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UPDATE: MEDICARE PAYMENTS FOR END STAGE RENAL DISEASE DRUGS

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EXECUTIVE SUMMARY: UPDATE: MEDICARE PAYMENTS FOR END STAGE RENAL DISEASE DRUGS
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WHY WE DID THIS STUDY

Prior to 2011, Medicare paid dialysis facilities for the treatment of end stage renal disease (ESRD) using a combination of a fixed rate (known as the "composite rate") and separate payment amounts based on average sales prices (ASP) for certain drugs. As of January 2011, Federal law required the Centers for Medicare & Medicaid Services (CMS) to bundle Medicare reimbursement for almost all ESRD treatments—including drugs that were previously billed separately—into one payment rate. By implementing the bundled rate, CMS sought to eliminate incentives to overuse separately billable drugs and to promote equitable payment and access to services in ESRD facilities that treat more costly patients. CMS is required to update this rate annually to reflect changes in the price of goods and services used to provide ESRD care. CMS used the PPI for Prescription Drugs, a price proxy published by the Bureau of Labor Statistics, to update the prescription drugs portion of the base rate for the ESRD payment bundle. However, a 2010 OIG study questioned the accuracy of this price proxy when used to estimate changes in prices for ESRD drugs.

HOW WE DID THIS STUDY

We obtained first-quarter 2012 average acquisition costs for the 11 drugs that were separately billable prior to the implementation of the ESRD payment bundle by surveying 3 large dialysis chains, a random sample of 200 independent (i.e., freestanding) dialysis facilities not affiliated with these chains, and 200 hospital-based dialysis facilities. We compared the average acquisition costs for each facility type to the amounts paid for these drugs under the base rate for the ESRD payment bundle. Using first-quarter 2009 data that we collected for the 2010 OIG report, we determined the extent that facility acquisition costs have changed in relation to the amounts estimated by the PPI for Prescription Drugs. Finally, to compare the prior and current payment methodologies for ESRD drugs, we compared the drugs' ASP-based payment amounts in first-quarter 2012 to the amounts paid under the ESRD base rate.

WHAT WE FOUND

In the first quarter of 2012, independent dialysis facilities could purchase ESRD drugs for less than the reimbursement amounts provided by the ESRD base rate (9 percent below, in the aggregate), but average acquisition costs for hospital-based dialysis facilities exceeded reimbursement amounts (5 percent above, in the aggregate). In the past 3 years, dialysis facilities' average acquisition costs for the majority of drugs under review have decreased, but average costs for epoetin alfa, a drug that represented more than three-quarters of the drug costs in responding facilities, have increased by at least 17 percent. We also found that although acquisition costs for most drugs decreased, the PPI for Prescription Drugs estimated a 25-percent increase in drug costs—meaning that this proxy was not an accurate predictor of cost changes for most drugs under review. Lastly, we found that if the ASP-based reimbursement had remained in effect for the first quarter of 2012, payment amounts for the bundle of ESRD drugs would have differed by less than a dollar per treatment.

WHAT WE RECOMMEND

Federal law required CMS to reduce the ESRD payment bundle's base rate for 2014 to reflect changes in utilization and should take into account recent drug sales and pricing data. Our findings show that acquisition costs for most of the drugs under review have decreased, but the costs for drugs that represented the majority of facilities' total drug costs have increased. This means that any savings resulting from a decrease in utilization may potentially be offset by the drugs' cost increase. In addition, although independent dialysis facilities could acquire the majority of ESRD drugs for less than Medicare reimbursement, any reductions to the ESRD base rate could potentially harm hospital-based dialysis facilities because these facilities had difficulty purchasing ESRD drugs for less than reimbursement, in the aggregate.

Therefore, we recommend that CMS rebase (i.e., redetermine the basis of) the ESRD base rate to reflect current trends in drug acquisition costs, as required by law; distinguish payments in the ESRD base rate between independent and hospital-based dialysis facilities; and consider updating the ESRD payment bundle using a factor that takes into account drug acquisition costs. CMS did not explicitly state whether it concurred with our first recommendation, did not concur with our second recommendation, and concurred with our third recommendation.

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OBJECTIVES

1. To compare first-quarter 2012 facility acquisition costs for selected end stage renal disease (ESRD) drugs to the amounts that Medicare Part B paid for these drugs under the new ESRD bundled base rate.
2. To determine how facility acquisition costs for selected ESRD drugs have changed in relation to inflation, from the first quarter of 2009 to the first quarter of 2012.
3. To compare the average sales price (ASP)-based reimbursement amounts for selected ESRD drugs to the amounts paid under the new ESRD bundled base rate.

BACKGROUND

Effective January 1, 2011, the Centers for Medicare & Medicaid Services (CMS) implemented a statutorily mandated change in the payment method for ESRD treatment to a comprehensive system that bundles the payment for services and drugs into a single per-treatment rate. To develop the base rate for the ESRD payment bundle, CMS used treatment counts from 2007 claims data and updated these to estimate 2011 average payment per treatment data. The payment bundle includes drugs that, prior to 2011, were billed separately and paid on the basis of 106 percent of the manufacturer-reported ASP.

The ESRD payment bundle sought to reduce the incentives to overutilize profitable ESRD drugs, particularly erythropoietin-stimulating agents (ESAs), which had been previously paid under the ASP-based payment methodology.[1] A December 2012 study by the Government Accountability Office (GAO) found that utilization of ESRD drugs in 2011 was about 23 percent lower, on average, than utilization in 2007, mostly because of a large decline in ESA use.[2] Because the ESRD base rate was based on 2007 utilization levels, CMS may have paid more than necessary for dialysis care in 2011. GAO concluded that the current payment bundle is excessive and that rebasing it could result in more appropriate payments to dialysis facilities and substantial savings for Medicare. A May 2013 Office of Inspector General (OIG) report had similar findings and reported

[1] 75 Fed. Reg. 49030, 49032 (Aug. 12, 2010).

[2] GAO, *End-Stage Renal Disease: Reduction in Drug Utilization Suggests Bundled Payment Is Too High* (GAO-13-190R), December 2012.

that Medicare and its beneficiaries could have saved $510 million on ESAs if CMS had adjusted payments to reflect utilization in 2011.[3]

Treatment of ESRD

ESRD is a condition in which the kidneys no longer function at the level necessary for day-to-day life. The loss of kidney function in ESRD is usually irreversible and permanent. Treatment options include kidney transplantation and dialysis. One common complication of ESRD is anemia, a deficiency in red blood cells. ESAs, such as epoetin alfa (trade name Epogen) and darbepoetin alfa (trade name Aranesp) treat anemia by increasing the number of red blood cells.

Most individuals with ESRD are eligible for benefits under Medicare Part B. In 2011, approximately 442,000 beneficiaries qualified for ESRD treatment under Medicare Part B.[4] Beneficiaries typically receive dialysis treatments from either independent (i.e., freestanding) or hospital-based facilities that are approved to furnish dialysis services directly to ESRD patients. Both types of dialysis facilities provide outpatient maintenance dialysis (including dialysis performed by an appropriately trained patient and caregiver at home). The majority (64 percent) of independent dialysis facilities are owned or managed by one of the three large chain organizations. Facilities are considered hospital based if they are integrated into a hospital's financial and administrative systems, among other criteria.[5] As of August 2012, independent dialysis facilities accounted for 94 percent of all facilities and hospital-based dialysis facilities represented only 6 percent.

Medicare Payments to Dialysis Facilities Prior to 2011

Composite Rate. Prior to January 1, 2011, CMS reimbursed dialysis facilities on the basis of a prospective payment system (PPS) known as the composite rate. Facilities received a fixed composite rate payment for each dialysis treatment they provided. The composite rate was composed of a labor and nonlabor portion, with an add-on adjustment for the area wage index. The rate included most items related to dialysis services, such as (1) labor costs; (2) certain laboratory services; and (3) certain drugs, such as antihistamines, glucose, and insulin.

Separately Billable Drugs. Certain drugs typically administered by physicians or other health care professionals were not included in the

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[3] OIG, *Medicare and Beneficiaries Could Save Millions If Dialysis Payments Were Adjusted for Anemia Management Drug Utilization* (A-01-12-00522), May 2013.

[4] The Henry J. Kaiser Family Foundation, *Medicare Enrollment: Hospital Insurance and/or Supplementary Medical Insurance Enrollees With End-Stage-Renal Disease, as of July 2011*. Accessed at http://www.statehealthfacts.org on February 21, 2013.

[5] 42 CFR § 413.174(c)(4)–(5).

composite rate.[6] Medicare paid for these separately billable drugs, including epoetin alfa and darbepoetin alfa, at 106 percent of their manufacturer-reported ASP when they were furnished in dialysis facilities.[7, 8] Previous OIG reports have found that many facilities, particularly the independent facilities owned or managed by a chain, could acquire the majority of the separately billable drugs for less than the Medicare payment amounts.[9]

Some policymakers raised concerns that the ASP-based reimbursement methodology created incentives for dialysis facilities to overutilize separately billable drugs.[10] When the reimbursement amounts exceeded the price that facilities paid to acquire the drugs, which happened with the ESA epoetin alfa, facilities could increase their profits by administering more of the drug. The Food and Drug Administration (FDA) has issued warnings that overuse of ESAs could harm patients because ESAs increase the risks of blood clots, strokes, heart attacks, and death.[11] In March 2007 and June 2011, FDA issued "black box" warnings on certain ESA labels, advising physicians to monitor red blood cell levels and adjust dosages to maintain the lowest levels necessary.[12, 13]

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[6] Epoetin alfa and darbepoetin alfa were covered as separately billable drugs even if they were self-administered by the patient and not by a physician or health care professional. CMS, *Medicare Benefit Policy Manual*, ch. 11, §§ 30.4.2 (rev. 1, Oct. 1, 2003) and 90 (rev. 8, March 5, 2004).

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

[8] With certain exceptions, including specific vaccines; 42 CFR § 414.904(e).

[9] For example, see OIG, *End Stage Renal Disease Drugs: Facility Acquisition Costs and Future Medicare Payment Concerns* (OEI-03-09-00280), September 2010; and OIG, *Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter 2006* (OEI-03-06-00590), June 2007.

[10] House Committee on Ways and Means, Subcommittee on Health, *Stark Announces a Hearing on Ensuring Kidney Patients Receive Safe and Appropriate Anemia Management Care*, June 26, 2007. Accessed at http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg49981/html/CHRG-110hhrg49981.htm on June 24, 2013. GAO, *End-Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility* (GAO-07-77), November 2006.

[11] FDA, *Public Health Advisory: erythropoiesis-stimulating agents (ESAs)*, March 9, 2007. Accessed at http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm124262.htm on April 5, 2013. FDA, *FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease*, June 24, 2011. Accessed at http://www.fda.gov/drugs/drugsafety/ucm259639.htm on April 5, 2013.

[12] Ibid.

[13] "Black box" warnings (alerts on the labels of prescription drugs to indicate serious or life-threatening risks) were issued for epoetin alfa (Epogen and Procrit) and darbepoetin alfa (Aranesp).

Medicare Bundled Payments to Dialysis Facilities

Effective January 1, 2011, section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), P.L. 110-275, required payment for all Part B items and services used in the treatment of ESRD, including drugs that were separately billable, to be combined into a single bundled rate.[14] By implementing the bundled rate, CMS sought to eliminate incentives to overuse separately billable drugs and to promote equitable payment and access to services in ESRD facilities that treat more costly patients.[15]

The ESRD PPS is being phased in over 4 years; full implementation began January 1, 2014. During the transition period, facilities receive a "blend of the payment rates" based on (1) payment rates under the new bundle system and (2) the previous composite rate and ASP-based payment methods. However, facilities were given a one-time opportunity to opt out of the phase-in.[16, 17] Eighty-seven percent of dialysis facilities opted out of the phase-in and accepted full payment under the ESRD PPS starting in January 2011.[18]

ESRD Payment Bundle. The ESRD PPS payment bundle is composed of payments for the various components of dialysis services, such as the composite rate, separately billable drugs, and laboratory tests. As described in the preamble to the August 2010 final rule that created the ESRD payment bundle, CMS calculated the ESRD base rate for 2011 using 2007 Medicare allowable payment (MAP) amounts (i.e., reimbursement) for each component included in the bundle and divided the MAP amounts by the number of dialysis treatments per patient in 2007.[19] CMS updated this amount to reflect estimated 2011 amounts.[20] This resulted in an overall payment amount of $229.63 per treatment in 2011.[21] CMS can further adjust this base rate for individual dialysis

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[14] Vaccines are excluded from the bundled rate.

[15] 75 Fed. Reg. 49030, 49032 (Aug. 12, 2010).

[16] The Act, § 1881(b)(14)(E)(ii).

[17] Facilities had to notify their respective Medicare contractors of their decision to opt out of the phase-in on or before November 1, 2010.

[18] 76 Fed. Reg. 18930, 18932 (Apr. 6, 2011).

[19] CMS used 2007 as the basis for the 2011 bundled rate because it had the lowest per-patient utilization when compared to 2008 and 2009.

[20] In accordance with section 1881(b)(14)(A)(ii) of the Act, the estimated 2011 total payments under the ESRD base rate must equal 98 percent of the estimated total amount of payments that would have been made in that year if the payment bundle had not been implemented. As a result, CMS applied a 2-percent budget-neutrality reduction to the base rate, as well as a reduction for an outlier adjustment and a standardization adjustment.

[21] 75 Fed. Reg. 49030, 49082 (Aug. 12, 2010).

facilities on the basis of factors such as its patient-level characteristics and volume of treatments administered.

Drugs in the ESRD Payment Bundle That Were Formerly Separately Billable. CMS identified and used the 11 highest expenditure separately billable ESRD drugs in 2007 as the primary basis for the "separately billable drugs" component of the payment bundle.[22] CMS selected these 11 drugs because they accounted for over 99 percent[23] (about $2.7 billion) of total Part B spending on ESRD drugs in 2007. Payments for epoetin alfa accounted for the majority ($1.9 billion) of total Part B spending on these 11 ESRD drugs.

Because CMS used MAP amounts from 2007, it had to project these data to estimate the per-treatment reimbursement in 2011 for each of the separately billable drugs. To calculate the percentage updates used to make these estimates, CMS (1) inflated the second-quarter 2010 ASP-based payment amounts (the most recently available at the time) by 3.9 percent (i.e., the inflation rate determined by the Producer Price Index (PPI) for Prescription Drugs[24]) and (2) calculated the percentage difference between these inflated ASP amounts and the average 2007 ASP payment amounts. See Table 1 and Appendix A for details on how CMS calculated the average per-treatment reimbursement amounts for each drug in the ESRD base rate.

[22] Although these drugs are now included in the ESRD payment bundle and are no longer billed separately when used to treat ESRD, we still refer them as "separately billable" to distinguish this group of drugs from other types included in the payment bundle.

[23] 75 Fed. Reg. 49030, 49079 (Aug. 12, 2010).

[24] The term "PPI for Prescription Drugs" refers to the Bureau of Labor Statistics' (BLS) PPI for Pharmaceuticals for Human Use (Prescription). This PPI reflects price changes associated with the average mix of all prescription drugs in the overall economy. According to CMS, reliability and timeliness of data publishing are factors for choosing the PPI for Prescription Drugs as the price proxy. CMS also stated that the PPI for Prescription Drugs includes an appropriate level of aggregation for use in the Medicare market baskets (see footnote 26 for definition of market basket), including former Part D drugs covered in the ESRD payment bundle, and reflects competitive pricing in efficient markets. 75 Fed. Reg. 49030, 49152 (Aug. 12, 2010).

Table 1: Part B Payments for Top 11 Separately Billable Drugs

Separately Billable Drugs (Part B)	MAP Amounts in 2007	Per-Treatment Reimbursement in 2007	Percentage Update to Estimate 2011 Amounts	Estimated Per-Treatment Reimbursement in 2011
Epoetin alfa	$1,876,926,573	$51.08	7.0%	$54.65
Paricalcitol	$322,849,348	$8.79	-3.2%	$8.50
Darbepoetin alfa	$167,935,970	$4.57	-9.0%	$4.16
Iron sucrose	$166,219,339	$4.52	2.6%	$4.64
Doxercalciferol	$76,901,723	$2.09	16.6%	$2.44
Sodium ferric gluconate	$68,086,707	$1.85	-0.2%	$1.85
Alteplase recombinant	$26,697,321	$0.73	16.9%	$0.85
Levocarnitine	$5,026,446	$0.14	-22.5%	$0.11
Vancomycin	$3,583,504	$0.10	-3.1%	$0.09
Calcitriol	$3,125,613	$0.09	-26.3%	$0.06
Daptomycin	$1,234,405	$0.03	30.1%	$0.04
Total	**$2,718,586,948***			

Source: 75 Fed. Reg. 49030, 49068, 49080 (Aug. 12, 2010).
* Individual amounts do not add to total because of rounding.

Annual Updates to the ESRD Payment Bundle

Beginning in 2012, CMS was required to update the payment bundle annually to reflect the changes over time in the prices of an appropriate mix of goods and services used to provide ESRD care.[25, 26] CMS uses indexes published by BLS to measure the annual rate of price change in each category (e.g., wages and salaries, pharmaceuticals, capital-related costs).[27] For example, CMS used PPI for Prescription Drugs as the price proxy for measuring growth in ESRD drugs for the pharmaceutical category (i.e., the "separately billable drugs" component). After applying the adjustments for 2012, CMS set the base rate for the payment bundle at $234.81 per treatment.[28]

Rebasing the ESRD Payment Bundle

MIPPA required GAO to report on, among other things, trends in the utilization of ESRD drugs and to submit a report to Congress on the ESRD payment bundle no later than March 1, 2013.[29] GAO analyzed trends in utilization from 2007 through 2011 and the implications of these trends for

[25] The Act, § 1881(b)(14)(F)(i). 76 Fed. Reg. 70228, 70231–70232 (Nov. 10, 2011).

[26] The term "market basket" is used to refer to the mix of goods and services used to produce ESRD care. This term is also commonly used to denote the "input price index" (i.e., cost categories, their respective weights, and price proxies combined) derived from that market basket. The term "ESRDB market basket" in the final rule that implements the ESRD payment bundle refers to this input price index.

[27] 75 Fed. Reg. 49030, 49154–60 (Aug. 12, 2010).

[28] 76 Fed. Reg. 70228, 70231 (Nov. 10, 2011).

[29] Section 153(d) of MIPPA.

the ESRD bundled payment rate.[30] GAO found that the utilization of certain dialysis drugs in 2011 was lower than in 2007 and recommended that Congress consider requiring CMS to rebase the ESRD bundled payment rate as soon as possible and to rebase it periodically thereafter using the most currently available data.

To reflect the findings in GAO's report, the American Taxpayer Relief Act of 2012 authorized CMS to make reductions to the ESRD bundled payment rate on or after January 1, 2014.[31] These reductions should reflect the estimate of the change in utilization of the ESRD drugs between 2007 and 2012 and should take into account the most recently available ASP data and price changes for ESRD drugs.[32]

Previous OIG Work

A May 2013 OIG report found that Medicare and its beneficiaries could have saved $510 million for the ESAs epoetin alfa and darbepoetin alfa and $19 million for certain iron supplements if the 2011 ESRD base rate had been adjusted to reflect utilization of anemia management drugs during 2011.[33] We recommended that CMS adjust the base rate to realize program savings associated with decreased utilization of ESAs and iron supplements. CMS concurred with this recommendation.

Before the implementation of the ESRD payment bundle, OIG issued several reports demonstrating that Medicare payments for certain separately billable ESRD drugs were consistently higher than the reported facility acquisition costs.[34] A September 2010 report found that drug acquisition costs in independent dialysis facilities and hospital-based

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[30] GAO, *End-Stage Renal Disease: Reduction in Drug Utilization Suggests Bundled Payment Is Too High* (GAO-13-190R), December 2012.

[31] Section 1881(b)(14)(I) of the Act, as added by section 632(a) of the American Taxpayer Relief Act, P.L. 112-240.

[32] Part B claims dated on or after April 1, 2013, incur a 2-percent reduction in payment, in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (see CMS Medicare FFS Provider e-News, *Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program – "Sequestration,"* March 8, 2013). This mandatory payment reduction (also known as sequestration) is applied after the beneficiary's coinsurance has been determined, meaning that the beneficiary's portion of the cost is not reduced. Under sequestration, the effective payment rate for most Part B drugs is 104.3 percent of the volume-weighted ASP.

[33] OIG, *Medicare and Beneficiaries Could Save Millions If Dialysis Payments Were Adjusted for Anemia Management Drug Utilization* (A-01-12-00522), May 2013.

[34] For example, see 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; *Medicare Reimbursement for End Stage Renal Disease Drugs: Third Quarter 2006* (OEI-03-06-00590), June 2007; and *End Stage Renal Disease Drugs: Facility Acquisition Costs and Future Medicare Payment Concerns* (OEI-03-09-00280), September 2010.

dialysis facilities were, in the aggregate, 10 percent and 7 percent below the Medicare payment amounts, respectively.

In the September 2010 report, we also compared the changes in independent dialysis facilities' acquisition costs for 11 separately billable ESRD drugs to changes in the PPI for Prescription Drugs.[35] We found that from 2003 to 2009, PPI data indicated that prescription drug prices had increased, while the majority of acquisition costs for independent facilities had decreased. In addition, we found that first-quarter 2009 Medicare payments to independent dialysis facilities for epoetin alfa would have been $113 million higher if CMS had based reimbursement on changes in the PPI for Prescription Drugs instead of the ASP-based system in place at that time. We recommended that CMS develop a more accurate method for estimating changes in the prices of ESRD drugs included in the ESRD bundled rate. CMS did not concur with our recommendation and moved forward with using the PPI for Prescription Drugs as a price predictor.

METHODOLOGY

Data Collection

ESRD Drug Acquisition Cost Data for First Quarter 2012. In December 2012, we sent online surveys to (1) 3 large chains of independent dialysis facilities, (2) a random sample of 200 smaller independent dialysis facilities not owned or managed by these chains, and (3) all 200 hospital-based dialysis facilities not enrolled in the 340B program.[36] Several of the responding smaller independent dialysis facilities owned multiple dialysis units and provided data for these additional facilities. In total, we received responses from the 3 large chain companies, 522 smaller independent dialysis facilities, and 125 hospital-based dialysis facilities. See Appendix B for a description of the facilities included in our analysis.

The online surveys requested first-quarter 2012 acquisition cost information for each of the 11 drugs under review. We selected these 11 drugs because they are included in the separately billable drugs component of the ESRD base rate.[37] Specifically, we asked each facility to

[35] OIG, *End Stage Renal Disease Drugs: Facility Acquisition Costs and Future Medicare Payment Concerns* (OEI-03-09-00280), September 2010.

[36] The 340B program requires drug manufacturers to provide drugs to covered entities at or below statutorily defined ceiling prices (42 U.S.C. § 256b). Therefore, we excluded all 340B-covered facilities, which accounted for 44 percent of hospital-based dialysis facilities in our sample.

[37] The 11 drugs are alteplase recombinant, darbepoetin alfa (Aranesp), calcitriol, daptomycin, doxercalciferol, epoetin alfa (Epogen), iron sucrose, levocarnitine, paricalcitol, sodium ferric gluconate complex, and vancomycin HCl.

provide the total amount paid, the amount of rebates and discounts received, the net amount paid, the number of units purchased, and the average acquisition cost for each of the 11 drugs. We defined "average acquisition cost" as the total amount paid (net of all rebates and discounts) divided by the total number of units purchased during that quarter.

ESRD Drug Acquisition Cost Data for First Quarter 2009. We accessed the dialysis facility acquisition cost data gathered in our September 2010 report. These data represent the volume-weighted average acquisition cost paid in independent and hospital-based dialysis facilities for separately billable ESRD drugs in the first quarter of 2009.[38]

ESRD Base Rate Amounts for the Drugs That Were Formerly Separately Billable. For each of the 11 drugs included in the separately billable drugs portion of the ESRD payment bundle, we calculated the per-unit payment amount in the 2012 ESRD base rate. We calculated these figures using information from the final rules that implemented the 2011 and 2012 ESRD base rates.[39] See Appendix A for a detailed description of our methodology to calculate the per-unit reimbursement amount for the drugs included in the ESRD base rate.

Medicare ASP-Based Payment Amounts. We obtained first-quarter 2012 ASP-based Medicare payment amounts for the 11 drugs from CMS's Web site. These are the reimbursement amounts that CMS paid for Part B drugs dispensed in a non-ESRD setting or for drugs provided by an ESRD facility that chose to phase in the bundled payment method.

PPI for Prescription Drugs Data. We obtained from BLS's Web site the index base data from the PPI for Prescription Drugs for the first quarter of 2009 (the quarter used to collect acquisition cost data in our September 2010 report) and the first quarter of 2012.

Data Analysis

Comparing Acquisition Cost to the ESRD Base Rate. We calculated the overall volume-weighted average acquisition cost per unit (hereinafter referred to as "average acquisition cost") for each of the 11 drugs by (1) totaling the amount paid, net of any discounts and rebates, among all

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[38] For our September 2010 report (*End Stage Renal Disease Drugs: Facility Acquisition Costs and Future Medicare Payment Concerns*, OEI-03-09-00280), we collected acquisition cost data for 10 of the 11 drugs included in our current review; we did not collect acquisition cost data for daptomycin, but we instead collected cost data for iron dextran. However, daptomycin was included in the ESRD payment bundle and iron dextran was not.

[39] The final rule implementing the 2011 ESRD payment bundle can be found at 75 Fed. Reg. 49030 (Aug. 12, 2010). A subsequent rule, found at 76 Fed. Reg. 70228 (Nov. 10, 2011), provides the percentage updates used to calculate the base rate for the payment bundle in 2012.

independent and among all hospital-based dialysis facilities and (2) dividing that by the total units purchased.[40] 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 drug's average cost.[41, 42]

For both facility types (i.e., independent and hospital-based), we calculated the aggregate difference between the first-quarter 2012 average acquisition costs and the total estimated amounts that would have been spent for those units in the 2012 ESRD base rate for the 11 drugs. To do so, we:

- calculated the total net 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 each facility, by its payment portion in the ESRD base rate to calculate the total amount that facilities would have paid for all these drugs if their acquisition cost equaled the ESRD base rate amount; 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 if the acquisition cost had been equal to the ESRD base rate amount.

We calculated the percentage difference between each of the 11 drugs' portion of the 2012 base rate and the first-quarter 2012 average acquisition costs reported by independent and hospital-based dialysis facilities. We further analyzed the data for independent facilities by calculating the aggregate percentage difference between the ESRD base rate amount and acquisition costs in (1) three large chains of independent dialysis facilities and (2) the independent dialysis facilities not owned or managed by these three large companies.

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[40] Some facilities provided the per-unit average acquisition costs, but did not provide the total amounts paid or total units purchased for all drugs. Because these facilities did not provide their totals, we did not include those totals in our calculations of average acquisition costs.

[41] Among the independent dialysis facilities not associated with the three large chains, we identified and removed an average of 0.8 responses per drug because these responses met the outlier criterion. Among hospital-based dialysis facilities, this number was 1.3. We removed no more than four outliers for any single drug in either facility type.

[42] There was significant variability in acquisition costs for sodium ferric gluconate at the independent facilities not associated with the three large chains; therefore, we did not use the same outlier criteria for this drug. Instead, we identified and excluded four responses from smaller independent facilities with amounts that were more than 80 percent higher or lower than the average acquisition cost for this drug.

Changes in Acquisition Costs. To determine whether actual per-unit drug costs had increased, decreased, or remained the same, we compared average facility acquisition costs in the first quarter of 2009 (obtained from our September 2010 report)[43] to those in the first quarter of 2012. We determined the percentage change in the average costs for this period for each drug. We did not collect cost data for 1 of the 11 drugs (daptomycin) as part of our previous report, so this part of our analysis included 10 of the drugs covered under the "separately billable drugs" component of the ESRD base rate.

To determine whether the PPI for Prescription Drugs had been an accurate predictor of price change for the 10 drugs, we calculated the rate at which the PPI had increased between the first quarter of 2009 and the first quarter of 2012. To determine whether acquisition costs had changed at the same rate as PPI for Prescription Drugs, we multiplied this rate by each drug's first-quarter 2009 average acquisition cost to estimate first-quarter 2012 prices. We compared this estimate to the actual average acquisition costs of each drug for dialysis facilities in the first quarter of 2012.

Comparison of Payment Methodologies. We compared first-quarter 2012 ASP-based Medicare payment amounts for the 11 ESRD drugs to the amounts paid under the ESRD base rate. To compare the two methodologies, we first multiplied each drug's units per treatment included in the base rate of the ESRD payment bundle by the first-quarter 2012 ASP payment amounts. We summed these amounts to estimate the total MAP per treatment based on the ASP payment amounts. We compared this figure to the actual MAP per treatment in the 2012 ESRD base rate. See Appendix A for more detail about determining the units and MAP amounts per treatment.

Limitations

We did not evaluate the appropriateness of payments for the entire ESRD payment bundle and the utilization figures used to calculate the base rate. We also did not evaluate the medical necessity of the drugs used to treat ESRD or the clinical appropriateness of the drugs' use in dialysis facilities. In addition, we did not account for individual facility adjustments to the base rate, such as a low-volume adjustment. Instead, we focused only on the unadjusted portion of the ESRD base rate that included drugs that were previously billed separately. Data are based on self-reported information from dialysis facilities and we did not verify this information. The acquisition cost data provided in this report represent purchases for the

[43] OIG, *End Stage Renal Disease Drugs: Facility Acquisition Costs and Future Medicare Payment Concerns* (OEI-03-09-00280), September 2010.

drugs under review made by the majority of the dialysis facilities during the first quarter of 2012. 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 Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Independent dialysis facilities purchased ESRD drugs for less than the drugs' reimbursement amounts in the ESRD base rate, but the acquisition costs for hospital-based facilities exceeded reimbursement amounts, in the aggregate

Consistent with the trend described in our prior ESRD drug pricing reports, first-quarter 2012 aggregate acquisition costs among responding independent dialysis facilities for the 11 ESRD drugs were below the reimbursement portion of the ESRD base rate for these drugs. However, the first-quarter 2012 aggregate acquisition costs for hospital-based dialysis facilities were above the drugs' reimbursement amounts in the ESRD base rate, meaning that these facilities could not purchase the entire bundle of drugs for less than they were reimbursed.

In the aggregate, independent dialysis facilities acquired the 11 drugs for an average of 9 percent less than the drugs' reimbursement amount in the ESRD base rate

In the first quarter of 2012, responding independent dialysis facilities paid between 5 and 54 percent below the per-unit reimbursement amounts in the ESRD base rate for 7 of the 11 drugs, on average. Average acquisition costs for the remaining 4 drugs were between 7 and 30 percent above their ESRD base rate amounts. One of these four drugs, epoetin alfa, represented over three-fourths of total spending ($337 million in the first quarter of 2012) in responding independent dialysis facilities for the drugs under review. Even with epoetin alfa's higher cost, aggregate acquisition costs for the responding independent facilities averaged 9 percent below the amounts represented in the ESRD base rate. This is because many of the other drugs' costs were lower than reimbursement in the aggregate; some of these drugs' costs were substantially lower. See Appendix C for the aggregate difference between the reimbursement amounts in the ESRD base rate and average acquisition costs paid by large chains and smaller independent facilities. See Table 2 for the percentage difference between the amounts in the ESRD base rate and the average acquisition costs reported by independent dialysis facilities for the first quarter of 2012.

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

Drug	Per-Unit Amount in the ESRD Base Rate	First-Quarter 2012 Average Acquisition Cost for Independent Facilities	Percentage Difference Between ESRD Base Rate Amount and Facility Cost
Daptomycin, 1 mg	$0.42	$0.54	30%
Darbepoetin alfa, 1 mcg	$2.79	$3.42	22%
Alteplase recombinant, 1 mg	$36.23	$42.30	17%
Epoetin alfa, per 1,000 units	$9.15	$9.79	7%
Calcitriol, 0.1 mcg	$0.37	$0.35	-5%
Levocarnitine, 1 g	$5.84	$5.20	-11%
Iron sucrose, 1 mg	$0.35	$0.26	-28%
Vancomycin HCl, 500 mg	$3.10	$2.22	-29%
Doxercalciferol, 1 mcg	$2.92	$1.73	-41%
Sodium ferric gluconate, 12.5 mg	$4.43	$2.41	-46%
Paricalcitol, 1 mcg	$3.43	$1.59	-54%

Source: OIG analysis of first-quarter 2012 average acquisition costs among responding independent dialysis facilities, 2013.

Aggregate spending on the 11 drugs in hospital-based dialysis facilities was 5 percent higher, on average, than the drug's reimbursement amount in the ESRD base rate

In the first quarter of 2012, hospital-based dialysis facilities could not purchase ESRD drugs for less than the amount reimbursed under the drug component of the ESRD base rate, in the aggregate.[44] Aggregate spending in responding hospital-based dialysis facilities averaged 5 percent more than the payment amount represented in the ESRD base rate. Hospital-based facilities acquired 5 of the 11 drugs at prices averaging between 4 and 30 percent higher than the drug's per-unit amount reflected in the ESRD base rate. Two of these drugs, epoetin alfa and darbepoetin alfa, accounted for nearly two-thirds of total spending by the hospital-based facilities to purchase the drugs under review.

The average acquisition costs for remaining six drugs were between 7 and 25 percent below the ESRD base rate amount. See Table 3 for each drug's average acquisition cost in responding hospital-based facilities, as compared to the payment amounts in the ESRD base rate.

[44] Although hospital-based facilities could not purchase individual ESRD drugs for less than the drug component amount in the ESRD base rate, they may have been able to provide ESRD treatment, including drugs, for less than the payment amount for entire ESRD base rate.

Table 3: Medicare ESRD Base Rate Payment Amounts and Average Acquisition Costs for Responding Hospital-Based Dialysis Facilities

Drug	Per-Unit Amount in the ESRD Base Rate	First-Quarter 2012 Average Acquisition Cost for Hospital-Based Facilities*	Percentage Difference Between ESRD Base Rate Amount and Facility Cost
Daptomycin, 1 mg	$0.42	$0.54	30%
Darbepoetin alfa, 1 mcg	$2.79	$3.25	16%
Epoetin alfa, per 1,000 units	$9.15	$10.48	14%
Iron sucrose, 1 mg	$0.35	$0.39	9%
Levocarnitine, 1 g	$5.84	$6.07	4%
Calcitriol, 0.1 mcg	$0.37	$0.34	-7%
Alteplase recombinant, 1 mg	$36.23	$33.57	-7%
Doxercalciferol, 1 mcg	$2.92	$2.51	-14%
Sodium ferric gluconate, 12.5 mg	$4.43	$3.61	-18%
Vancomycin HCl, 500 mg	$3.10	$2.51	-19%
Paricalcitol, 1 mcg	$3.43	$2.58	-25%

Source: OIG analysis of first-quarter 2012 average acquisition costs among responding hospital-based dialysis facilities, 2013.
* Acquisition cost data apply only to the responding facilities that purchased the drugs under review.

Dialysis facilities could not purchase epoetin alfa for less than the drug's per-unit ESRD base rate amount, on average

On average, epoetin alfa was purchased by independent dialysis facilities at the rate of $9.79 per 1,000 units and by hospital-based facilities at the rate of $10.48 per 1,000 units in the first quarter of 2012. As a result, acquisition costs at independent and hospital-based facilities were 7 and 14 percent above the amount represented in the 2012 ESRD base rate for the drug (i.e., $9.15 per 1,000 units), respectively. For the drugs under review, epoetin alfa represented more than three-quarters of the costs in responding independent facilities and more than a fifth of costs in responding hospital-based facilities. We estimate that if Medicare had reimbursed on the basis of the per-unit payment amount in the ESRD base rate for epoetin alfa only, responding independent facilities would have been reimbursed $22 million less than the amount they spent to purchase the drug in the first quarter of 2012.

A few of the facilities expressed concern about price increases for epoetin alfa. During the first quarter of 2012, only one of the responding smaller independent dialysis facilities and none of the large chains could purchase epoetin alfa for less than the amount reflected in the ESRD base rate, on average. Less than 10 percent of responding hospital-based facilities that purchased the drug could do so for less than the ESRD base rate amount. However, spending in hospital-based facilities was concentrated on the

other ESA, darbepoetin alfa. None of these facilities could acquire darbepoetin alfa for less than the drug's per-unit ESRD base rate amount, on average.

Although the average facility acquisition costs for the majority of drugs under review decreased in the past 3 years, costs for ESAs have increased

Changes in independent dialysis facilities' acquisition costs between first-quarter 2009 and first-quarter 2012 ranged from a decrease of 52 percent (paricalcitol) to an increase of 35 percent (darbepoetin alfa). Similarly, acquisition costs in hospital-based facilities displayed a wide range of changes, from a decrease of 37 percent (paricalcitol) to an increase of 26 percent (darbepoetin alfa). Although the extent of the percentage change varied by drug, the general trend of cost changes was similar among the two types of dialysis facilities. Alteplase was the only drug for which the acquisition cost *increased* in independent dialysis facilities but *decreased* in hospital-based facilities during the period under review. See Table 4 for the changes in average acquisition costs for the drugs under review.

Table 4: Changes in Average Acquisition Costs for Responding Dialysis Facilities

	Independent Facilities			Hospital-Based Facilities		
Drug	**Average Acquisition Cost in First-Quarter 2009**	**Average Acquisition Cost in First-Quarter 2012**	**Percentage Difference**	**Average Acquisition Cost in First-Quarter 2009**	**Average Acquisition Cost in First-Quarter 2012**	**Percentage Difference**
Darbepoetin alfa, 1 mcg	$2.54	$3.42	35%	$2.59	$3.25	26%
Alteplase recombinant, 1 mg	$33.40	$42.30	27%	$34.23	$33.57	-2%
Epoetin alfa, per 1,000 units	$8.37	$9.79	17%	$8.82	$10.48	19%
Calcitriol, 0.1 mcg	$0.33	$0.35	6%	$0.30	$0.34	14%
Levocarnitine, 1 g	$5.35	$5.20	-3%	$6.78	$6.07	-10%
Iron sucrose, 1 mg	$0.31	$0.26	-18%	$0.39	$0.39	-1%
Vancomycin HCl, 500 mg	$2.70	$2.22	-18%	$2.71	$2.51	-7%
Doxercalciferol, 1 mcg	$2.94	$1.73	-41%	$3.39	$2.51	-26%
Sodium ferric gluconate, 12.5 mg	$4.40	$2.41	-45%	$4.78	$3.61	-24%
Paricalcitol, 1 mcg	$3.29	$1.59	-52%	$4.10	$2.58	-37%

Source: OIG analysis of first-quarter 2009 and first-quarter 2012 average acquisition costs from responding dialysis facilities, 2013.

Average acquisition costs at dialysis facilities have decreased for the majority of drugs in 3 years

By the first quarter of 2012, average acquisition costs had decreased for 6 and 7 of the 10 drugs for which we had collected first-quarter 2009 acquisition cost data in responding independent and hospital-based dialysis facilities, respectively.[45] For responding independent dialysis facilities, the decrease in average acquisition costs ranged from 3 to 52 percent; for responding hospital-based facilities, the decrease ranged from 1 to 37 percent (see Table 4).

Average acquisition costs at dialysis facilities have increased for the ESAs epoetin alfa and darbepoetin alfa by at least 17 percent in 3 years

Between the first quarter of 2009 and the first quarter of 2012, average acquisition costs for epoetin alfa increased by 17 percent and 19 percent in the responding independent and hospital-based dialysis facilities, respectively. As a result, in the first quarter of 2012, independent dialysis facilities spent $1.42 more and hospital-based facilities $1.66 more to purchase 1,000 units of the drug, on average, than they did in the first quarter of 2009 (see Table 4).

The other ESA included in the bundle, darbepoetin alfa, also experienced similar price increases during this time.[46] The average acquisition cost for darbepoetin alfa increased by 35 percent and 26 percent for responding independent and hospital-based dialysis facilities, respectively. In referring to the price increase for darbepoetin alfa, one hospital-based facility noted that the drug's acquisition cost had continued to climb since the first quarter of 2012 and that it anticipates an additional increase in 2013.

The PPI for Prescription Drugs was not an accurate predictor of cost changes between 2009 and 2012 for most drugs under review

The PPI for Prescription Drugs overestimated first-quarter 2012 acquisition costs for nearly all of the 10 drugs under review. According to the PPI data, prescription drug prices increased by 25 percent between the first quarter of 2009 and the first quarter of 2012, even though acquisition costs for the majority of the drugs under review decreased. As a result, the PPI price estimates were, on average, 54 percent and 37 percent higher

[45] We had not collected first-quarter 2009 acquisition cost data for daptomycin in our previous report.

[46] Epoetin alfa and darbepoetin alfa are produced by the same manufacturer.

than first-quarter 2012 average acquisition costs in independent and hospital-based facilities, respectively.

The PPI for Prescription Drugs overestimated the average acquisition cost for 8 of the 10 drugs in independent dialysis facilities and 9 of the 10 drugs in hospital-based dialysis facilities. As was the case in our previous report, the PPI was not an accurate predictor of cost for epoetin alfa. Between the first quarter of 2009 and the first quarter of 2012, average acquisition costs for this drug increased by 17 percent in independent dialysis facilities and 19 percent in hospital-based facilities, whereas the PPI increased by 25 percent. If the PPI for Prescription Drugs had been an accurate predictor of changes in acquisition cost, independent facilities would have paid $10.43 for 1,000 units of the drug instead of the $9.79 actually paid (7-percent difference) and hospital-based facilities would have paid $10.99 for 1,000 units instead of the $10.48 actually paid (5-percent difference).

The PPI for Prescription Drugs underestimated the average acquisition cost for 2 of the 10 drugs in independent dialysis facilities and just 1 of the drugs in hospital-based facilities. The PPI underestimated the amounts paid by both types of facilities to acquire darbepoetin alfa. Independent facilities paid on average $3.42 in the first quarter of 2012 to purchase 1 mcg of darbepoetin alfa; using the PPI rate, these facilities would have paid $3.16. Hospital-based facilities paid on average $3.25 for 1 mcg of darbepoetin alfa, which is very close to the PPI-based estimate of $3.23.

If ASP-based reimbursement had remained in effect for the first quarter of 2012, payment amounts for the bundle of ESRD drugs would have differed by less than a dollar per treatment

Overall, the ESRD base rate paid $72.23 per treatment in 2012 for 11 ESRD drugs that, prior to 2011, were separately billable and paid on the basis of 106 percent of each drug's ASP. We estimate that if the units per treatment remained consistent since CMS calculated the initial ESRD base rate (using 2007 claims data), the ESRD base rate reimbursement would have been slightly higher ($0.83 more) than per-treatment payment based on first-quarter 2012 ASP amounts for the 11 drugs. This is true even after accounting for the standardization, outlier, and budget neutrality adjustments to the base rate. See Table 5 for the price differences in payment methodologies.

Table 5: Comparison of the Former and Current ESRD Payment Methodologies

Drug	Units per Treatment in the ESRD Base Rate	Estimated Cost per Treatment Based on First-Quarter 2012 ASP Payment	Medicare Reimbursement per Treatment in the 2012 ESRD Base Rate
Daptomycin, 1 mg	0.10	$0.05	$0.04
Darbepoetin alfa, 1 mcg	1.39	$4.46	$3.88
Alteplase recombinant, 1 mg	0.02	$0.91	$0.79
Epoetin alfa, per 1,000 units	5.57	$53.57	$51.00
Calcitriol, 0.1 mcg	0.16	$0.17	$0.06
Levocarnitine, 1 g	0.02	$0.16	$0.10
Vancomycin HCl, 500 mg	0.03	$0.08	$0.09
Iron sucrose, 1 mg	12.23	$3.93	$4.33
Doxercalciferol, 1 mcg	0.78	$1.11	$2.28
Sodium ferric gluconate, 12.5 mg	0.39	$1.85	$1.73
Paricalcitol, 1 mcg	2.32	$5.11	$7.94
Total		**$71.41***	**$72.23***

Source: OIG analysis, 75 Fed. Reg. 49030, 49068, 49080 (Aug.12, 2010), and CMS first-quarter 2012 payment amounts, 2013.
* Individual amounts do not add to total because of rounding.

CONCLUSION AND RECOMMENDATIONS

On January 1, 2011, Medicare payment for the treatment of ESRD changed dramatically to a system that bundles all costs related to ESRD care into a single per-treatment payment amount. The ESRD payment bundle sought to promote equitable payment and access to services by targeting greater payments to ESRD facilities that treat more costly patients and to reduce the incentives to overuse separately billable drugs. To comply with statutory requirements, CMS developed the ESRD base rate of the payment bundle using claims data from 2007. However, drug utilization during 2007 did not fully reflect the impact of new safety data, changes to Medicare policies and procedures that address overutilization of ESAs and quality of care, and incentives provided under the payment bundle to furnish services more efficiently. A May 2013 OIG report found a decline in use of certain ESRD drugs since 2007, and CMS concurred with the report's recommendation to adjust the ESRD bundled base rate to realize program savings associated with decreased utilization.

Furthermore, Federal law requires CMS to reduce the ESRD payment bundle's base rate for 2014 to reflect changes in the utilization and prices of ESRD drugs and to take into account the most recently available data on drug sales. Our findings show that dialysis facilities' acquisition costs for the majority of the ESRD drugs have also decreased. However, since our last report on ESRD drug pricing, the costs for ESAs (drugs representing the majority of total drug costs for facilities) have steadily increased. This means that although dialysis facilities are using ESAs to a lesser extent, any savings may potentially be offset by the drugs' cost increase. However, without taking both the payment and utilization aspects into account, we are unable to estimate the extent to which this may be occurring.

Even with the cost increase for ESAs, independent dialysis facilities could still acquire ESRD drugs for less than Medicare reimbursement, in the aggregate. However, our findings also indicate that any reductions to the ESRD base rate for the bundle may potentially harm hospital-based dialysis facilities, as such facilities experienced difficulties purchasing drugs for less than reimbursement, in the aggregate, even prior to any reduction that may result from the American Taxpayer Relief Act. When making adjustments to the ESRD base rate, CMS should carefully consider the implications it may have on hospital-based dialysis facilities.

Therefore, we recommend that CMS:

Rebase the ESRD base rate to reflect current trends in drug acquisition costs, as required by law

The base rate for the ESRD payment bundle should more accurately reflect the amounts paid by facilities to purchase drugs used to treat ESRD. Overall, there has been a downward trend in the average prices that facilities pay to acquire ESRD drugs, with the exception of the ESAs. ESAs represent the majority of dialysis facility costs for drugs used in treating ESRD. However, the amounts in the bundled base rate do not reflect pricing decreases or increases. If the payment amounts do not adequately reflect acquisition costs, it may influence facility decisions on which drugs to purchase. This gap between acquisition costs and payment amounts may potentially cost the program additional dollars or may result in certain facilities' paying more to acquire the drugs than the amount provided under the ESRD base rate.

Beginning in 2014, CMS is required to rebase the ESRD base rate for the payment bundle using updated ASP data for the drugs under review. We recommend that CMS complete this rebasing and ensure that it takes into account the current trends in drug acquisition costs and utilization when doing so.

Distinguish payments in the ESRD base rate between independent and hospital-based dialysis facilities

When CMS rebases the ESRD base rate, it should adjust reimbursement for independent dialysis facilities and hospital-based dialysis facilities to account for the differences in their acquisition costs. If necessary, CMS should seek legislative authorization to do so. In the aggregate, independent facilities could purchase the bundle of ESRD drugs for less than the ESRD base rate; however, responding hospital-based facilities could not. Our prior reports have shown that hospital-based facilities have typically paid more than independent facilities to purchase ESRD drugs, and this current report shows that this disparity has grown. Although we did not take into account additional adjustments that may have boosted reimbursement to an individual facility, such as a low-volume adjustment, it appears that hospital-based facilities have difficulties purchasing drugs at prices that would be financially advantageous, in the aggregate. In fact, in some cases, it appears that hospital-based facilities are unable to recoup the total amount paid to purchase ESRD drugs. CMS should ensure that the ESRD base rate covers the costs paid by hospital-based facilities to purchase the drugs used to treat ESRD, and the agency could consider using an add-on adjustment for this facility type.

Consider updating the ESRD payment bundle using a factor that takes into account drug acquisition costs

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 changes in the ESRD payment bundle. Our September 2010 report found that the average acquisition cost for the majority of drugs purchased by dialysis facilities had decreased, while the PPI substantially increased. We recommended that CMS develop a more accurate method for estimating changes in the prices of ESRD drugs. CMS stated that it did not concur with the recommendation because the downward trajectory of average acquisition costs was influenced largely by payment changes and, as a result, was not suitable for inferring future price trends. However, we found in our current report that the PPI has continually increased at a time when costs for most of the drugs purchased by facilities have decreased. We therefore continue to believe that CMS should use a more accurate cost predictor when updating the ESRD payment bundle.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on our draft report, CMS concurred with one of our three recommendations. CMS did not state whether or not it concurred with one recommendation and did not concur with another recommendation.

CMS concurred with our third recommendation, to consider updating the ESRD bundled rate using a factor that takes into account drug acquisition costs. CMS said it will consider our findings regarding the accuracy of the PPI for Prescription Drugs in its continual evaluation of the ESRD market basket, particularly when rebasing and revising the market basket index. CMS also stated that it will evaluate alternative data sources to determine whether it can improve the relevance of the ESRD drug price proxy (while maintaining a price proxy that is reliable, timely, and available).

In commenting on our first recommendation, to rebase the ESRD base rate to reflect current trends in drug acquisition costs, as required by law, CMS did not state whether it concurred. But CMS did say that our report will assist the agency in determining price adjustments to the ESRD payment bundle in the future. CMS responded that it has implemented section 632(a) of the American Taxpayer Relief Act of 2012, which required a reduction in the ESRD payment bundle. CMS stated that, as required by law, it took into account the most recently available ASP data, as well as drug price changes reflected in the ESRD market basket percentage increase factor when determining the reduction amount. CMS also noted that the statute did not specify to take into account drug acquisition costs. However, for the purposes of this report, we interpreted drug acquisition costs and drug sales prices to be essentially the same. We ask that in its final management decision, CMS more clearly indicate the distinction between drug acquisition and sales prices and indicate whether it concurs with our recommendation and what steps, if any, it plans to take to implement it.

Finally, CMS did not concur with our second recommendation, to distinguish payments in the ESRD base rate between independent and hospital-based dialysis facilities. CMS stated that section 1881(b)(14)(A)(i) of the Act required the implementation of a single-payment system for providers of dialysis services. CMS also noted that the ESRD payment bundle includes several payment adjusters, as well as an outlier policy to cover more expensive dialysis treatments and facility-level adjustments to enhance payments for smaller facilities. CMS stated that it has the statutory authority to review the appropriateness of all

of the payment adjusters as a whole, no later than January 2016. CMS said it will then consider appropriate modifications to the payment system to improve the accuracy of Medicare's payment for renal dialysis services, including drugs and biologicals. Although the additional payment adjusters currently included in the ESRD payment bundle may increase reimbursement enough to cover the costs of acquiring ESRD drugs at hospital-based facilities, we believe that distinguishing payment between the different facility types would help to ensure that hospital-based facilities are paid appropriately at this time.

We did not make any changes to the report based on CMS's comments. The full text of CMS's comments is provided in Appendix D.

APPENDIX A

Detailed Methodology for Calculating the Individual-Drug Payment Portions of the ESRD Base Rate

In calculating the individual-drug payment portions of the ESRD base rate, we followed CMS's methodology for developing the ESRD base rate in 2011, the first year the rate was implemented. CMS developed the 2011 base rate using 2007 Medicare allowable payment amounts for each service included in the ESRD payment bundle, as well as the number of 2007 dialysis treatments. To calculate the unadjusted per-treatment base rate, CMS divided the sum of the Medicare allowable payments for each service by the number of dialysis treatments.

Eleven separately billable ESRD drugs accounted for 99.8 percent of total Part B spending on separately billable ESRD drugs in 2007. CMS selected these 11 drugs as the basis for the pharmaceutical category (i.e., the "separately billable drugs" component) of the ESRD payment bundle. Using data provided in 75 Fed. Reg. 49030, 49068 (Aug. 12, 2010), the rule that implements the ESRD payment bundle, we calculated the average unadjusted Medicare allowable payment amount per treatment for each of the 11 drugs. See Table A-1 for this information.

Table A-1: Medicare Allowable Payments per Treatment in 2007

Part B Drug	Total 2007 Medicare Allowable Payments	Total Dialysis Treatments in 2007	Average Medicare Allowable Payment per Treatment
Epoetin alfa	$1,876,926,573	36,747,662	$51.08
Paricalcitol	$322,849,348	36,747,662	$8.79
Darbepoetin alfa	$167,935,970	36,747,662	$4.57
Iron sucrose	$166,219,339	36,747,662	$4.52
Doxercalciferol	$76,901,723	36,747,662	$2.09
Sodium ferric gluconate	$68,086,707	36,747,662	$1.85
Alteplase recombinant	$26,697,321	36,747,662	$0.73
Levocarnitine	$5,026,446	36,747,662	$0.14
Vancomycin HCl	$3,583,504	36,747,662	$0.10
Calcitriol	$3,125,613	36,747,662	$0.09
Daptomycin	$1,234,405	36,747,662	$0.03

Source: OIG analysis, 75 Fed. Reg. 49030, 49068 (Aug. 12, 2010).

To arrive at the base rate, CMS then adjusted the 2007 Medicare allowable payment amounts for each service included in the ESRD payment bundle to reflect estimated prices in 2011. These adjustments were based on the

latest available ASP data, which represented the second quarter of 2010. CMS updated these prices using the PPI for Prescription Drugs.

Section 1881(b)(14)(A)(ii) of the Act also required the ESRD payment bundle to be 98 percent budget neutral in 2011. This means that the estimated total payments for 2011 under the ESRD payment bundle must equal 98 percent of the estimated total payments for dialysis services that would have been made if the bundled rate had not been implemented. CMS applied the following adjustments to the base rate to comply with this requirement:

- 94.07-percent adjustment to ensure that the total projected ESRD payments were equal to estimated total payments for dialysis services that would have been made if the bundled payment system had not been implemented,
- 99-percent adjustment to ensure that the outlier policy was budget neutral, and
- 98-percent adjustment to account for the budget neutrality requirement.

We then calculated the Medicare allowable payment per treatment for each of the 11 drugs included in the base rate by applying these adjustments (see Table A-2).

Table A-2: Medicare Allowable Payments per Treatment in the 2011 Base Rate

		Adjustments Applied to the Medicare Allowable Payment				
Part B Drug	**Average Medicare Allowable Payment per Treatment in 2007**	**Multiplied by: Adjustment to Reflect Estimated 2011 Prices**	**Multiplied by: Standardization Adjustment**	**Multiplied by: Outlier Adjustment**	**Multiplied by: Budget Neutrality Adjustment**	**Equals: Reimbursement Per Treatment in 2011 Base Rate**
Epoetin alfa	$51.08	1.07	0.9407	0.99	0.98	$49.88
Paricalcitol	$8.79	0.97	0.9407	0.99	0.98	$7.76
Darbepoetin alfa	$4.57	0.91	0.9407	0.99	0.98	$3.80
Iron sucrose	$4.52	1.03	0.9407	0.99	0.98	$4.24
Doxercalciferol	$2.09	1.17	0.9407	0.99	0.98	$2.23
Sodium ferric gluconate	$1.85	1.00	0.9407	0.99	0.98	$1.69
Alteplase recombinant	$0.73	1.17	0.9407	0.99	0.98	$0.78
Levocarnitine	$0.14	0.78	0.9407	0.99	0.98	$0.10
Vancomycin HCl	$0.10	0.97	0.9407	0.99	0.98	$0.09
Calcitriol	$0.09	0.74	0.9407	0.99	0.98	$0.06
Daptomycin	$0.03	1.30	0.9407	0.99	0.98	$0.04

Source: OIG analysis, 75 Fed. Reg. 49030, 49080–2 (Aug. 12, 2010).

Dialysis facilities report the appropriate Healthcare Common Procedure Coding System (HCPCS) code on their Medicare claims and bill the units of service in multiples of the units shown in the HCPCS narrative description. This is also the unit that Medicare used as the basis for payment for separately billable drugs prior to the ESRD payment bundle.[47] To calculate the amount reflected in the ESRD base rate, we divided the 2007 average Medicare allowable payment per treatment by the average 2007 payment for a single HCPCS unit (i.e., billing unit) to determine the number of billing units reflected in the base rate (see Table A-3).

Table A-3: Billing Units Reflected in the ESRD Base Rate for Each Drug

Part B Drug	HCPCS Code	Billing Unit	Average Medicare Allowable Payment per Treatment in 2007	Divided by: Average 2007 Payment Amount for a Billing Unit	Equals: Number of Billing Units in the ESRD Base Rate
Epoetin alfa	J0886	1,000 units	$51.08	$9.17	5.57
Paricalcitol	J2501	1 mcg	$8.79	$3.79	2.32
Darbepoetin alfa	J0882	1 mcg	$4.57	$3.29	1.39
Iron sucrose	J1756	1 mg	$4.52	$0.37	12.23
Doxercalciferol	J1270	1 mcg	$2.09	$2.68	0.78
Sodium ferric gluconate	J2916	12.5 mg	$1.85	$4.76	0.39
Alteplase recombinant	J2997	1 mg	$0.73	$33.21	0.02
Levocarnitine	J1955	1 g	$0.14	$8.07	0.02
Vancomycin HCl	J3370	500 mg	$0.10	$3.43	0.03
Calcitriol	J0636	0.1 mcg	$0.09	$0.54	0.16
Daptomycin	J0878	1 mg	$0.03	$0.34	0.10

Source: OIG analysis, 75 Fed. Reg. 49030, 49080–2 (Aug. 12, 2010), CMS ASP Drug Pricing Files (2007).

We then updated the 2011 per-treatment reimbursement amounts to reflect the amounts in the 2012 ESRD base rate. To calculate the reimbursement per treatment in the 2012 ESRD base rate, we multiplied the 2011 per-treatment amounts by 2.1 percent to adjust for the market basket increases and then by 0.1520 percent for the wage-index budget neutrality adjustment. We then divided the 2012 reimbursement per treatment by the billing units in the ESRD base rate to calculate reimbursement per billing unit in 2012. See Table A-4 for the per-treatment reimbursement amounts.

[47] CMS, *2007 ASP Drug Pricing Files*. Accessed at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/01b_2007aspfiles.html on June 20, 2013.

Table A-4: Reimbursement per Billing Unit in the 2012 Base Rate

		Adjustments Applied 2011 Base Rate for 2012				
Part B Drug	**Reimbursement Per Treatment in 2011 Base Rate**	**Multiplied by: Market Basket Adjustment**	**Multiplied by: Wage-Index Budget Neutrality Adjustment**	**Equals: Reimbursement Per Treatment in 2012 Base Rate**	**Divided by: Number of Billing Units in the Base Rate**	**Equals: Reimbursement per Billing Unit in 2012***
Epoetin alfa	$49.88	1.021	1.001520	$51.00	5.57	$9.15
Paricalcitol	$7.76	1.021	1.001520	$7.94	2.32	$3.43
Darbepoetin alfa	$3.80	1.021	1.001520	$3.88	1.39	$2.79
Iron sucrose	$4.24	1.021	1.001520	$4.33	12.23	$0.35
Doxercalciferol	$2.23	1.021	1.001520	$2.28	0.78	$2.92
Sodium ferric gluconate	$1.69	1.021	1.001520	$1.73	0.39	$4.43
Alteplase recombinant	$0.78	1.021	1.001520	$0.79	0.02	$36.23
Levocarnitine	$0.10	1.021	1.001520	$0.10	0.02	$5.84
Vancomycin HCl	$0.09	1.021	1.001520	$0.09	0.03	$3.10
Calcitriol	$0.06	1.021	1.001520	$0.06	0.16	$0.37
Daptomycin	$0.04	1.021	1.001520	$0.04	0.10	$0.42

Source: OIG analysis, 75 Fed. Reg. 49030, 49080–82 (Aug. 12, 2010), 76 Fed. Reg. 70228, 70231 (Nov. 10, 2011), and CMS ASP Drug Pricing Files (2007).
*Amounts may not equal exact reimbursement because of rounding.

APPENDIX B

Detailed Methodology for Selecting Dialysis Facilities

Large Chains of Independent Dialysis Facilities. We classified three chains of independent dialysis facilities (Davita, Fresenius, and Dialysis Clinic Inc.) as large chains. As of August 2012, these 3 companies owned 3,349 (64 percent) of the 5,219 independent dialysis facilities listed in CMS's Certification and Survey Provider Enhanced Reports database. We contacted representatives from these three companies and sent them the online survey on acquisition costs. All three companies responded to our request in January 2013.

Smaller Independent Dialysis Facilities. To ensure that smaller independent facilities were represented, we sent surveys to a random sample of 200 of the 1,870 remaining independent dialysis facilities not owned or managed by one of the 3 large chains. Of these, 177 replied (89 percent); however, we excluded 50 facilities because they had been subsequently acquired by one of the 3 large chains and their acquisition costs were thus included as part of the larger companies' responses. We excluded an additional two facilities because they indicated on the survey that they qualified for 340B pricing.[48] Therefore, we received complete data from 125 smaller independent dialysis facilities. Several of the responding facilities owned multiple dialysis units and provided cost information for 397 additional facilities (for a total of 522 respondents not affiliated with the 3 large independent dialysis companies).

Hospital-Based Dialysis Facilities. As of August 2012, there were 356 hospital-based dialysis facilities. We identified and excluded 156 hospitals that qualified for 340B pricing.[49] In December 2012, we sent online surveys requesting acquisition cost data to the remaining 200 hospital-based dialysis facilities. These were the same requests for first-quarter 2012 data that we sent to the independent dialysis facilities.

[48] We excluded these facilities because the 340B program requires drug manufacturers to provide drugs to 340B-covered entities at or below statutorily defined ceiling prices. 42 U.S.C. § 256b.

[49] To identify 340B-covered facilities, we downloaded the covered entities file from the Health Resources and Services Administration's Web site on November 14, 2012, and identified those covered during the first quarter of 2012 (i.e., the quarter for which we requested cost data).

We received responses from 177 hospital-based dialysis facilities (89 percent), but could not use data provided by 53 of these facilities.[50] Of the remaining 124 respondents, 1 hospital provided data on an additional hospital, resulting in valid data representing 125 hospital-based dialysis facilities.

[50] We excluded these 53 facilities for the following reasons: 9 reported that they had either discontinued outpatient dialysis services or provided primarily inpatient dialysis; 9 had been acquired by 1 of the large chains; 33 responded that they qualified for 340B pricing; and 2 received Department of Veterans Affairs pricing, which is heavily discounted compared to prices in the marketplace.

APPENDIX C

Difference Between Medicare Reimbursement and Costs Paid by Large Chain and Smaller Independent Dialysis Facilities

In the aggregate, first-quarter 2012 acquisition costs among the three large chains averaged 8 percent below the drugs' respective reimbursement amounts in the ESRD base rate. In the first quarter of 2012, these chains purchased 7 of the 11 drugs under review for less than the drugs' respective reimbursement amounts in the ESRD base rate. Average acquisition costs ranged between 4 and 54 percent less than the amount in the ESRD base rate. Costs for the remaining 4 of the 11 drugs exceeded reimbursement by 7 to 30 percent.

Among responding independent dialysis facilities that were not owned or managed by these three large chains, acquisition costs averaged 11 percent below the drugs' respective reimbursement amounts in the ESRD base rate, in the aggregate. In the first quarter of 2012, these facilities purchased the same seven drugs for less than the ESRD base rate reimbursement amounts; the facilities' average acquisition costs ranged from 8 and 49 percent below the ESRD base rate for these seven drugs. Costs for the remaining 4 of the 11 drugs exceeded reimbursement by 9 to 32 percent. See Table C-1 for the differences in average acquisition costs for the two types of independent dialysis facilities.

Table C-1: ESRD Base Rate Payment Amounts and Average Acquisition Costs for Large Chains and Smaller Independent Dialysis Facilities

Drug	Per-Unit Amount in the ESRD Base Rate	First-Quarter 2012 Average Acquisition Costs for Large Chains	First-Quarter 2012 Average Acquisition Costs for Smaller Independent Facilities*
Alteplase recombinant, 1 mg	$36.23	$41.89	$44.51
Calcitriol, 0.1 mcg	$0.37	$0.35	$0.32
Daptomycin, 1 mg	$0.42	$0.54	$0.55
Darbepoetin alfa, 1 mcg	$2.79	$3.46	$3.33
Doxercalciferol, 1 mcg	$2.92	$1.73	$1.78
Epoetin alfa, per 1,000 units	$9.15	$9.78	$9.96
Iron sucrose, 1 mg	$0.35	$0.26	$0.25
Levocarnitine, 1 g	$5.84	$5.15	$5.39
Paricalcitol, 1 mcg	$3.43	$1.56	$2.03
Sodium ferric gluconate, 12.5 mg	$4.43	$2.54	$2.26
Vancomycin HCl, 500 mg	$3.10	$2.18	$2.54

Source: OIG analysis of first-quarter 2012 average acquisition costs among responding independent dialysis facilities, 2013.
* Acquisition cost data apply only to the responding facilities that purchased the drugs under review.

APPENDIX D

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JAN - 8 2014

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Administrator

SUBJECT: Office of Inspector General Draft Report: "Update: Medicare Payments for End Stage Renal Disease Drugs," (OEI-03-12-00550)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the above subject report. The objectives of this review were to: 1) compare first-quarter-2012 facility acquisition costs for selected End Stage Renal Disease (ESRD) drugs to the amounts that Medicare Part B paid for these drugs under the new ESRD bundled rate; 2) determine how facility acquisition costs for selected ESRD drugs have changed in relation to inflation, from the first quarter of 2009 to the first quarter of 2012 and; 3) compare the average sale price (ASP) based reimbursement amounts for selected ESRD drugs to the amounts paid under the new ESRD bundled rate.

Our response to each recommendation follows.

Recommendation:

Rebase the ESRD base rate to reflect current trends in drug acquisition costs, as required by law.

Response:

The CMS implemented section 632(a) of the American Taxpayer Relief Act of 2012 (ATRA), which requires the Secretary to reduce the single payment amount for renal dialysis services to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (other than oral-only ESRD-related drugs) between 2007 and 2012. As the law requires, CMS took into account the most recently available data on ASP and changes in prices for drugs and biologicals reflected in the ESRD market basket percentage increase factor in determining the reduction amount. The statute did not specify to take into account drug acquisition costs.

The final regulation was issued on November 22, 2013 (See 78 FR 72156) and included a reduction amount which will be phased in over three to four years by offsetting the reduction against the market basket minus productivity adjustment and other payment impacts to create an overall zero percent impact for all ESRD facilities from the previous year's payments for calendar

years (CYs) 2014 and 2015. For CY 2016, CMS will evaluate how to apply the balance of the reduction when we conduct an analysis of the case-mix adjustments, required by section 632(c) of ATRA, and implement the inclusion of oral-only ESRD-related drugs and biologicals, after 2016 as required by section 632(b) of ATRA. At that time, this evaluation will assist us in determining if we should apply the balance of the reduction in CY 2016 or provide one additional transition year so that the entire amount is applied to the base rate no later than CY 2017. Consistent with the law, the final rule will achieve savings for the Medicare program while ensuring greater accuracy under the ESRD payment system.

Recommendation:

Distinguish payment in the ESRD base rate between independent and hospital-based dialysis facilities.

Response:

The CMS does not concur with this recommendation. Section1881(b)(14)(A)(i) of the Act requires that CMS implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services. As a result, the ESRD PPS applies a single base rate that reflects the average cost of a dialysis treatment across all ESRD facility types.

The ESRD PPS includes several patient-level payment adjusters for those patients who are more expensive to treat, including case-mix adjusters and an outlier policy. In addition, the ESRD PPS includes several facility-level adjusters, including one to enhance payment for those facilities that are at a disadvantage because of size, such as the low volume payment adjustment.

It is important to note that section 632 of ATRA requires that no later than January 1, 2016, CMS bundle in the cost of oral only ESRD related drugs, conduct an analysis of the case-mix payment adjustments, and make appropriate revisions to such case mix payment adjustments. This statutory authority gives us the opportunity and flexibility to review the appropriateness of all of the payment adjusters as a whole. At that time, CMS will consider appropriate modifications to the payment system to improve the accuracy of Medicare's payment for renal dialysis services, including drugs and biologicals included in the payment bundle.

Recommendation:

Consider updating the ESRD bundled rate using a factor that takes into account drug acquisition costs.

Response:

The CMS concurs with the recommendation. We are appreciative of the work of OIG in reviewing the acquisition costs related to the drugs used in furnishing ESRD services. OIG found a range of price changes in the average facility acquisition costs from 2009 to 2012 (first quarter), with the majority of drugs under review experiencing a decrease while Epoetin Alfa, the drug that accounted for over 70 percent of the per-treatment payment in 2011, increased between

17 to 19 percent. By comparison, OIG reported that the Producer Price Index (PPI) drug index, used in the ESRD bundled market basket, increased by about 25 percent.

We will consider these findings in our continual evaluation of the ESRD market basket, particularly during the next rebasing and revising of the market basket index. As we have done for all of the market baskets developed by CMS, we will base the decision on which price proxy is used on four criteria: reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data are collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

At the time the PPI for prescription drugs was chosen for use in the ESRD market basket, we believed that it adequately met these criteria. While we still believe that it is a reliable, timely, and available proxy, the OIG work has raised important questions about its relevance. We will be evaluating alternative data sources and methods to determine if we can improve the relevance of the ESRD drug price proxy while maintaining the other three criteria. For instance, the data used in the OIG analysis is based on acquisition cost data, which is not data that is readily available in a public or timely manner. Additionally, the ESRD annual market basket updates are based on a projection and any price proxy ultimately will need to be forecasted. The more restrictive or specific a price series, the more difficult it can be to accurately forecast future price movements. Finally, the price proxy should also reflect price trends associated with an efficient market; therefore, to the extent market inefficiencies exist, there would be concerns with using direct cost or price data.

The CMS thanks the OIG for the opportunity to review and comment on this draft report.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office.

Stephanie Yeager served as the team leader for this study, and Stefanie Vance served as the lead analyst. Central office staff who provided support include Clarence Arnold, Meghan Kearns, and Christine Moritz.

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