Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE AND BENEFICIARIES COULD SAVE MILLIONS IF DIALYSIS PAYMENTS WERE ADJUSTED FOR ANEMIA MANAGEMENT DRUG UTILIZATION

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EXECUTIVE SUMMARY

If the Centers for Medicare & Medicaid Services had adjusted the payments for dialysis services to reflect calendar year 2011 anemia management drug utilization, we estimated that Medicare and beneficiaries could have saved $510 million for erythropoiesis-stimulating agents and $19 million for iron supplements.

WHY WE DID THIS REVIEW

In calendar year (CY) 2011, Medicare and beneficiaries paid approximately $10 billion for dialysis services under a bundled end-stage renal disease (ESRD) prospective payment system (PPS) that went into effect on January 1, 2011. The anemia management drugs Epogen, Aranesp, Venofer, and Ferrlecit represent approximately 25 percent of the base rate payment made to dialysis facilities for each dialysis treatment furnished to a beneficiary. We anticipated that the claims data the Centers for Medicare & Medicaid Services (CMS) used to calculate the base rate payment, which reflects CY 2007 utilization of anemia management drugs, would not reflect CY 2011 utilization because of the change in the payment methodology and because the Food and Drug Administration recently recommended more conservative dosing of Epogen and Aranesp. In addition, CMS stated that the change in payment method reduces incentives to overuse drugs that used to be paid for separately.

The objective of this review was to determine the potential cost savings to Medicare and beneficiaries of adjusting, or rebasing, the ESRD base rate to reflect CY 2011 utilization of anemia management drugs Epogen, Aranesp, Venofer, and Ferrlecit.

BACKGROUND

Almost all people with ESRD have anemia. The erythropoiesis-stimulating agent (ESA) drugs Epogen and Aranesp and the iron supplements Venofer and Ferrlecit were the most commonly prescribed anemia management drugs in CY 2011. CMS developed the ESRD PPS base rate using CY 2007 utilization and payment data for ESAs and iron supplements.

Before January 1, 2011, dialysis facilities billed Medicare separately for Epogen, Aranesp, Venofer, and Ferrlecit, and Medicare made separate payments for them. However, as of that date, these anemia management drugs are now included in the PPS payment bundle, and Medicare no longer reimburses dialysis facilities for them separately. To comply with statutory requirements, CMS used CY 2007 claims and cost report data for ESAs and iron supplements to calculate the base rate for that payment bundle. As in any PPS, those providing the services—in this report, dialysis facilities—keep the difference if Medicare payments exceed costs for bundled services, and they are liable for the difference if the costs exceed Medicare payments.

HOW WE CONDUCTED THIS REVIEW

We reviewed a stratified random sample of dialysis treatments to estimate (1) the difference between the base rate reimbursement for ESAs and iron supplements and the reimbursement for

ESAs and iron supplements actually furnished and (2) the quantities of Epogen, Aranesp, Venofer, and Ferrlecit actually furnished in CY 2011 and the number of dialysis treatments furnished in CY 2011.

WHAT WE FOUND

Using our sample results, we estimated that Medicare and beneficiaries could have saved $510 million for the ESAs Epogen and Aranesp and $19 million for the iron supplements Venofer and Ferrlecit during CY 2011 if the ESRD base rate had been adjusted to reflect current utilization of anemia management drugs. In addition, through our analysis of the CY 2011 sample items, we identified limitations that CMS should consider when it relies on ESRD claims data for program oversight. These limitations include inaccuracies in the quantities of drugs claimed and the inability to determine the extent of drug waste or overfill usage.

WHAT WE RECOMMEND

We recommend that CMS:

- adjust the bundled base rate to realize program savings associated with decreased utilization of ESAs and iron supplements;
- remind dialysis facilities of the importance of claims accuracy; and
- develop new policies, procedures, or other guidance for recording drug waste and overfill on ESRD claims.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and described corrective actions it had taken and plans to take.

TABLE OF CONTENTS

INTRODUCTION

WHY WE DID THIS REVIEW

In calendar year (CY) 2011, Medicare and beneficiaries paid approximately $10 billion for dialysis services under a bundled end-stage renal disease (ESRD) prospective payment system (PPS) that went into effect on January 1, 2011. The anemia management drugs Epogen, Aranesp, Venofer, and Ferrlecit represent approximately 25 percent of the base rate payment made to dialysis facilities for each dialysis treatment furnished to a beneficiary. We anticipated that the claims data the Centers for Medicare & Medicaid Services (CMS) used to calculate the base rate payment, which reflects CY 2007 utilization of anemia management drugs, would not reflect CY 2011 utilization because of the change in the payment methodology and because the Food and Drug Administration (FDA) recently recommended more conservative dosing of Epogen and Aranesp. In addition, CMS stated that the change in payment method reduces incentives to overuse drugs that used to be paid for separately.

OBJECTIVE

Our objective was to determine the potential cost savings to Medicare and beneficiaries of adjusting, or rebasing, the ESRD base rate to reflect CY 2011 utilization of anemia management drugs Epogen, Aranesp, Venofer, and Ferrlecit.

BACKGROUND

Medicare, which is administered by CMS, provides health insurance coverage to eligible beneficiaries with ESRD under Title XVIII of the Social Security Act (the Act). Chronic kidney disease causes reduced kidney function. ESRD, the last stage in chronic kidney disease, is permanent kidney failure that requires a regular course of maintenance dialysis or a kidney transplant.

Dialysis Treatments

Dialysis is a treatment that replaces the function of the kidneys by removing waste and excess water from the body. There are two types of dialysis treatments: hemodialysis and peritoneal dialysis. In hemodialysis, an artificial kidney is used to remove waste and excess fluid from blood. Hemodialysis is typically furnished three times a week in 3- to 5-hour sessions. In peritoneal dialysis, blood is cleaned inside the abdomen (the peritoneal cavity). Peritoneal dialysis is furnished continuously, rather than as individual sessions.

Medicare covers three dialysis treatments per week. CMS considers each hemodialysis treatment to be a single dialysis treatment. CMS equates 1 week (7 days) of peritoneal dialysis to three dialysis treatments.[1]

[1] CMS, *Medicare Benefit Policy Manual*, Pub. 100-02, ch. 11, § 30.1.B; CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, § 80.4.

Dialysis Facilities

Dialysis facilities provide outpatient dialysis treatments to ESRD patients. Beneficiaries may receive dialysis either at a Medicare-certified dialysis facility or at home. A dialysis facility can be either a freestanding unit or a hospital-based facility. There were approximately 5,700 outpatient dialysis facilities in the United States in CY 2011. Freestanding units provided beneficiaries with approximately 94 percent of dialysis treatments in CY 2011. A small number of for-profit companies own the majority of dialysis facilities.

Anemia and End-Stage Renal Disease

An individual whose blood is low in oxygen-carrying capacity has anemia. Almost all people with ESRD have anemia because diseased kidneys generally do not produce enough erythropoietin, a natural hormone that stimulates the bone marrow to produce red blood cells. As a result, the bone marrow makes fewer red blood cells, which are needed to carry oxygen to vital organs.

Dialysis facilities monitor anemia using laboratory tests that measure hemoglobin (the protein that carries oxygen in red blood cells) and hematocrit (the percentage of red blood cells in whole blood).

Commonly Prescribed Anemia Management Drugs

Erythropoiesis-stimulating agents (ESA) are drugs used to treat anemia in ESRD patients. These drugs act similarly to erythropoietin to stimulate the production of red blood cells. There are two methods of administering ESAs: intravenously and subcutaneously. The intravenous method requires a larger dose. Drugs in the ESA class are Epogen (epoetin alfa) [2] and Aranesp (darbepoetin alfa). Medicare covers Epogen and Aranesp for the treatment of anemia associated with ESRD beneficiaries who are on dialysis.

Many anemic ESRD patients are also treated with iron supplements because iron is necessary for the production of red blood cells. Medicare covers the iron supplements Venofer (iron sucrose) and Ferrlecit (sodium ferric gluconate complex) to treat iron-deficiency anemia when they are furnished to ESRD beneficiaries who are receiving ESA therapy.

Medicare claims data show that Epogen, Aranesp, Venofer, and Ferrlecit were the most commonly prescribed anemia management drugs in CY 2011. In this report, we refer to the anemia management drugs by their brand names rather than their generic names.

[2] Epoetin alfa is also available under the brand name Procrit. Amgen, the manufacturer of the drug, has the exclusive right to promote and sell epoetin alfa, with the brand name of Epogen, for dialysis use in the United States. Amgen licensed to Johnson & Johnson the exclusive right to promote and sell Procrit for nondialysis use in the United States. Because the scope of this audit includes only dialysis services, Epogen is used to refer to epoetin alfa throughout the report.

Changes to the End-Stage Renal Disease Payment System

Before January 1, 2011, Medicare used a single payment rate to reimburse dialysis facilities for the costs of dialysis treatments and certain routine drugs, laboratory tests, and supplies. In addition, dialysis facilities could receive payments for separately billable injectable drugs, such as ESAs and iron supplements, and nonroutine laboratory tests.

Effective January 1, 2011, the ESRD PPS combined the single payment rate and separate reimbursements for dialysis services into a bundled per-treatment base rate. The CY 2011 base rate for a dialysis treatment was $229.63. Medicare adjusts the base rate for geographic factors, patient characteristics, and facility characteristics to determine the per-treatment payment to dialysis facilities.[3] In addition, dialysis facilities that treat beneficiaries with unusually high resource requirements, measured through the utilization of specific services including ESAs and iron supplements, are entitled to outlier payments—that is, additional payments beyond the otherwise applicable PPS payment amounts. After a beneficiary's Part B deductible[4] is met, Medicare reimburses dialysis facilities 80 percent of the base rate and all applicable adjustments for each dialysis treatment furnished. Beneficiaries are responsible for the remaining 20 percent.

The Act required that estimated total payments under the PPS for 2011 be equal to 98 percent of the estimated total payments for dialysis services, including separately billable drugs, that would have been made if the ESRD PPS had not been implemented (section 1881(b)(14)(A)(ii)). It also required Medicare to use per-patient utilization data from 2007, 2008, or 2009, whichever was lowest, to estimate total 2011 payments. CMS determined that 2007 had the lowest per-patient utilization of dialysis services included in the ESRD PPS payment bundle and, therefore, used 2007 claims data to develop the base rate.

Reimbursement for Anemia Management Drugs in the Base Rate

The PPS payment bundle includes Epogen, Aranesp, Venofer, and Ferrlecit used to treat anemia.[5] We calculated that approximately 25 percent of the CY 2011 base rate represented reimbursement for the ESA drugs Epogen and Aranesp and the iron supplements Venofer and Ferrlecit. For each treatment furnished, we calculated that the base rate included the reimbursement amounts in Table 1 for each of the four drugs.[6] We also calculated the quantities

[3] CMS offered dialysis facilities the option to elect to be reimbursed 100 percent by the bundled ESRD PPS and required facilities to make this election by November 1, 2010. Approximately 87 percent of dialysis facilities elected this option. CMS uses a blended payment rate (during a 4-year transition period) to reimburse each dialysis treatment to facilities that did not elect the bundled ESRD PPS payment. The blended payment rate is composed of (1) the former single payment rate and separate reimbursements and (2) the bundled ESRD PPS payment. In CY 2011, the first year of the transition period, the blended payment rate was 75 percent of the former single payment rate and separate reimbursements and 25 percent of the bundled ESRD PPS payment.

[4] In each CY, a cash deductible must be satisfied before payment is made under Medicare Part B.

[5] The CY 2011 payment bundle also includes calcitriol, doxercalciferol, paricalcitol, levocarnitine, alteplase, vancomycin, and daptomycin (generic drug names).

[6] We used information from the *Federal Register*, Volume 75, No. 155, Aug. 12, 2010.

of the drugs reflected in these reimbursement amounts (Table 1 and Appendix A).

Table 1: Anemia Management Drugs in the Base Rate

Drug	Per-Treatment Reimbursement Included in the Base Rate	Quantity of the Drug Reflected in the Base Rate	Per-Treatment Billing Units Reflected in the Base Rate[7]	Reimbursement per Billing Unit
Epogen	$49.88	5,570.00 units	55.70	$0.896
Aranesp	$3.79	1.39 micrograms	1.39	$2.727
Venofer	$4.23	12.23 milligrams	12.23	$0.346
Ferrlecit	$1.69	4.88 milligrams	0.39	$4.333

The bundled ESRD PPS addresses congressional concerns about Medicare expenditures for separately billable services and the overutilization of ESA drugs by creating an incentive to furnish dialysis services more efficiently. As in any PPS, those providing the services—in this report, dialysis facilities—keep the difference if Medicare payments exceed costs for bundled services, and they are liable for the difference if the costs exceed Medicare payments.

Food and Drug Administration Safety Concerns About Erythropoiesis-Stimulating Agents

FDA first approved Epogen for the treatment of anemia in 1989 and approved Aranesp in 2001. The product labels for these drugs have been updated several times to incorporate new safety information. FDA approved new labeling for both drugs in March 2007 that included a warning that ESAs increased patients' risk for death and serious cardiovascular events when they are dosed to achieve a target hemoglobin of greater than 12 g/dL. FDA-approved labels for Epogen and Aranesp in November 2007 recommended individualized dosing of these drugs to maintain a patient's hemoglobin within a target range of 10 to 12 g/dL.

On June 24, 2011, FDA recommended more conservative dosing of ESAs in patients with chronic kidney disease because of more data showing this population had increased risk of cardiovascular events when using ESAs. For patients with chronic kidney disease on dialysis, the FDA-approved labels for Epogen and Aranesp now recommend that health care professionals initiate ESA treatment when the hemoglobin level is less than 10 g/dL. The FDA-approved labels recommend that if the hemoglobin level approaches or exceeds 11 g/dL, the dose be reduced or interrupted. The recommendation that ESAs be dosed to achieve and maintain a hemoglobin level within the target range of 10 to 12 g/dL has been removed from the label.

Medicare Oversight of Erythropoiesis-Stimulating Agents

Emerging scientific data on the use of ESAs prompted CMS to expand its ESA-monitoring

[7] Dialysis facilities record anemia management drugs on their Medicare claims using the appropriate Healthcare Common Procedure Coding System (HCPCS) code and bill the units of service in multiples of the units shown in the HCPCS narrative description.

policy, effective January 1, 2008.[8] Under this policy, Medicare reduces payment for ESAs by 25 percent if (1) a beneficiary's reported hemoglobin is greater than 13 g/dL (or hematocrit is greater than 39 percent) and (2) the dialysis facility does not indicate on its Medicare claim that it had applied and maintained appropriate dose reductions. Medicare reduces payments for ESAs by 50 percent if a beneficiary's reported hemoglobin exceeds 13 g/dL (or hematocrit exceeds 39 percent) for 3 or more consecutive months.[9]

In addition, medically unlikely edits[10] limit payment for Epogen to a maximum dosage of 400,000 units per month and payment for Aranesp to a maximum dosage of 1,200 micrograms per month.[11] The ESA-monitoring policy does not apply to home dialysis patients who self-administer ESAs.

The Act required that CMS implement an ESRD Quality Incentive Program (QIP) (section 1881(h)). Under the QIP, dialysis facilities that do not meet or exceed established performance measures will be paid up to 2 percent less for their services. The Act also requires that the established performance measures include "measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management …" (section 1881(h)(2)(A)).

Reductions apply to payments for dialysis services furnished on or after January 1, 2012. The anemia management performance measures that determined 2012 payment reductions were the (1) percentage of beneficiaries whose average hemoglobin levels were less than 10 g/dL and (2) percentage of patients whose average hemoglobin levels were greater than 12 g/dL; a lower percentage for each of these measures indicates better performance. These performance measures reflect the November 2007 FDA-approved labeling for ESAs. To have received full payment, dialysis facilities must have met or exceeded the performance standard for each quality measure during the CY 2010 performance period.

Although CMS did not publish the QIP proposed and final regulations until mid-2010 and early-2011 and CMS measured the performance for 2010, the legislation that implemented the

[8] See CMS, "Modification to the National Monitoring Policy for Erythropoietic Stimulating Agents (ESAs) for End-Stage Renal Disease (ESRD) Patients Treated in Renal Dialysis Facilities," *Medicare Claims Processing Manual*, Transmittal 1307 (Change Request 5700; July 20, 2007).

[9] Dialysis facilities are required to report hemoglobin or hematocrit levels for their beneficiaries receiving ESAs on their Medicare claims for payment. See the *Medicare Claims Processing Manual*, Pub. 100-04, ch. 8, §§ 60.4 and 60.7.

[10] Medically unlikely edits identify claims before they are processed by CMS for payment that have ESAs in excess of the maximum dosages and return these claims to providers for correction.

[11] CMS's previous national ESA-monitoring policy, implemented in April 2006, reduced payment for ESAs by 25 percent if a beneficiary's reported hemoglobin was greater than 13 g/dL (or hematocrit was greater than 39 percent) and the dialysis facility did not indicate that the ESA dosage had been reduced and maintained. The medically unlikely edits limited payment for Epogen to a maximum dosage of 500,000 units per month and payment for Aranesp to a maximum dosage of 1,500 micrograms per month.

QIP was enacted in July 2008.[12] Therefore, dialysis facilities could have reasonably expected that 2012 performance measures would have reflected FDA-approved labeling in effect during the CY 2010 performance period.

HOW WE CONDUCTED THIS REVIEW

We used CMS's National Claims History file to identify CY 2011 dialysis treatments reimbursed under the ESRD PPS and grouped those treatments by beneficiary and calendar month (beneficiary-month).[13] Using medical records, we reviewed a stratified random sample of 180 beneficiary-months to determine the number of paid dialysis treatments and the quantities of any Epogen, Aranesp, Venofer, and Ferrlecit administered to the beneficiaries. We used our sample results to estimate (1) the difference between the base rate reimbursement for ESAs and iron supplements and the reimbursement for ESAs and iron supplements actually furnished and (2) the quantities of Epogen, Aranesp, Venofer, and Ferrlecit actually furnished by dialysis facilities in CY 2011 and the number of dialysis treatments furnished by dialysis facilities in CY 2011. Our objective did not require that we identify or review any internal controls or that we determine whether the Medicare payments for the dialysis treatments were appropriate. Our review enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file, but we did not assess the completeness of the file.

Our fieldwork consisted of contacting the dialysis facilities that billed for the beneficiary-months we sampled. We also contacted CMS officials. We conducted our fieldwork from August through October 2012.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix B contains the details of our scope and methodology, Appendix C contains our statistical sampling methodology, Appendix D contains our methodology for determining reimbursement for anemia management drugs, and Appendixes E and F contain our sample results and estimates.

FINDINGS

Using our sample results, we estimated that Medicare and beneficiaries could have saved $510 million for the ESAs Epogen and Aranesp and $19 million for the iron supplements

[12] Section 1881(h) of the Act was added by section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (P.L. No. 110-275), which was enacted on July 15, 2008.

[13] Each hemodialysis treatment was considered a single dialysis treatment. We converted peritoneal dialysis to dialysis treatments by dividing the number of days peritoneal dialysis was billed during a beneficiary-month by 7 and multiplying the result by 3.

Venofer and Ferrlecit during CY 2011 if the ESRD base rate had been adjusted to reflect current utilization of anemia management drugs. During CY 2011, the average per-treatment utilization of these anemia management drugs was generally significantly less than the quantities of these drugs reflected in the base rate.

In addition, through our analysis of the CY 2011 sample items, we identified limitations that CMS should consider when it relies on ESRD claims data for program oversight. These limitations include inaccuracies in the quantities of drugs claimed and the inability to determine the extent of drug waste or overfill usage.

UTILIZATION OF ANEMIA MANAGEMENT DRUGS IN 2011 WAS SIGNIFICANTLY LESS THAN THE UTILIZATION REFLECTED IN THE BASE RATE

Erythropoiesis-Stimulating Agents

The average per-treatment utilization of Epogen and Aranesp was significantly less than the quantities of these drugs reflected in the base rate. We estimated that the average per-treatment utilization of Epogen was 4,342.41 units, 22 percent less than the quantity reflected in the base rate. We estimated that the average per-treatment utilization of Aranesp was 0.529 micrograms, 62 percent less than the quantity reflected in the base rate (Table 2).

Table 2: Erythropoiesis-Stimulating Agents in the Base Rate Compared With Calendar Year 2011 Utilization

Drug	Quantity of the Drug Reflected in the Base Rate	Estimated CY 2011 Average per Treatment Utilization	Difference
Epogen	5,570.00 units	4,342.41 units	(22 percent)
Aranesp	1.39 micrograms	0.529 micrograms	(62 percent)

Using our sample results, we estimated that Medicare and beneficiaries could have saved $510 million during CY 2011 if the ESRD base rate had been adjusted to reflect current utilization of Epogen and Aranesp.

To comply with the Act, CMS developed the base rate using CY 2007 claims and cost report data. However, officials from many of the dialysis facilities in our sample indicated that ESA utilization had decreased since 2007 because of FDA recommendations and new safety warnings for Epogen and Aranesp. Some facilities also cited the ESA-monitoring policy and the QIP, which were designed to prevent overutilization of ESAs and to improve quality of care, as contributing to decreased utilization.

On the basis of our review of the medical records for the 180 sample items, we determined that dialysis facilities furnished ESAs to beneficiaries intravenously for 74 percent of the sample items and subcutaneously for 15 percent of the sample items. For 11 percent of the sample items, beneficiaries did not receive any ESAs.

Iron Supplements

The average per-treatment utilization of Ferrlecit was significantly lower than the quantity reflected in the base rate, even though the average per-treatment utilization of Venofer was higher than the quantity of Venofer reflected in the base rate.

We estimated that the average per-treatment utilization of Ferrlecit was 2.36 milligrams, 51.6 percent less than the quantity reflected in the base rate. We estimated that the average per treatment utilization of Venofer was 13.29 milligrams, 8.7 percent higher than the quantity reflected in the base rate (Table 3).

Table 3: Iron Supplements in the Base Rate Compared With Calendar Year 2011 Utilization

Drug	Quantity of the Drug Reflected in the Base Rate	Estimated CY 2011 Average per Treatment Utilization	Difference
Ferrlecit	4.88 milligrams	2.36 milligrams	(51.6 percent)
Venofer	12.23 milligrams	13.29 milligrams	8.7 percent

Using the results of our sample, we estimated that Medicare and beneficiaries could have saved $19 million during CY 2011 if the ESRD base rate had been adjusted to reflect current utilization of Venofer and Ferrlecit.

Officials from dialysis facilities in our sample indicated that the use of iron supplements varies, depending on clinical practices and patients' response.

MEDICARE END-STAGE RENAL DISEASE CLAIMS DATA HAVE LIMITATIONS THAT COULD IMPACT PROGRAM OVERSIGHT

CMS relies on Medicare claims data to develop new and adjust existing payment systems, to monitor payment systems and implementation of policies, and to calculate Medicare payments to providers. Through our analysis of the CY 2011 sample items, we identified the following limitations that CMS should consider when it relies on ESRD claims data.

Inaccurate Number of Units Administered Reported

The amounts of anemia management drugs billed on Medicare claims did not always match the amounts documented in the medical records. Facility medical records showed that for 8 percent of the sample items from freestanding facilities, the amounts of Epogen, Venofer, or Ferrlecit billed did not match the amounts administered, resulting in a net overstatement of the amounts billed. For 20 percent of the sample items from hospital-based facilities, the amounts of Epogen, Aranesp, or Ferrlecit billed did not match the amounts administered, resulting in a net overstatement of the amounts of Epogen billed and a net understatement of the amounts of Aranesp and Ferrlecit billed.

Drug Waste Cannot Be Determined

When a provider must discard the remainder of a single-use vial or package after administering a dose of a drug to a Medicare beneficiary, Medicare pays for the amount of drug discarded as well as the dose administered, up to the amount of the drug as indicated on the vial. CMS allows Medicare contractors, which process claims for CMS, to decide whether to require providers to use the modifier JW on claims to identify discarded drugs from single-use vials or packages. For example, from a single-use vial labeled to contain 50 billable units of a drug, 25 units are administered to the beneficiary and 25 units are discarded. The 25-unit dose would be billed on 1 claim line, while the discarded 25 units would be billed on another claim line using the JW modifier (*Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 17, § 40). If the modifier is not required, then the total amount of the drug administered and discarded would be billed on one claim line. Although Medicare no longer pays for ESRD drugs separately, use of the JW modifier enables CMS to monitor drug waste and identify issues that may affect Medicare reimbursement, such as changes in packaging that may increase or decrease costs to providers or manipulation of billed drug waste to qualify for outlier payments.

Venofer is available only in single-use vials. None of the eight dialysis facilities in our sample with discarded amounts of Venofer used the JW modifier on their Medicare claims. In all instances, the total amount of the drug administered and discarded was billed on one claim line, and CMS cannot determine from the claims data the extent to which these dialysis facilities actually administered or discarded Venofer.

Overfill Administered Not Disclosed

Manufacturers may intentionally include excess product, or overfill, in drug containers to compensate for product loss during the proper preparation and administration of a drug. However, Medicare payment is based on the amount of drug indicated on the FDA-approved labeling, and providers may not bill Medicare for any overfill administered to patients. In November 2011, CMS advised dialysis facilities that it had incorporated its overfill policy into its ESRD outlier policy and that it would be using the overfill policy to determine blended payments under the ESRD PPS transition. This overfill policy instructs dialysis facilities to report only units and charges for ESRD-related drugs and biologicals actually purchased, as indicated on the FDA-approved labeling.[14] Facilities that do not follow the overfill policy could receive overpayments.

Dialysis facilities for 78 percent of sample items indicated that they used all the available product in a vial when administering drugs to patients. Dialysis facilities in our sample reported the dose of the drugs actually furnished to beneficiaries on their Medicare claims. However, only one chain of dialysis facilities developed a methodology to disclose on its Medicare claims what portion of the dose represented overfill.

[14] 76 Fed. Reg. 70228, 70243-70244 (Nov. 10, 2011).

CONCLUSION

We recognize that CMS faced numerous challenges when developing the bundled ESRD PPS. CMS was required to balance the needs of highly vulnerable beneficiaries with those of the dialysis industry, in which a small number of for-profit companies own the majority of facilities. In addition, to comply with statutory requirements, CMS developed the base rate using utilization data from CY 2007. However, the utilization of anemia management drugs during this year could not have fully reflected the impact of new safety data, changes to Medicare policies and programs to address overutilization of ESAs and quality of care, and the incentive to furnish services more efficiently under the PPS. Further, while ESRD claims data may represent the best information available to develop the base rate and to monitor effects of the PPS, these data have limitations.

We validated ESRD claims data, and our results show that Medicare and beneficiaries could have saved a significant amount if the base rate had been adjusted to reflect CY 2011 utilization of anemia management drugs. These results are consistent with those of a recent Government Accountability Office (GAO) report that examined trends in the utilization of ESRD drugs from 2007 through 2011 using ESRD claims data.[15] In late December 2012, Congress passed legislation requiring that the base rate be reduced to reflect changes in the utilization of ESRD drugs (American Taxpayer Relief Act of 2012, section 632(a)). Preliminary analysis of ESRD claims data indicate that per-treatment utilization of ESAs and iron supplements continued to decline during the first 8 months of CY 2012.

RECOMMENDATIONS

We recommend that CMS:

- adjust the bundled base rate to realize program savings associated with decreased utilization of ESAs and iron supplements;
- remind dialysis facilities of the importance of claims accuracy; and
- develop new policies, procedures, or other guidance for recording drug waste and overfill on ESRD claims.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and described corrective actions it had taken and plans to take.

CMS's comments are included in their entirety as Appendix G.

[15] *End-Stage Renal Disease: Reduction in Drug Utilization Suggests Bundled Payment Is Too High* (GAO-13-190R), December 7, 2012.

APPENDIX A: REIMBURSEMENT FOR ANEMIA MANAGEMENT DRUGS INCLUDED IN THE BASE RATE

To calculate reimbursement for Epogen, Aranesp, Venofer, and Ferrlecit included in the CY 2011 base rate, we followed CMS's methodology for developing the rate.[16]

CMS developed the CY 2011 base rate using CY 2007 Medicare allowable payment amounts for each service included in the ESRD PPS payment bundle, including Epogen, Aranesp, Venofer, and Ferrlecit, as well as the number of CY 2007 dialysis treatments (section 1881(b)(14)(A)(ii) of the Act). The per-treatment base rate represents the sum of the Medicare allowable payments for each service divided by the corresponding number of dialysis treatments.

To determine the CY 2007 Medicare allowable payment per treatment attributable to Epogen, Aranesp, Venofer, and Ferrlecit, we divided each drug's total CY 2007 Medicare allowable payments by the number of CY 2007 dialysis treatments (Table 1).

Table 1: Calendar Year 2007 MedicareAllowable Payments per Treatment

Drug	CY 2007 Total Medicare Allowable Payments[17]	Divided by: CY 2007 Dialysis Treatments[18]	Equals: CY 2007 Average Medicare Allowable Payment per Treatment
Epogen	$1,876,926,573	36,747,662	$51.08
Aranesp	$167,935,970	36,747,662	$4.57
Venofer	$166,219,339	36,747,662	$4.52
Ferrlecit	$68,086,707	36,747,662	$1.85

To arrive at the CY 2011 base rate, CMS adjusted the CY 2007 Medicare allowable payment amounts for each service included in the base rate to reflect estimated CY 2011 prices. In addition, the ESRD PPS had to be 98 percent budget neutral in 2011 (section 1881(b)(14)(A)(ii) of the Act). That is, the estimated total payments for CY 2011 under the PPS must equal 98 percent of the estimated total payments for dialysis services that would have been made if the PPS had not been implemented. CMS applied the following adjustments to the base rate to comply with this requirement:

- a standardization adjustment of 94.07 percent to ensure that total projected PPS payments were equal to estimated total payments for dialysis services that would have been made if the PPS had not been implemented,

- a 99-percent adjustment to ensure that the ESRD PPS outlier policy was budget neutral, and

[16] We did not round the results at each step of our calculations; however, we rounded the amounts in this Appendix for clarity of presentation.

[17] 75 Fed. Reg. 49030, 49068 (Aug. 12, 2010).

[18] 75 Fed. Reg. at 49068.

- a 98-percent adjustment to account for the budget neutrality requirement.

To calculate the Medicare allowable payment (or reimbursement) per treatment for Epogen, Aranesp, Venofer, and Ferrlecit included in the CY 2011 base rate, we applied CMS's adjustments to the CY 2007 average Medicare allowable payment per treatment for each of the four drugs (Table 2).

Table 2: Medicare Allowable Payments per Treatment in the Calendar Year 2011 Base Rate

Drug	CY 2007 Average Medicare Allowable Payment per Treatment	Multiplied by: Adjustment To Reflect Estimated 2011 Prices[19]	Multiplied by: Standardization Adjustment[20]	Multiplied by: Outlier Adjustment[21]	Multiplied by: 98-Percent Budget Neutrality Adjustment[22]	Equals: Medicare Reimbursement per Treatment in CY 2011 Base Rate
Epogen	$51.08	1.070	0.9407	0.99	0.98	$49.88
Aranesp	$4.57	0.910	0.9407	0.99	0.98	$3.79
Venofer	$4.52	1.026	0.9407	0.99	0.98	$4.23
Ferrlecit	$1.85	0.998	0.9407	0.99	0.98	$1.69
Total						**$59.59**

Total reimbursement for the four anemia management drugs ($59.59) is approximately 25 percent of the CY 2011 base rate of $229.63.

Dialysis facilities record anemia management drugs on their Medicare claims using the appropriate HCPCS code and bill the units of service in multiples of the units shown in the HCPCS narrative description. The HCPCS codes and narrative descriptions for Epogen, Aranesp, Venofer, and Ferrlecit are shown below (Table 3).

Table 3: Healthcare Common Procedure Coding System Codes and Narrative Descriptions

Drug	HCPCS	HCPCS Narrative Description
Epogen	Q4081	Injection, epoetin alfa, 100 units
Aranesp	J0882	Injection, darbepoetin alfa, 1 microgram (mcg)
Venofer	J1756	Injection, iron sucrose, 1 milligram (mg)
Ferrlecit	J2916	Injection, sodium ferric gluconate complex in sucrose injection, 12.5 milligrams (mg)

To calculate the quantities of Epogen, Aranesp, Venofer, and Ferrlecit reflected in the base rate, we divided the CY 2007 average Medicare allowable payment per treatment by the average

[19] 75 Fed. Reg. at 49080.

[20] 75 Fed. Reg. at 49081.

[21] 75 Fed. Reg. at 49082.

[22] 75 Fed. Reg. at 49082.

CY 2007 payment for a single HCPCS unit (or billing unit) to determine the number of billing units reflected in the base rate. We multiplied the number of billing units reflected in the base rate by the quantity of the drug indicated in the HCPCS narrative description to calculate the quantity of each drug reflected in the CY 2011 base rate (Table 4).

Table 4: Quantities of Drugs Reflected in the Base Rate

Drug	CY 2007 Average Medicare Allowable Payment per Treatment	Divided by: CY 2007 Average Payment for a Single Billing Unit[23]	Equals: Number of Billing Units Reflected in the Base Rate	Multiplied by: Quantity of Drug in HCPCS Description	Equals: Quantity of Drug Reflected in the Base Rate
Epogen	$51.08	$0.9170	55.70	100 units	5,570 units
Aranesp	$4.57	$3.2900	1.39	1 mcg	1.39 mcg
Venofer	$4.52	$0.3697	12.23	1 mg	12.23 mg
Ferrlecit	$1.85	$4.7578	0.39	12.5 mg	4.88 mg

We calculated each drug's reimbursement per billing unit in the CY 2011 base rate by dividing the Medicare allowable payment per treatment included in the CY 2011 base rate by the number of billing units reflected in the base rate (Table 5).

Table 5: Reimbursement per Billing Unit in the Calendar Year 2011 Base Rate

Drug	Medicare Reimbursement per Treatment in CY 2011 Base Rate	Divided by: Number of Billing Units Reflected in the CY 2011 Base Rate	Equals: Reimbursement per Billing Unit
Epogen	$49.88	55.70	$0.896
Aranesp	$3.79	1.39	$2.727
Venofer	$4.23	12.23	$0.346
Ferrlecit	$1.69	0.39	$4.333

[23] In CY 2007, Medicare paid dialysis facilities 106 percent of the appropriate average sales price (ASP) for each separately billable drug furnished. CY 2007 quarterly ASP payment limits are available online at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/01b_2007aspfiles.html. Accessed November 9, 2012.

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our nationwide audit covered 3,070,158 beneficiary-months with 37,279,226 dialysis treatments valued at $9,031,065,241.[24] Our objective did not require that we identify or review any internal controls or that we determine whether the Medicare payments for the dialysis treatments were appropriate. Our objective also did not require that we determine dialysis facilities' acquisition costs for anemia management drugs. The Office of Inspector General is conducting a separate evaluation of acquisition costs for ESRD drugs included in the PPS payment bundle. Our review enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file, but we did not assess the completeness of the file.

Our fieldwork consisted of contacting the dialysis facilities that billed for the beneficiary-months we sampled and contacting CMS officials. We conducted our fieldwork from August through October 2012.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials;
- held discussions with GAO staff regarding their legislatively mandated analysis of changes in ESA utilization under the ESRD PPS that was required by the Medicare Improvements for Patients and Providers Act of 2008 (section 153(d)(1));
- used CMS's National Claims History file to identify CY 2011 dialysis treatments reimbursed under the ESRD PPS and grouped those treatments by beneficiary-months;
- identified 2 strata from which we selected our sample items (stratum 1 contained 2,889,908 beneficiary-months with dialysis treatments furnished by freestanding facilities, and stratum 2 contained 180,250 beneficiary-months with dialysis treatments furnished by hospital-based facilities);
- selected a stratified random sample of 180 beneficiary-months: 150 from stratum 1 and 30 from stratum 2 (Appendix C);
- contacted officials from 179 dialysis facilities that billed for dialysis treatments furnished during the 180 sampled beneficiary-months and obtained payment and medical records to

[24] Each hemodialysis treatment was considered a single dialysis treatment. We converted peritoneal dialysis to dialysis treatments by dividing the number of days peritoneal dialysis was billed during a beneficiary-month by 7 and multiplying the result by 3.

validate the number of paid treatments and the dosages of any Epogen, Aranesp, Venofer, and Ferrlecit administered to the beneficiaries;

- calculated the amount that the dialysis facilities were reimbursed under the base rate for ESAs and iron supplements on the basis of the number of paid dialysis treatments for each of the sample items (Appendix D);

- calculated reimbursement for ESAs and iron supplements that dialysis facilities actually furnished on the basis of the medical records for each sample item[25] (Appendix D);

- used our sample results to (1) estimate the difference between the base rate reimbursement for ESAs and iron supplements and the reimbursement for ESAs and iron supplements actually furnished and (2) estimate the quantities of Epogen, Aranesp, Venofer, and Ferrlecit furnished by dialysis facilities in CY 2011 and the number of dialysis treatments furnished by dialysis facilities in CY 2011 (Appendix E);

- discussed the results of our review with CMS officials; and

- briefed staff members of the House of Representatives Ways and Means Health Subcommittee, at their request, about this audit.[26]

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[25] Amounts actually furnished include the dose of drug administered and the amount of drug discarded (if any) from a single-use vial, up to the amount of the drug as indicated on the vial used.

[26] Because our report had not been issued to CMS for formal comment, we could not discuss specific information concerning our findings and recommendations. However, we did indicate to Subcommittee staff that our findings were consistent with a recommendation to rebase the base rate.

APPENDIX C: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consisted of nationwide Medicare outpatient dialysis claims for CY 2011.

SAMPLING FRAME

The sampling frame was an Access database of 3,070,158 beneficiary-months that contained 37,279,226 dialysis treatments[27] with payments totaling $9,031,065,241. Each beneficiary-month met the following conditions:

- contained treatments furnished only by providers being 100-percent reimbursed under the ESRD PPS;
- contained treatments furnished by only 1 type of dialysis facility, either hospital based or freestanding;
- contained treatments furnished by no more than 2 different dialysis facilities; and
- contained between 3 and 14 dialysis treatments (inclusive).

SAMPLE UNIT

The sample unit was a beneficiary-month.

SAMPLE DESIGN

Our sample design was a stratified random sample with the following two strata:

Stratum	Type of Dialysis Facility	Number of Beneficiary-Months	Medicare- and Beneficiary-Paid Amount for Dialysis Treatments	Number of Dialysis Treatments
1	Freestanding	2,889,908	$8,485,861,648	35,074,831
2	Hospital Based	180,250	545,203,593	2,204,395
Total		**3,070,158**	**$9,031,065,241**	**37,279,226**

[27] Each hemodialysis treatment was considered a single dialysis treatment. We converted peritoneal dialysis to dialysis treatments by dividing the number of days peritoneal dialysis was billed during a beneficiary-month by 7 and multiplying the result by 3.

SAMPLE SIZE

We randomly selected 150 beneficiary-months from stratum 1 and 30 beneficiary-months from stratum 2. Our total sample size was 180 beneficiary-months.

SOURCE OF RANDOM NUMBERS

We used the Office of Inspector General, Office of Audit Services (OAS), statistical software to generate the random numbers for each stratum.

METHOD OF SELECTING SAMPLE UNITS

We consecutively numbered the sample units in each stratum. After generating 150 random numbers for stratum 1 and 30 random numbers for stratum 2, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate (1) the dollar value of potential cost savings for reimbursement of ESAs and iron supplements furnished by dialysis facilities in CY 2011 and (2) the quantity of billing units of Epogen, Aranesp, Venofer, and Ferrlecit furnished in CY 2011 and the number of dialysis treatments furnished by dialysis facilities in CY 2011. We used the estimates of billing units and treatments to estimate the average quantity of billing units of each drug furnished per dialysis treatment.

APPENDIX D: METHODOLOGY FOR DETERMINING REIMBURSEMENT

REIMBURSEMENT UNDER THE BASE RATE

For each sample item, we determined the number of paid dialysis treatments from the dialysis facility's payment records. We multiplied the number of paid treatments by the Medicare reimbursement per treatment in the CY 2011 base rate (Appendix A) for each drug to calculate the dialysis facility's reimbursement for ESAs and iron supplements under the base rate.

For example, if a sample item represented 13 paid dialysis treatments, we calculated ESA and iron supplement reimbursement under the base rate as follows:

Drug	Sample Item Paid Treatments	Multiplied by: Medicare Reimbursement per Treatment in CY 2011 Base Rate	Equals: Reimbursement Under the Base Rate
Epogen	13	$49.88	$648.44
Aranesp	13	$3.79	$49.27
ESA Reimbursement			**$697.71**
Venofer	13	$4.23	$54.99
Ferrlecit	13	$1.69	$21.97
Iron Supplement Reimbursement			**$76.96**

REIMBURSEMENT FOR DRUGS ACTUALLY FURNISHED

For each sample item, we determined the number of billing units of Epogen, Aranesp, Venofer, and Ferrlecit actually furnished to the beneficiary using the dialysis facility's medical records.[28] We multiplied the number of billing units of each drug that were actually furnished by the reimbursement per billing unit in the CY 2011 base rate (Appendix A) to calculate the dialysis facility's reimbursement for ESAs and iron supplements actually furnished.

For example, if the medical records for a sample item indicated that the patient received 650 billing units of Epogen and 200 billing units of Venofer, we calculated reimbursement for the ESAs and iron supplements actually furnished as follows:

[28] Amounts actually furnished include the dose of drug administered and the amount of drug discarded (if any) from a single-use vial, up to the amount of the drug as indicated on the vial used.

Drug	Billing Units Furnished	Multiplied by: Medicare Reimbursement per Billing Unit in CY 2011 Base Rate	Equals: Reimbursement For Billing Units Furnished
Epogen	650	$0.896	$582.40
Aranesp	0	$2.727	$0.00
ESA Reimbursement			**$582.40**
Venofer	200	$0.346	$69.20
Ferrlecit	0	$4.333	$0.00
Iron Supplement Reimbursement			**$69.20**

APPENDIX E: SAMPLE RESULTS AND ESTIMATES OF COST SAVINGS

Erythropoiesis-Stimulating Agents
Sample Results

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Reimbursement Differences	Value of Reimbursement Differences
1	2,889,908	$8,485,861,648	150	$100,608	150	$25,022
2	180,250	545,203,593	30	19,613	30	4,704
Total	**3,070,158**	**$9,031,065,241**	**180**	**$120,221**	**180**	**$29,726**

Estimated Cost Savings
(Limits Calculated for a 90-Percent Confidence Level)

Point Estimate	$510,329,453
Lower Limit	$260,234,832
Upper Limit	$760,424,073

Iron Supplements
Sample Results

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Reimbursement Differences	Value of Reimbursement Differences
1	2,889,908	$8,485,861,648	150	$11,097	150	$723
2	180,250	545,203,593	30	2,163	30	895
Total	**3,070,158**	**$9,031,065,241**	**180**	**$13,260**	**180**	**$1,618**

Estimated Cost Savings
(Limits Calculated for a 90-Percent Confidence Level)

Point Estimate	$19,315,597
Lower Limit	($11,198,547)
Upper Limit	$49,829,742

APPENDIX F: ESTIMATES OF DIALYSIS TREATMENTS PAID AND UNITS OF DRUGS FURNISHED

DIALYSIS TREATMENTS PAID

Stratum	Frame Size	Sample Size	Number of Treatments
1	2,889,908	150	1,875
2	180,250	30	365
Total	**3,070,158**	**180**	**2,240**

Estimated Treatments Paid

Point Estimate 38,311,203

ARANESP

Stratum	Frame Size	Sample Size	Number of Units
1	2,889,908	150	25
2	180,250	30	3,290
Total	**3,070,158**	**180**	**3,315**

Estimated Units of Aranesp Furnished

Point Estimate 20,249,068

EPOGEN

Stratum	Frame Size	Sample Size	Number of Units
1	2,889,908	150	84,284
2	180,250	30	6,626
Total	**3,070,158**	**180**	**90,910**

Estimated Units of Epogen Furnished

Point Estimate 1,663,631,256

FERRLECIT

Stratum	Frame Size	Sample Size	Number of Units
1	2,889,908	150	330
2	180,250	30	145
Total	**3,070,158**	**180**	**475**

Estimated Units of Ferrlecit Furnished

Point Estimate 7,229,006

VENOFER

Stratum	Frame Size	Sample Size	Number of Units
1	2,889,908	150	25,850
2	180,250	30	1,850
Total	**3,070,158**	**180**	**27,700**

Estimated Units of Venofer Furnished

Point Estimate 509,142,895

ESTIMATES OF UNITS OF DRUGS FURNISHED PER DIALYSIS TREATMENT

	Aranesp	Epogen	Ferrlecit	Venofer
Estimated Billing Units	20,249,068	1,663,631,256	7,229,006	509,142,895
Divide Units by: Estimated Treatments	38,311,203	38,311,203	38,311,203	38,311,203
Equals Estimated Billing Units per Treatment	0.529	43.424	0.189	13.29
Multiply by: HCPCS Billing Unit	1 microgram	100 units	12.5 milligrams	1 milligram
Equals Estimated Average per Treatment Utilization	0.529 micrograms	4342.41 units	2.36 milligrams	13.29 milligrams

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: APR - 4 2013

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare and Beneficiaries Could Save Millions If Dialysis Payments Were Adjusted for Anemia Management Drug Utilization (A-01-12-00522)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on this OIG Draft Report. The objective of this study was to determine the potential cost savings to Medicare and beneficiaries of adjusting, or rebasing, the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) base rate to reflect calendar year (CY) 2011 utilization of anemia management drugs Epogen, Aranesp, Venofer and Ferrlecit. OIG's report estimates that Medicare and beneficiaries could have saved $510 million for the Erythropoiesis-stimulating agents (ESAs), Epogen, and Aranesp, and $19 million for the iron supplements Venofer and Ferrlecit during calendar year (CY) 2011 if the ESRD PPS base rate had been adjusted to reflect current utilization of anemia management drugs. Additionally, OIG's analysis of the sample claims in CY 2011 identified inaccuracies in the quantities of drugs claimed and noted an inability to determine the extent of drug waste or overfill usage. CMS appreciates OIG's efforts in working with us to help identify potential vulnerabilities in our payment systems, as well as billing issues and associated coding errors. CMS's responses to OIG's recommendations are discussed below.

Recommendation 1

The OIG recommends that CMS adjust the bundled base rate to realize program savings associated with decreased utilization of ESAs and iron supplements.

CMS Response

The CMS concurs with this recommendation. Section 632 of the American Taxpayer Relief Act of 2012 requires the Secretary to reduce the single payment amount for ESRD services beginning in 2014 based on the Secretary's estimate of the changes in utilization of drugs and biologicals from 2007 to 2012. CMS will be completing its analysis and providing a proposal for public comment in the CY 2014 ESRD PPS proposed rule that specifically addresses this issue.

Recommendation 2

The OIG recommends that CMS remind dialysis facilities of the importance of claims accuracy.

CMS Response

The CMS concurs with the recommendation. In the CY 2012 ESRD PPS final rule (76 FR 70244), we noted that the same policy for billing of Part B drugs applies under the ESRD PPS. ESRD facilities may only report units and charges for drugs and biologicals actually purchased. Additionally, CMS is in the process of updating the Internet Only Manuals: Pub. 100-02, Medicare Benefit Policy Manual, Chapter 11, End Stage Renal Disease (ESRD), to reflect the new ESRD PPS. Section 20.3 of this manual will mirror the CY 2012 ESRD PPS final rule by reiterating that Medicare will not pay for additional medications (or intentional overfill) in drug containers provided at no cost to the ESRD facility, and that ESRD facilities may not receive additional payment under the ESRD PPS when they furnish drug overfill to Medicare beneficiaries. Furthermore, CMS will provide additional educational guidance reminding ESRD facilities of the importance of submitting accurate claims.

Recommendation 3

The OIG recommends that CMS develop new policies, procedures, or other guidance for recording drug waste and overfill on ESRD claims.

CMS Response

The CMS concurs with this recommendation. While it may not be feasible to include non-paid items on the ESRD PPS claims, CMS concurs with the importance of providing guidance to providers, specifically ESRD facilities, and developing policies on the importance of claims accuracy. CMS will also consider ways to capture this data. As mentioned above in CMS's response to OIG's second recommendation, CMS is in the process of updating Pub. 100-02, Medicare Benefit Policy Manual, Chapter 11, ESRD, to reflect the new ESRD PPS, including stating that Medicare will not pay for additional medications in drug containers provided at no cost to the ESRD facility, and that ESRD facilities may not receive additional payment under the ESRD PPS when they furnish drug overfill to Medicare beneficiaries. Again, CMS will provide additional educational outreach to ESRD facilities, on the importance of submitting accurate claims.

The CMS thanks OIG for the work done on this issue and looks forward to working on this and other issues in the future.