average, responding independent chain facilities could purchase 10 of the 11 drugs under review for less than responding independent nonchain facilities in the first quarter of 2009. For these 10 drugs, average acquisition costs among chains ranged from 3 percent to 26 percent less than average acquisition costs among nonchains. For the 11th drug, chains actually paid 2 percent more, on average.

For responding independent chain facilities, average acquisition costs were less than the Medicare payment amounts for all 11 drugs. However, among responding independent nonchain facilities, there were three drugs for which the average acquisition costs exceeded the Medicare payment amounts (by 1 percent to 7 percent) in the first quarter of 2009. These three drugs accounted for 22 percent of total Medicare payments to independent facilities for separately billable ESRD drugs in 2008. The average acquisition costs among responding chain and nonchain facilities for all 11 drugs are presented in Table 3.

Table 3: Medicare Payment Amounts and Average Acquisition Costs for Responding Chain and Nonchain Independent Dialysis Facilities

Separately Billable Drug	First-Quarter 2009 Medicare Payment Amount	First-Quarter 2009 Average Acquisition Cost for Chains	First-Quarter 2009 Average Acquisition Cost for Nonchains
Alteplase recombinant, 1 mg*	$34.10	$33.38	$34.50
Iron dextran, 50 mg	$11.78	$11.20	$11.75
Sodium ferric gluconate, 12.5 mg	$4.74	$4.39	$4.62
Epoetin alfa, per 1,000 units	$9.20	$8.36	$9.15
Paricalcitol, 1 μg*	$3.66	$3.28	$3.90
Doxercalciferol, 1 μg	$3.31	$2.94	$3.30
Vancomycin HCl, 500 mg	$3.08	$2.70	$2.91
Iron sucrose, 1 mg	$0.37	$0.31	$0.38
Darbepoetin alfa, 1 μg	$3.06	$2.56	$2.51
Levocarnitine, 1 g	$6.71	$5.34	$5.81
Calcitriol, 0.1 μg	$0.45	$0.32	$0.43

Source: OIG analysis of first-quarter 2009 average acquisition costs among responding independent facilities, November 2009.

In the aggregate, drug acquisition costs at hospital-based dialysis facilities were 7 percent below Medicare payment amounts

In the first quarter of 2009, aggregate acquisition costs for ESRD drugs among responding hospital-based dialysis facilities averaged 7 percent below Medicare payment amounts. For these facilities, average acquisition costs for 5 of the 11 ESRD drugs under review were between 4 percent and 33 percent below Medicare payment amounts. Average acquisition costs for epoetin alfa and darbepoetin alfa (two products that accounted for 73 percent of Medicare drug spending in hospital-based facilities in 2008) were 4 percent and 15 percent below the Medicare payment amounts, respectively.

For 6 of the 11 drugs, average acquisition costs among responding hospital-based facilities ranged from 0.4 percent to 12 percent above the Medicare payment amount (for 3 of these drugs, the difference was 1 percent or less). These six drugs accounted for 23 percent of total Medicare payments to hospital-based facilities in 2008. Table 4 illustrates the percentage difference between Medicare payment amounts and average acquisition costs reported by hospital-based dialysis facilities in the first quarter of 2009.

Table 4: Medicare Payment Amounts and Average Acquisition Costs for Responding Hospital-Based Dialysis Facilities

Separately Billable Drug	First-Quarter 2009 Medicare Payment Amount	First-Quarter 2009 Average Acquisition Cost	Percentage Difference	Percentage of Medicare Payments to Hospital-Based Facilities for Separately Billable Drugs in 2008
Paricalcitol, 1 μg	$3.66	$4.10	12.0%	9.7%
Iron sucrose, 1 mg	$0.37	$0.39	5.4%	4.4%
Doxercalciferol, 1 μg	$3.31	$3.39	2.4%	3.0%
Levocarnitine, 1 g	$6.71	$6.78	1.0%	0.2%
Sodium ferric gluconate, 12.5 mg	$4.74	$4.78	0.8%	3.1%
Alteplase recombinant, 1 mg	$34.10	$34.23	0.4%	3.0%
Epoetin alfa, per 1,000 units	$9.20	$8.82	-4.1%	29.6%
Iron dextran, 50 mg	$11.78	$11.22	-4.8%	0.4%
Vancomycin HCl, 500 mg	$3.08	$2.71	-12.0%	0.2%
Darbepoetin alfa, 1 μg	$3.06	$2.59	-15.4%	43.2%
Calcitriol, 0.1 μg	$0.45	$0.30	-33.3%	0.1%
Aggregate			**-7.0%**	**96.9%**

Source: OIG analysis of first-quarter 2009 average acquisition costs among responding hospital-based dialysis facilities, November 2009.

Over the past several years, average acquisition costs for 7 of the 11 drugs under review have decreased among responding independent dialysis facilities

As Table 5 illustrates, 7 of the 11 separately billable ESRD drugs under review have actually seen a decrease in their average acquisition costs for responding independent dialysis facilities over the last several years.[48] Costs for two of the drugs were at least 50 percent less in the first quarter of 2009 than in 2003. In contrast, only four drugs became more expensive for independent dialysis facilities during this time period. These four drugs accounted for only 3 percent of total Medicare payments to independent facilities for separately billable ESRD drugs in 2008.

Table 5: Changes in Average Acquisition Costs Among Independent Dialysis Facilities From 2003 to the First Quarter of 2009

Separately Billable Drug	2003 Average Acquisition Cost	Third-Quarter 2006 Average Acquisition Cost	First-Quarter 2009 Average Acquisition Cost	Percentage Change From 2003 to First Quarter of 2009
Doxercalciferol, 1 μg	$2.33	$2.16	$2.94	26.2%
Alteplase recombinant, 1 mg	$28.90	$32.48	$33.40	15.6%
Iron dextran, 50 mg	$10.01	$11.29	$11.21	12.0%
Vancomycin HCl, 500 mg	$2.69	$2.46	$2.70	0.4%
Sodium ferric gluconate, 12.5 mg	$4.43	$4.34	$4.40	-0.7%
Darbepoetin alfa,* 1 μg	$2.59	$2.82	$2.54	-1.9%
Iron sucrose, 1 mg	$0.32	$0.32	$0.31	-3.1%
Epoetin alfa, per 1,000 units	$8.82	$8.56	$8.37	-5.1%
Paricalcitol, 1 μg	$3.53	$3.40	$3.29	-6.8%
Levocarnitine, 1 g	$11.22	$7.00	$5.35	-52.3%
Calcitriol, 0.1 μg	$0.87	$0.37	$0.33	-62.1%

Source: OEI-03-04-00120; OEI-03-06-00200; OEI-03-06-00590; OIG analysis of first-quarter 2009 average acquisition costs among responding independent facilities, November 2009.

* Darbepoetin alfa did not yet have its own Medicare billing code in 2003. Therefore, the price given in the 2003 column is for 2005, the first year it had a Medicare billing code.

[48] Darbepoetin alfa did not yet have its own Medicare billing code in 2003. Therefore, all analyses of its acquisition cost changes used data starting in 2005, the first year it had a Medicare billing code.

During a period when acquisition costs for many ESRD drugs decreased, the index CMS plans to use as the basis for future payment changes increased by 39 percent

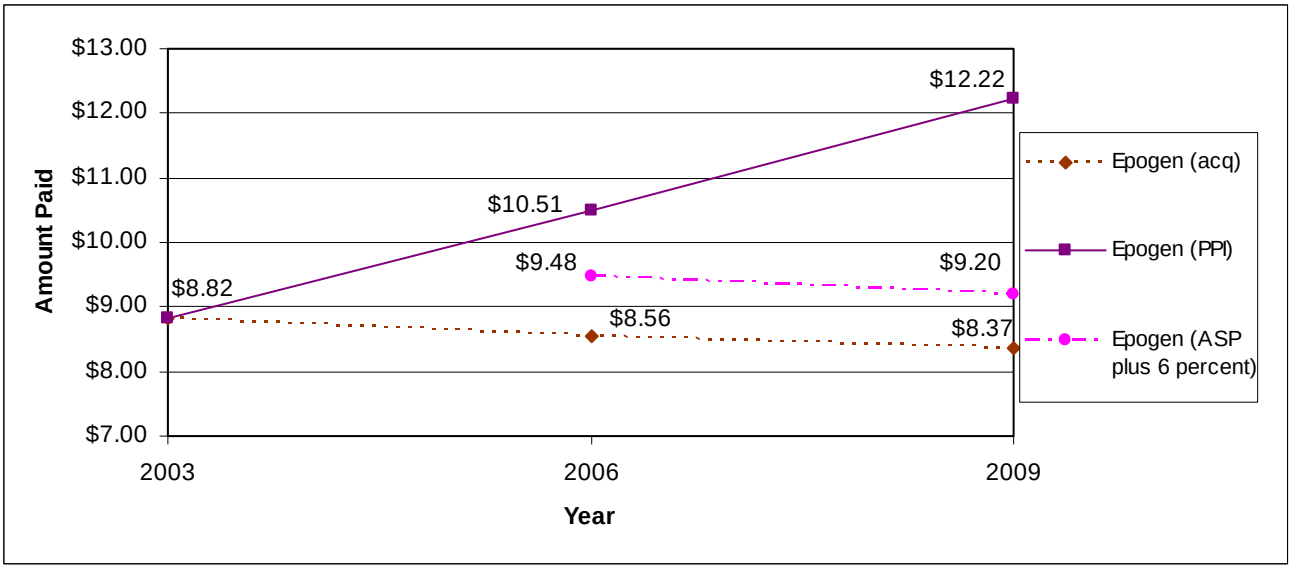
CMS plans to use the PPI for Prescription Drugs (a measure that reflects price changes associated with the average mix of all the prescription drugs sold in pharmacies) as the basis for annual adjustments to the prescription drug portion of the new bundled rate. According to PPI data, prices for all prescription drugs were 39 percent higher in the first quarter of 2009 than in 2003.[49] However, facility acquisition costs for the drugs that account for the majority of Medicare expenditures in independent dialysis facilities actually decreased during this same period.

For example, the average acquisition cost among responding independent dialysis facilities for 1,000 units of epoetin alfa fell from $8.82 in 2003 to $8.37 in the first quarter of 2009. In other words, on average, independent facilities paid 5 percent less for the highest expenditure ESRD drug in early 2009 than they did several years earlier. If the PPI for Prescription Drugs had been an accurate predictor for changes in the acquisition cost of epoetin alfa since 2003, dialysis facilities would have paid $12.22 for 1,000 units of the drug in the first quarter of 2009.[50] This amount would be 46 percent higher than epoetin alfa's average acquisition cost among responding independent dialysis facilities (and 33 percent higher than the ASP-based payment amount). Had the Medicare payment amount for epoetin alfa since 2003 been based on changes in the PPI for Prescription Drugs, total program payments to all independent dialysis facilities for the drug in the first quarter of 2009 alone would have been $113 million higher than actual payments under the current ASP-based system. As Graph 1 illustrates, if past trends continue, this gap would continue to expand substantially in future years.

[49] BLS, *Databases, Tables & Calculators by Subject.* Accessed at http://www.bls.gov/data on November 25, 2009.

[50] Under the Act, as amended by section 3401(h) of the PPACA, ESRD bundled payment amounts must be updated by the increase in the ESRDB price index minus a productivity adjustment. The PPI for Prescription Drugs is one part of the ESRDB index. We did not address changes in the productivity adjustment when performing our calculations using the PPI for Prescription Drugs. Had we done so, the differences in our figures may have been reduced, but the general trends would have likely remained the same.

Graph 1: Changes in Epoetin Alfa Average Acquisition Cost Versus Changes in the PPI for Prescription Drugs Since 2003



Source: OEI-03-04-00120; OEI-03-06-00590; OIG analysis of first-quarter 2009 average acquisition costs among responding independent facilities; OIG analysis of BLS data, November 2009.

RECOMMENDATION

CMS currently pays all dialysis facilities at 106 percent of ASPs for most separately billable ESRD drugs. Under the current system, we found that aggregate acquisition costs for ESRD drugs at both independent and hospital-based dialysis facilities were below Medicare payment amounts. In addition, when we compared acquisition costs among responding independent dialysis facilities to costs from prior OIG reports, we found that 7 out of the 11 separately billable ESRD drugs under review have actually seen a decrease in their average acquisition costs over the last several years. The cost of epoetin alfa, a drug responsible for more than $1.4 billion in annual Medicare spending in dialysis facilities, fell by 5 percent. During this same period, the PPI for Prescription Drugs increased by 39 percent.

If the new bundled system is implemented as planned and acquisition costs for the majority of separately billable ESRD drugs decrease (as they have in the past) while price indexes rise, the existing gap between Medicare payment amounts and dialysis facility acquisition costs will continue to grow each year. As a result, payments under the new bundled system would not accurately reflect facility acquisition costs, potentially costing the program additional hundreds of millions of dollars per year. Therefore, we recommend that CMS:

Develop a more accurate method for estimating changes in the prices of ESRD drugs

CMS decided to use the PPI for Prescription Drugs (a measure that reflects price changes associated with the average mix of all the prescription drugs sold in pharmacies) as the proxy for drug price increases under the assumption that "… the price changes associated with the assortment of drugs administered in ESRD facilities should, over time, be similar to the average prescription drug price changes observed across the entire economy."[51] However, average acquisition costs for the majority of the drugs purchased by dialysis facilities have actually decreased during the period under review. At the same time, there has been a substantial increase in CMS's chosen index. Therefore, the agency should develop a new method for estimating changes that more accurately reflects historical trends in the pricing of drugs that make up the pharmaceutical category of the ESRDB price index.

[51] 75 Fed. Reg. 49030, 49160 (Aug. 12, 2010).

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS did not concur with our recommendation. In its response to the draft report, CMS stated that the downward trajectory of average acquisition costs documented in OIG's analysis was influenced largely by changes in CMS's payment mechanism for separately billable ESRD drugs. Specifically, CMS believes that the decrease in the average acquisition cost of epoetin alfa during the period under review was caused by an above-market Medicare payment amount in the baseline year of OIG's analysis (2003) and the subsequent decrease in the payment amount for epoetin alfa after the ASP-based system was implemented. CMS states that, as a result, OIG's figures are not suitable for inferring future price trends as the market for epoetin alfa becomes more competitive.

CMS's view is that it is more appropriate to look at recent quarterly price changes—changes that CMS states have not been distorted by changes in payment policy—that show an increase in the cost of epoetin alfa since the end of 2008. CMS goes on to state its belief that underlying market forces are driving these recent increases and that future costs should resemble changes in general pharmaceutical prices rather than past trends. Therefore, CMS expects that future ESRD drug price growth will more closely reflect market-based price drivers, such as those measured by the PPI for Prescription Drugs. CMS expects that, beginning in 2011, the PPI for Prescription Drugs will grow 3.4 percent annually for the first 5 years of the bundled rate payment system and states that this trend is consistent with the recently observed trend in the cost of epoetin alfa.

OIG fully appreciates the difficulty that CMS faces in implementing the new bundled rate payment system, especially in terms of estimating future costs for all items and services related to ESRD care. OIG also realizes that the historical average acquisition cost data presented in this report may not necessarily be predictive of future trends in the costs of separately billable drugs. Nevertheless, based on our findings, we remain concerned that Medicare could end up paying too much for these drugs once the bundled rate is implemented, potentially costing the program and its beneficiaries hundreds of millions of dollars a year. We are especially concerned that CMS's chosen index, the PPI for Prescription Drugs, has consistently averaged annual growth above 4 percent (and over 7 percent in 2008 and 2009). During this same

period, the ASP for epoetin alfa has seen a more modest increase and, according to CMS's response, never matched the growth of the PPI for Prescription Drugs. Given the risks to the program of overpaying for prescription drugs, OIG intends to work with CMS to carefully monitor the cost of epoetin alfa and other ESRD drugs in the future.

APPENDIX ~ A

Medicare Expenditures in 2008 for Drugs Under Review

Separately Billable Drug	Payment Ranking in Independent Dialysis Facilities	Total Payment in Independent Dialysis Facilities	Payment Ranking in Hospital-Based Dialysis Facilities	Total Payment in Hospital-Based Dialysis Facilities
Epoetin alfa, per 1,000 units	1	$ 1,382,667,793	2	$34,287,338
Paricalcitol, 1 μg*	2	$282,709,514	3	$11,244,877
Iron sucrose, 1 mg	3	$130,808,384	4	$5,055,486
Doxercalciferol, 1 μg	4	$50,504,917	7	$3,495,384
Sodium ferric gluconate, 12.5 mg	5	$49,256,017	5	$3,625,818
Darbepoetin alfa, 1 μg	6	$43,185,051	1	$50,052,297
Alteplase recomb, 1 mg	7	$16,575,330	6	$3,531,937
Levocarnitine, 1 g	8	$2,543,581	12	$211,776
Vancomycin HCL, 500 mg	9	$1,714,940	11	$234,703
Calcitriol, 0.1 mcg	11	$1,025,188	13	$145,580
Iron dextran, 50 mg	16	$316,878	8	$427,609
Total		**$1,961,307,593**		**$112,312,805**

Source: Office of Inspector General analysis of 2008 National Claims History File, 95-percent complete.

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

APPENDIX ~ B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUN 1 0 2010

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Acting Administrator and Chief Operating Officer

SUBJECT: Office of Inspector General (OIG) Draft Report: "End Stage Renal Disease Drugs: Facility Acquisitions Costs and Future Medicare Payment Concerns" (OEI-03-09-00280)

Thank you for the opportunity to comment on the OIG Report: "End Stage Renal Disease Drugs: Facility Acquisition Costs and Future Medicare Payment Concerns". The Centers for Medicare & Medicaid Services (CMS) recognizes the critical nature of paying appropriately for services for its beneficiaries and is committed to ensuring that payment updates for providers of End Stage Renal Disease (ESRD) treatments are calculated fairly and appropriately.

Beginning in 2011, CMS will implement the ESRD Prospective Payment System. At that time, ESRD providers will begin receiving a "bundled" payment for providing services to Medicare beneficiaries. That bundled payment is intended to pay for renal dialysis services inclusive of several covered pharmaceuticals.

When Medicare began covering ESRD patients in 1973, providers were permitted to bill separately for prescription drugs, including Erythropoietin (Epo) (which represents about two-thirds of the industry's total drug costs). At that time, the payment rate for Epo was set according to statute at $10 per 1,000 units (see section 1881(b)(11)(B) of the Social Security Act). For other commonly used drugs of ESRD patients, payment rates were set to Average Wholesale Price minus 5 percent.

Beginning in 2006, the agency was required to pay for drugs using the average sales price of the respective drugs, plus six percent (ASP+6). The analyses that the OIG has conducted carefully documents the downward trajectory of price growth in average acquisition cost (AAC) over a short historical period that has been largely influenced by the change in CMS's payment mechanism. We do, however, have some reservations regarding the OIG's recommendation for projecting price changes for drugs in ESRD facilities. The rationale for those concerns is articulated below.

OIG RECOMMENDATION

CMS should develop a more accurate method for estimating changes in prices of ESRD drugs.

CMS RESPONSE

The CMS does not concur with the OIG recommendation. Medicare's Epo payment rate was originally set via statute, and was too high (as were the payment rates for other ESRD drugs). Medicare payment rates dropped significantly when the switch was required to be made to the ASP+6 payment. Because the original Epo price, along with its corresponding average acquisition cost, were clearly above-market prices, our position is that these figures do not represent a suitable baseline for inferring future price trends in a market that has been evolving toward one that is closer to a competitive market. Thus, it is our view that future ESRD drug price growth will more closely reflect market-based price drivers, such as those measured on average by the Producer Price Index for Prescription Drugs (Rx PPI). We believe that the Rx PPI is, therefore, an appropriate price proxy.

Our primary technical concern with the report's findings is related to the dates that are the starting and ending points of the analysis. For instance, the starting point for data on AAC is 2003, when the AAC for Epo was $8.82. This, of course, was a time when Medicare was paying ESRDs $10 per 1,000 units of the drug. We believe that the AAC is not reflective of an efficient market because (i) it was considerably higher than the cost to the manufacturer to produce the drug (which appears to be supported by the findings in a 1997 OIG report on the subject), and (ii) the overly generous payment rate provided minimal incentive for ESRD providers to negotiate strongly with the drug's manufacturers on price.

The OIG report then compares that 2003 figure to the AAC for Epo from 2009 (the ending point) when it was $8.37 (a decline of 5 percent). The observed downward trend, of course, was driven largely by the implementation of the ASP+6 payment policy - which lowered Epo payments and gave ESRD providers a greater financial reason to push back on the drug manufacturers during their price negotiations.

Our view is that instead of beginning the analysis at a price point acknowledged to be artificially high, it is more appropriate to look at more recent quarterly price changes, which provide for finer detail and permits an analysis of growth trends without distortion from changes in payment policy. For example, looking at quarterly data shows that growth in the average sales price of Epo (and in the AAC, we suspect) appears to have bottomed out in 2008 (see table below), indicating to us that the market has been operating more efficiently. Since then, the four-quarter percent change moving average (PCHMA) for ASPs reached 4.5 percent in the 4th quarter of 2009 and currently sits at 3.7 percent according to price data from the CMS website effective for the 2nd quarter of 2010.

From a starting point/ending point perspective, we are not surprised that the AACs estimated for 2009 are lower than those estimated for 2003; however, analysis of quarterly data indicates upward pressure more recently in the market. We believe that the market for Epo is now more efficient, since ESRD providers have a direct incentive to negotiate effectively with

manufacturers and to purchase Epo at the best price they can obtain. Further, we expect that it is underlying general economic forces that are increasingly driving these more recent price changes in the now more efficient market for Epo. That is, we do not expect the future to look like the past, but to resemble more closely general price trends for pharmaceuticals.

Year & Quarter	ASP EPO (ESRD)	4 qtr PCMA	Rx PPI	4 qtr PCMA
05Q1	9.317		4.155	
05Q2	9.250		4.228	
05Q3	9.307		4.371	
05Q4	9.313		4.378	
06Q1	9.570		4.492	
06Q2	9.245		4.565	
06Q3	9.392		4.590	
06Q4	9.202	0.6%	4.577	6.4%
07Q1	9.283	-0.8%	4.678	5.4%
07Q2	9.224	-0.9%	4.723	4.3%
07Q3	9.104	-1.9%	4.789	4.1%
07Q4	9.058	-2.0%	4.831	4.4%
08Q1	8.963	-2.1%	4.980	5.0%
08Q2	9.073	-2.4%	5.080	6.0%
08Q3	9.071	-1.8%	5.119	6.6%
08Q4	9.097	-1.3%	5.201	7.1%
09Q1	9.201	0.3%	5.338	7.3%
09Q2	9.440	1.7%	5.420	7.1%
09Q3	9.620	3.3%	5.499	7.2%
09Q4	9.583	4.5%	5.551	7.0%
10Q1	9.537	4.8%	5.742	7.1%
10Q2	9.442	3.7%	5.786	7.1%

While the four-quarter percent change moving average for the Rx PPI has been in the 7.0 percent range, beginning in 2011, we expect growth to average 3.4 percent annually for the first five years of the ESRD PPS. These trends are consistent with the observed trends recently experienced for Epo.

Finally, listed below are the underlying considerations the Office of the Actuary takes into account when selecting price proxies for incorporation into the market baskets.

Appropriate choice of a CMS market basket price proxy should:

- reflect "market" price changes that providers would likely face under competitive (efficient) conditions
- reflect the appropriate level of aggregation given the cost category in the market basket

- be regularly published and publically available
- be based on technically sound methodologies and independent from policy impacts

We believe the Rx PPI meets these criteria and is an appropriate price proxy for use in calculating the drug price component of the ESRD market basket index. In examining other possible proxies, we were not able to find suitable alternatives that satisfied these principles.

We would like to thank the OIG for their efforts to study this critical issue. We believe it is extremely important for the agency to take great care in selecting fair and appropriate means by which we pay providers. Again, we thank you for the opportunity to review and comment.

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, Prescription Drug Pricing Unit.

Roman Strakovsky served as the lead analyst for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed to the report include Stephanie Yeager; other staff who contributed include Natasha Franklin.

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 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. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/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 for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.