GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

December 7, 2012

Congressional Committees

Subject: *End-Stage Renal Disease: Reduction in Drug Utilization Suggests Bundled Payment Is Too High*

Most individuals with end-stage renal disease (ESRD)—a condition of permanent kidney failure—are eligible for Medicare regardless of their age.[1] The most common treatment for individuals with ESRD is dialysis, which removes excess fluids and toxins from the bloodstream. In 2011, Medicare spent about $10.1 billion on dialysis care (including beneficiary cost sharing) for about 365,000 beneficiaries.[2]

The Centers for Medicare & Medicaid Services (CMS), the agency within the Department of Health and Human Services (HHS) that administers the Medicare program, recently changed the way Medicare pays for dialysis care, as required by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).[3] Prior to 2011, Medicare paid dialysis facilities a single rate for providing a dialysis treatment and certain related items and services, which is a common form of Medicare payment known as bundling. Medicare paid separately for certain other dialysis-related items and services that were not covered under the bundled payment, such as injectable drugs used to treat complications associated with ESRD. Effective January 1, 2011, the bundled payment for dialysis care was expanded to include payment for items and services such as injectable ESRD drugs and their oral equivalents for which Medicare previously had paid separately.[4]

[1]Medicare coverage generally begins in the fourth month after patients start dialysis. For individuals who have employer group coverage, Medicare is the secondary payer for the first 30 months of Medicare entitlement, after which Medicare becomes the primary payer. 42 U.S.C. § 1395y(b)(1)(C). Most individuals diagnosed with ESRD are eligible to receive Medicare benefits under Medicare Part A, Part B, and Part D. 42 U.S.C. §§ 426-1, 1395w-101(a)(3)(A). Medicare Part A covers inpatient hospital, skilled nursing facility, and hospice care, as well as some home health care, and generally does not require a monthly premium. Medicare Part B covers outpatient dialysis treatment, injectable ESRD drugs, certain oral ESRD drugs, physician services, hospital outpatient services, and certain other services, such as physical therapy. Beneficiaries enrolled in Part B are required to pay a monthly premium. To receive most Part B-covered services, beneficiaries are required to meet an annual deductible and typically pay 20 percent coinsurance. Medicare Part D covers outpatient prescription drugs and generally requires payment of a monthly premium, meeting an annual deductible, and paying part of the cost associated with each prescription.

[2]Medicare expenditure amounts throughout this report include beneficiary cost sharing.

[3]Pub. L. No. 110-275, 122 Stat. 2494.

[4]See 75 *Fed. Reg.* 49030, 49197 (Aug. 12, 2010) (to be codified at 42 C.F.R. §§ 413.171 et seq.). Effective January 1, 2014, the bundled payment will be expanded again to include payment for certain oral, dialysis-related drugs that do not have injectable equivalents. These drugs currently are covered under Medicare Part D.

Pursuant to MIPPA, CMS based the new bundled payment rate on the utilization of dialysis and related items and services, such as ESRD drugs, in 2007.[5] Although MIPPA did not explicitly authorize CMS to further recalculate this rate—referred to as rebasing the payment rate—to account for changes over time in the utilization of dialysis and related items and services, such as ESRD drugs, beginning in 2012 CMS is required to annually increase the bundled payment amount to account for changes in the prices of bundled items and services and for changes in productivity.[6] Accordingly, CMS increased the 2011 bundled rate by 2.1 percent for 2012 and will increase the rate by 2.3 percent for 2013.[7]

Implementation of the new bundled payment system was consistent with our 2006 recommendation that the bundled payment be expanded to include payment for all ESRD services to improve efficiency and remove financial incentives to provide more injectable drugs than necessary.[8] We and others have emphasized that, when CMS makes such payment changes, it is important for the bundled payment rate to accurately reflect the expected costs of beneficiaries' care to help ensure that any improvements in efficiency are not realized at the expense of beneficiaries' access to and quality of care.[9]

MIPPA required us to report on, among other things, trends in the utilization of ESRD drugs.[10] As discussed with the committees of jurisdiction, this report examines trends in the utilization of ESRD drugs from 2007 through 2011 and the implications of these trends for the accuracy of the bundled payment rate. To determine trends in ESRD drug utilization, we analyzed claims for Medicare Part B payments to dialysis facilities for those years and 2012. We focused our analysis on three types of

[5]MIPPA required CMS to calculate the bundled payment rate to reflect the utilization level per patient of dialysis and related items and services in 2007, 2008, or 2009, whichever year had the lowest utilization per beneficiary. See Pub. L. No. 110-275, § 153(b), 122 Stat. 2553 (relevant provision codified at 42 U.S.C. § 1395rr(b)(14)(A)(ii)). CMS determined that utilization per patient was lowest in 2007.

[6]CMS is required to provide for annual increases in the bundled payment on the basis of the changes in price relative to the previous year for a market basket of an appropriate mix of dialysis-related items and services, with each such increase subject to reductions to account for productivity improvements. Reducing the annual increase to account for productivity improvements could cause payment rates for a year to be less than such payment rates for the preceding year. Pub. L. No. 110-275, § 153(b), 122 Stat. 2553 (as amended by Pub. L. No. 111-148, § 3401(h), 124 Stat. 119, 485 (2010)) (relevant provision codified at 42 U.S.C. § 1395rr(b)(14)(F)(i)).

[7]For 2012 payments: See preamble I.B.2.b., 76 *Fed. Reg.* 70,228, 70,232 (Nov. 10, 2011); for 2013 payments: see preamble II.C.3.d., 77 *Fed. Reg.* 67,450, 67,457 (Nov. 9, 2012).

[8]See 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 (Washington, D.C.: Nov. 13, 2006).

[9]See, for example, GAO, *End-Stage Renal Disease: CMS Should Assess Adequacy of Payment When Certain Oral Drugs Are Included and Ensure Availability of Quality Monitoring Data*, GAO-11-365 (Washington, D.C.: Mar. 23, 2011) and *End-Stage Renal Disease: CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System*, GAO-10-295 (Washington, D.C.: Mar. 31, 2010); and Joseph P. Newhouse, Melinda Beeuwkes Buntin, and John D. Chapman, "Risk Adjustment and Medicare: Taking a Closer Look," *Health Affairs*, vol. 16, no. 5 (1997).

[10]Pub. L. No. 110-275, § 153(d), 122 Stat. 2559. MIPPA also required us to report on the payment adjustment that Medicare provides to facilities that provide a low volume of dialysis treatments. We will provide this information in a future report.

drugs—erythropoiesis stimulating agents (ESA), intravenous (IV) iron, and IV vitamin D—that were incorporated into the bundled payment in 2011. ESAs, which consist primarily of epoetin alfa (brand name Epogen®), accounted for about 73 percent (approximately $2.2 billion) of Medicare expenditures on ESRD drugs in 2010, and the three types of drugs combined accounted for about 96 percent of ESRD drug expenditures in that year.[11] To measure utilization across multiple drugs that may differ in their dosage, we expressed utilization in dollars by multiplying the number of units of a drug administered by the price that Medicare paid for these drugs in the first quarter of 2011.[12] To measure changes in utilization, we calculated the percentage difference between utilization in a given quarter and its average level in 2007 and presented these results by drug type and for the three types of drugs combined. We also determined the extent to which utilization trends were driven by changes in the percentage of beneficiaries who received a given drug compared with changes in utilization per beneficiary who received it. To estimate how Medicare expenditures on dialysis in 2011 would have differed if the bundled rate was rebased to reflect the average 2011 drug utilization level, we first multiplied total Medicare expenditures for dialysis services in 2011 by the percentage of the bundled rate attributable to ESRD drugs.[13] We multiplied the resulting amount by the percentage change between 2007 and 2011 in the average ESRD drug utilization level. We did not evaluate the impact on Medicare expenditures of changes in the utilization of bundled items and services other than the types of ESRD drugs in our analysis. We also did not address how the expansion of the bundled payment beginning in 2014 to include certain ESRD drugs that do not have injectable equivalents could affect

[11]There are three types of ESAs—epoetin alfa, darbepoetin alfa (brand name Aranesp®), and peginesatide (brand name Omontys®). In 2010, Epogen accounted for 93 percent of Medicare expenditures on ESAs, and Aranesp accounted for the remaining 7 percent. Epogen and Aranesp are produced by a single manufacturer—Amgen Inc.—and the patents for these drugs are set to expire by May 2015 and May 2024, respectively. Omontys was approved in 2012 by FDA to treat anemia for dialysis patients with chronic kidney disease.

[12]If Medicare's price—referred to as the Average Sales Price (ASP)—for the first quarter of 2011 was unavailable, we used the most recent available ASP in our calculations. CMS has noted that there are some situations in which a manufacturer intentionally includes an amount of a drug in addition to the amount indicated on the drug label—called drug overfill. This overfill amount is supplied at no extra charge to the provider and is intended to compensate for product loss during the proper preparation and administration of a drug. CMS indicated that it is inappropriate for providers to bill Medicare for overfill amounts and that such billing does not occur routinely. However, to the extent that Medicare paid for overfill amounts, we included such amounts when calculating utilization.

[13]Dialysis facilities had the option to be excluded from a 4-year phase-in of the new bundled payment system, and about 87 percent of facilities elected to do so, thereby receiving all of their payments under the new system beginning in 2011. For the remaining 13 percent of facilities, a quarter of their payment rate in 2011 was based on the new bundled payment system while the remainder of their payment rate was based on the payment system that existed previously. As a result, in our calculation of total expenditures for this estimate, we included one quarter of expenditures associated with these facilities. The percentage (30.55 percent) of the bundled payment associated with the three types of drugs in our analysis is based on the Medicare expenditure amounts per treatment for individual items and services in the bundle that CMS presented in its final rule for the new bundled payment system. See 75 *Fed. Reg.* 49,075 (Aug. 12, 2010).

the accuracy of the bundled payment.[14] We assessed the reliability of the Medicare claims data we analyzed by interviewing CMS officials knowledgeable about these data, reviewing relevant documentation, comparing our results to published sources, and examining the data for obvious errors. We determined that the data were sufficiently reliable for the purposes of our study. To help interpret trends in ESRD drug utilization and gain insight into the associated effect on beneficiaries, we interviewed ESRD clinical experts from the American Society of Nephrology, Renal Physicians Association, and National Kidney Foundation, and reviewed studies on recent trends.

We conducted this performance audit from May 2012 through December 2012 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.

Results in Brief

Utilization of ESRD drugs in 2011 was about 23 percent lower, on average, than it was in 2007, driven largely by a decline in the utilization of ESAs. As a result, Medicare may have paid more than necessary for dialysis care in 2011 because the bundled payment rate in that year was based on 2007 utilization levels. We estimated that Medicare expenditures on dialysis would have been about $650 million to $880 million lower in 2011 if the bundled payment rate were rebased to reflect the 2011 utilization level of ESRD drugs. Furthermore, this estimate of potential savings could be larger in future years if the level of ESRD drug utilization at the end of 2011 declines further, as preliminary data suggest. Rebasing the bundled payment rate to account for changes in ESRD drug utilization could help ensure that Medicare pays appropriately for dialysis services and also yield savings to Medicare. However, CMS officials indicated that they did not have immediate plans to rebase the rate and that the statute does not provide CMS with explicit authority to do so. Therefore, Congress should consider requiring the Secretary of HHS to rebase the ESRD bundled payment rate as soon as possible and on a periodic basis thereafter, using the most current available data.

Background

Treatment options for ESRD include kidney transplantation and dialysis.[15] Kidney transplants on a wide scale are not a practical option, as suitable donated organs are scarce. In contrast, dialysis is the treatment used by most beneficiaries with ESRD. Hemodialysis, during which a machine pumps blood through an artificial

[14]We previously recommended that CMS assess the adequacy of the bundled payment when the agency expands the payment to incorporate payments for oral ESRD drugs without injectable equivalents effective January 1, 2014, and CMS agreed with this recommendation. See GAO-11-365. CMS officials stated that they had not determined the methodology they will use to incorporate payments for these drugs into the bundled payment.

[15]ESRD is the last of five stages of chronic kidney disease. Chronic kidney disease is typically observed as a gradual decline in kidney function.

kidney and returns the cleansed blood to the body, is the most common form of dialysis. It is generally administered three times a week at facilities that provide these services.[16]

Complications associated with ESRD include anemia and mineral and bone disorder. Anemia is a condition in which an insufficient number of red blood cells is available to carry oxygen throughout the body. A diagnosis of anemia is determined by measuring the hemoglobin level in the blood—expressed in grams per deciliter (g/dL) of blood.[17] To treat anemia, providers may administer ESAs in conjunction with IV iron.[18] ESAs typically are administered intravenously but also may be administered subcutaneously, that is, through an injection under the skin.[19] Prior to June 24, 2011, the Food and Drug Administration (FDA) had recommended that ESAs be dosed to achieve and maintain hemoglobin levels within a target range of 10 to 12 g/dL. However, as of June 24, 2011, the FDA no longer recommends a target range for hemoglobin when dosing ESAs because clinical evidence indicates that hemoglobin targets above 11 are associated with increased risk of outcomes such as heart attack and stroke.[20] Instead, the FDA now recommends that providers use the lowest dose of ESAs sufficient to reduce the need for red blood cell transfusions, which can limit beneficiaries' access to and success of kidney transplants and have other adverse effects. Mineral and bone disorder is a complication of ESRD that can result in a variety of clinical conditions in dialysis patients, including bone fractures and cardiovascular disease. Treatment of mineral and bone disorder includes the administration of drugs such as IV vitamin D.[21]

CMS promotes and monitors the quality of anemia management and other aspects of dialysis care through initiatives such as the Quality Incentive Program (QIP). CMS implemented the QIP beginning on January 1, 2012, as required by MIPPA.[22] In 2012, Medicare reduced dialysis facilities' payments by up to 2 percent on the basis of the facilities' performance in 2010. CMS measured facility performance by the

[16]About 91 percent of dialysis patients in 2010 received hemodialysis in facilities that offer this service. Patients also can receive hemodialysis in their home, but only about 1 percent of all dialysis patients did so in 2010. Peritoneal dialysis is the other treatment method and generally occurs in the home. This type of dialysis utilizes the peritoneal membrane, which surrounds the patient's abdomen, as a natural blood filter. About 7 percent of dialysis patients in 2010 received peritoneal dialysis.

[17]Hemoglobin is a protein in red blood cells that carries oxygen.

[18]Iron is most commonly administered intravenously, but it also can be given orally.

[19]The subcutaneous method requires less epoetin than intravenous administration. See James S. Kaufman et al., "Subcutaneous Compared with Intravenous Epoetin in Patients Receiving Hemodialysis," *The New England Journal of Medicine*, vol. 339, no. 9 (1998).

[20]See Marc A. Pfeffer et al., "A Trial of Darbepoetin Alfa in Type 2 Diabetes and Chronic Kidney Disease," *The New England Journal of Medicine*, vol. 361 no. 21 (2009); Ajay K. Singh et al., "Correction of Anemia with Epoetin Alfa in Chronic Kidney Disease," *The New England Journal of Medicine*, vol. 355 no. 20 (2006); and Anatole Besarab et al., "The Effects of Normal as Compared with Low Hematocrit Values in Patients with Cardiac Disease Who Are Receiving Hemodialysis and Epoetin," *The New England Journal of Medicine*, vol. 339 no. 9 (1998).

[21]For this report, vitamin D refers to the active form of this vitamin, which generally is not available without a prescription. Vitamin D generally is administered intravenously, although a small number of patients—usually those who receive dialysis in their home—are treated with the oral form of the drug. The inactive form of vitamin D is available over the counter in the form of a dietary supplement.

[22]See Pub. L. No. 110-275, § 153(c), 122 Stat. 2556 (codified at 42 U.S.C. § 1395rr(h)).

percentages of beneficiaries who (1) had a hemoglobin level less than 10 g/dL; (2) had a hemoglobin level greater than 12 g/dL; and (3) received adequate dialysis.[23] For the QIP in 2013, CMS, consistent with the FDA's June 2011 recommendation, removed the measure indicating the percentage of beneficiaries who had a hemoglobin level less than 10 g/dL, and retained the remaining two measures. The Medicare Payment Advisory Commission (MedPAC) has expressed concern that, with the removal from the QIP of the measure indicating low hemoglobin levels, neither the 2013 QIP nor the new bundled payment system would hold dialysis facilities accountable for adverse outcomes, such as blood transfusions, associated with low hemoglobin levels.[24] CMS also promotes and monitors quality in ways other than the QIP. For example, CMS monitors outcomes such as the incidence of blood transfusions and stroke under the new bundled payment system and monitors and promotes the quality of dialysis care through regional private organizations called the ESRD Networks.[25]

ESRD Drug Utilization Declined Substantially from 2007 through 2011, Suggesting Bundled Rate Is Too High

In the final quarter of 2011, the utilization levels for ESRD drugs overall, and for the individual types of drugs in our analysis, were lower than in 2007, although utilization trends for individual drug types varied. In the final quarter of 2011, the utilization of ESRD drugs overall was about 31 percent below the average for all of 2007 (see fig. 1). The utilization trend for ESRD drugs overall is driven by ESA utilization. These trends generally were stable from 2007 through the middle of 2009, when CMS issued the proposed rule for the design and implementation of the new bundled payment system,[26] and declined gradually until the third quarter of 2010.[27] Following the third quarter of 2010, when CMS issued the final rule for the payment system, the decline accelerated sharply and continued after the FDA recommended more conservative dosing of ESAs in June 2011.[28] Utilization of IV iron in the final quarter of 2011 was about 9 percent below its average 2007 level. However, utilization increased after CMS issued the final rule, then declined in late 2011 after the FDA issued its ESA dosing recommendation. For IV vitamin D, utilization in the

[23]Lower percentages of both hemoglobin measures indicate better care. CMS defined adequate dialysis as having a urea reduction ratio (URR) of 65 percent or greater; a higher percentage for this measure indicates better care.

[24]MedPAC pointed out that, because blood transfusions are not included in the bundled payment, the payment system could create an incentive for some dialysis facilities to treat anemia with blood transfusions. MedPAC also stated that it was important to include measures that assess the adverse consequences of anemia under-treatment to help ensure that beneficiaries continue to have access to care for anemia management that is effective and appropriate. See Glenn M. Hackbarth, Chairman of the Medicare Payment Advisory Commission, to Donald M. Berwick, Administrator of CMS, Washington, D.C., August 30, 2011.

[25]These organizations are responsible for monitoring and promoting the quality of dialysis care in a specific geographic area, which generally consists of one or more states.

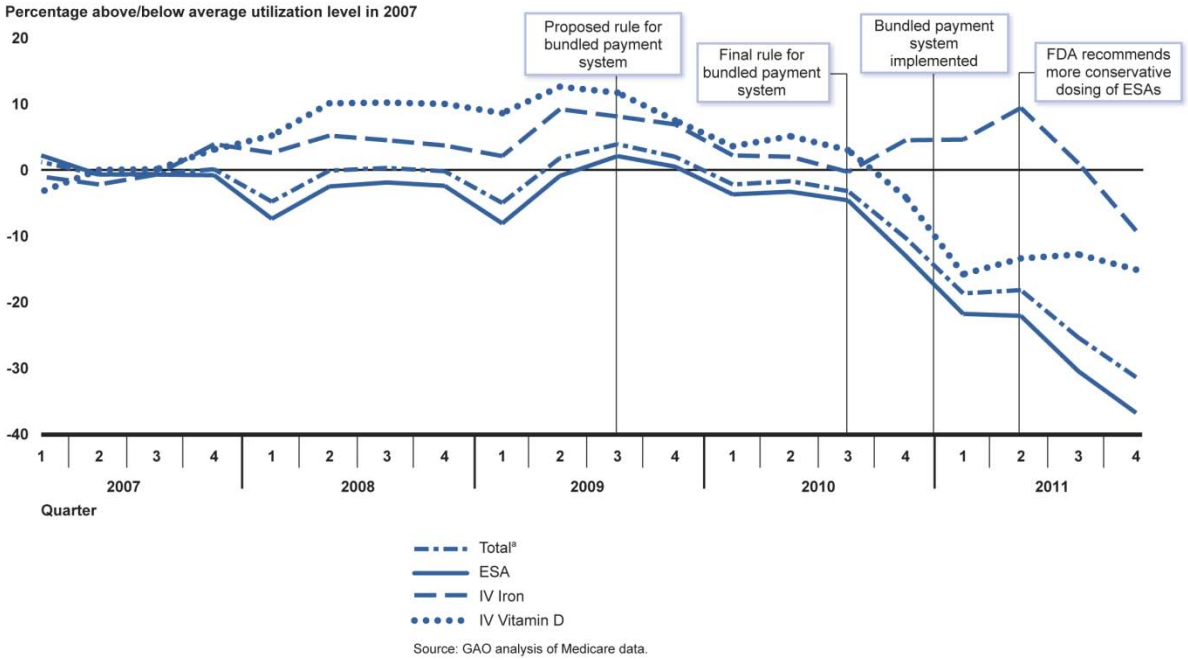
[26]74 *Fed. Reg.* 49,922 (Sept. 29, 2009).

[27]75 *Fed. Reg.* 49,430 (Aug. 12, 2010).

[28]See U.S. Food and Drug Administration, "FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease," (June 24, 2011), available at http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm (accessed Apr. 19, 2012).

final quarter of 2011 was about 15 percent below its average 2007 level. As with ESAs, utilization of IV vitamin D decreased sharply following the issuance of the final rule in late 2010 but then, unlike ESAs, stabilized in 2011.

Figure 1: Utilization of ESRD Drugs per Beneficiary per Quarter through 2011, Relative to Average Level in 2007



Notes: Utilization was expressed in dollars by multiplying the number of units per beneficiary of a drug administered in a given quarter by Medicare's Average Sales Price (ASP) for this drug in the first quarter of 2011.

ESA = erythropoietin stimulating agents; IV = intravenous.

[a]Includes utilization of ESAs, IV iron, and IV vitamin D.

The reductions in the utilization of ESAs, IV iron, and IV vitamin D from the third quarter of 2010 through the end of 2011 were driven primarily by lower utilization per beneficiary who received a given type of drug rather than a change in the share of ESRD beneficiaries who received it. Specifically, ESA utilization per beneficiary among those who received this type of drug declined by about 30 percent from the third quarter of 2010 through the end of 2011, but the share of beneficiaries on dialysis receiving ESAs fell just 5 percentage points, from 95 to 90 percent.[29] The utilization per beneficiary receiving IV iron declined by 16 percent while the share of ESRD beneficiaries receiving this type of drug increased from 70 to 75 percent. In addition, among those receiving IV vitamin D, utilization declined by about 14 percent, and the share of ESRD beneficiaries receiving this type of drug fell from about 74 to 70 percent.

[29]A small increase in the share of ESAs that were administered subcutaneously may have contributed somewhat to the decline in ESA utilization, as this mode of administration requires lower doses. According to the Dialysis Outcomes Practice Patterns Study (DOPPS), the percentage of dialysis patients nationally who received ESAs subcutaneously increased from about 1 percent in August 2010 to about 3 percent in December 2011. See *DOPPS Practice Monitor,* (October 2012), available at http://www.dopps.org, (accessed Nov. 8, 2012).

While we did not determine the specific causes of recent changes in ESRD drug utilization, the reductions in ESA and IV vitamin D utilization following the third quarter of 2010 are consistent with the financial incentive for facilities to provide dialysis care more efficiently under the new payment system effective January 1, 2011. The concurrent increase in IV iron utilization in late 2010 and early 2011 also may have been consistent with this financial incentive by allowing facilities to reduce provision of ESAs, because administering IV iron to dialysis patients can reduce the dose of ESAs required to achieve acceptable hemoglobin levels.[30] Therefore, facilities may have been able to treat beneficiaries' anemia at a lower cost because IV iron is less expensive than ESAs. The upward trend in IV iron utilization shifted to a decline following the second quarter of 2011. The ESRD clinicians we interviewed stated that this decline may have been related to two factors. They suggested that, because dialysis patients were given more IV iron in late 2010 and early 2011, these patients may have required less of the drug in the latter part of the year. In addition, some clinicians suggested that, because both ESAs and iron can be used to raise hemoglobin levels, the FDA's removal in June 2011 of the minimum target for hemoglobin levels could have reduced utilization of both drugs. CMS's removal of the minimum hemoglobin target from the QIP in 2013, which will link payments to dialysis organizations in that year to their performance in 2011, may have reinforced this trend.[31] Analysis by the United States Renal Data System (USRDS) showed a decline in average hemoglobin levels between September 2010 and September 2011, and CMS showed a reduction in median hemoglobin levels during that period.[32]

Our review of the limited information available and interviews with ESRD clinicians indicated that the effect on beneficiaries of recent changes in ESRD drug utilization is unclear. USRDS and CMS data showed an increase from 2010 to 2011 in the rate of blood transfusions.[33] However, CMS data also indicate that the incidence of stroke and heart failure, which have been linked to the use of ESAs, continued to improve during this time period. The ESRD clinicians we interviewed stated that the limited clinical evidence available was insufficient to determine the impact on beneficiaries of recent changes in ESRD drug utilization.

[30]See Avani D. Joshi, et al, *Utilization Patterns of IV Iron and Erythropoiesis Stimulating Agents in Anemic Chronic Kidney Disease Patients: A Multihospital Study*, Anemia, vol. 2012 (2012) and Daniel W. Coyne et al., "Ferric Gluconate Is Highly Efficacious in Anemic Hemodialysis Patients with High Serum Ferritin and Low Transferrin Saturation: Results of the Dialysis Patients' Response to IV Iron with Elevated Ferritin (DRIVE) Study," *Journal of the American Society of Nephrology*, vol. 18 (2007).

[31]CMS issued the proposed rule for the 2013 QIP in July 2011 and issued the final rule in November 2011. See 76 *Fed. Reg.* 40,498 (July 8, 2011) (proposed rule); 76 *Fed. Reg.* 70,228 (Nov. 10, 2011) (final rule).

[32]See CMS, *ESRD Prospective Payment System (ESRD PPS) Overview of 2011 Claims-Based Monitoring*, available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Spotlight.html (accessed Nov. 4, 2012); and U.S. Renal Data System, *USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States* (Bethesda, Md.: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2012).

[33]See CMS, *ESRD Prospective Payment System*, and USRDS, *USRDS 2012 Annual Data Report*.

The lower utilization of ESRD drugs overall in 2011 relative to the average 2007 level suggests that the bundled payment rate is too high and that Medicare is paying more than necessary for dialysis care. Our results indicate that ESRD drug utilization in 2011 was, on average, about 23 percent below the average 2007 level, and we estimated that Medicare payments for dialysis services would have been about $650 million lower in 2011 if the bundled payment amount reflected average ESRD drug utilization in that year.[34] This amount likely is a conservative estimate of the extent to which the current bundled payment is too high. Because ESRD drug utilization declined throughout 2011, by the fourth quarter utilization was 31 percent below the average 2007 level. If utilization for the entire year had been at the level of the fourth quarter, we estimated that annual Medicare payments for dialysis care in 2011 would have been about $880 million lower. Moreover, preliminary data indicate that ESRD drug utilization continued to fall in the first half of 2012, so estimates of potential savings could be larger in future years.[35] However, CMS officials indicated that they did not have plans to rebase the bundled payment rate and that the statute does not provide CMS with explicit authority to do so.

Conclusions

The new bundled payment system has the potential to improve the efficiency of dialysis care delivery, and realizing these efficiencies without compromising beneficiaries' access to and quality of care requires that the bundled payment rate accurately reflect the expected costs of providing dialysis. Our findings suggest that the current bundled payment rate is excessive given recent changes in ESRD drug utilization. Rebasing the bundled payment rate to account for the reductions in ESRD drug utilization could result in more appropriate payments to dialysis facilities and yield substantial savings for Medicare, but CMS officials indicated that they did not have immediate plans to do so. The potential effect on beneficiaries of such a payment change and the uncertainty surrounding the impact on them of recent changes in ESRD drug utilization underscore the importance of CMS's ongoing monitoring activities.

Matter for Congressional Consideration

Congress should consider requiring the Secretary of HHS to rebase the ESRD bundled payment rate as soon as possible and on a periodic basis thereafter, using the most current available data.

[34]This difference is entirely attributable to changes in the amount of drugs provided and not affected by price changes; however, CMS accounted for price increases when it determined the 2011 bundled rate. Of the estimated $650 million in potential savings in 2011, beneficiary cost sharing accounted for approximately $130 million (about $360 per beneficiary on dialysis in 2011).

[35]We calculated utilization for the first half of 2012 as we did for previous years. These preliminary results were based on Medicare claims that had been processed as of June 2012. Because some claims for ESRD drugs administered in the first half of 2012 had not yet been processed as of June 2012, we adjusted ESRD drug utilization during this period upward on the basis of the share of claims data that had been processed by June in previous years.

Agency and Industry Comments and Our Evaluation

In commenting on our draft report, HHS agreed with us that the ESRD bundled payment rate should reflect accurate data on the utilization of ESRD services, and it noted that Congress had not given it explicit authority to rebase the ESRD payment rate. CMS told us it has no immediate plans to rebase the bundled rate and did not mention any plans to seek authority to do so. Consequently, we have replaced our recommendation that CMS rebase the bundled payment rate and seek authority from Congress, if necessary, with a matter for Congressional consideration. We are now asking that Congress consider requiring HHS to rebase the ESRD payment rate, using the most current available data, as soon as possible and periodically thereafter.

We invited three organizations to provide oral comments on our draft report: the Kidney Care Council (KCC), which represents dialysis facility companies; the National Renal Administrators Association (NRAA), which represents independent dialysis facilities; and the Renal Physicians Association (RPA), which represents nephrologists who treat ESRD patients. Representatives from these organizations expressed their appreciation for the opportunity to review the draft, and representatives from the RPA noted that the report presented interesting data, some of which had not been previously available.

KCC stressed the importance of FDA actions to changes in the utilization of ESRD drugs. We recognize the impact of FDA decisions on drug utilization and noted in the draft report the importance of FDA's 2011 recommendation for more conservative dosing of ESAs, which was followed by a decline in ESA utilization.

KCC and NRAA also noted that rebasing the ESRD payment rate should take account of more than the utilization of injectable drugs. We do not disagree with this point, but did not address other factors that might be considered in rebasing because our mandate from Congress was to examine injectable drugs. We would expect CMS to consider utilization and other factors in rebasing.

RPA noted that evidence regarding the appropriate level of ESA utilization is still in flux and expressed unease that, if CMS did not rebase frequently, an ESRD payment rate might be retained when it was no longer appropriate. We agree that more frequent rebasing may be appropriate when key components of the bundle are in flux. Requiring CMS to rebase periodically means that it can rebase as often as the data and clinical evidence suggest is necessary.

KCC and NRAA said the Average Sales Price (ASP) does not accurately reflect drug prices, and KCC said that Epogen prices have risen by as much as 15 percent since the beginning of 2012. According to KCC, the price increase is due to a reduction in manufacturers' rebates, which will not be incorporated into the ASP until late 2013. Our report does not directly address drug prices; however, CMS has the explicit authority to update the bundled payment rate to account for changes in drug prices by updating the prices in its market basket of ESRD drugs and services.

KCC said the bundled rate had already been reduced 2 percent in anticipation of lower ESRD drug utilization. MIPPA reduced ESRD payments to 98 percent of what they would have been without the additional bundling that MIPPA requires. However, the law did not provide and we are not aware of such a justification for the 2 percent reduction.

Both KCC and NRAA pointed to apparent differences between our analysis and those of CMS and MedPAC. We do not believe that the MedPAC and CMS analyses are comparable with our analysis. MedPAC, which in March 2012 recommended a 1 percent update in the payment rate, used CMS claims data through 2010 and therefore did not incorporate evidence of the continuing decline in utilization shown in 2011 claims. CMS, in updating the ESRD market basket by 2.3 percent for 2013, took account of price changes but not changes in the mix of drugs. CMS has explicit authority to adjust the bundled payment rate for price increases but does not have specific authority to adjust for utilization changes.

– – – – –

We are sending copies of this report to the Secretary of Health and Human Services. The report will also be available at no charge on our website at http://www.gao.gov. If you or your staff have any questions about this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Individuals making key contributions to this report include Phyllis Thorburn, Assistant Director; Todd D. Anderson; Alison Binkowski; William Black; George Bogart; Elizabeth T. Morrison; and Brian O'Donnell.

James Cosgrove
Director, Health Care

Enclosures – 2

Enclosure I

List of Committees

The Honorable Max Baucus
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Camp
Chairman
The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Enclosure II

Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 30 2012

James C. Cosgrove
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "End-Stage Renal Disease: Reduction in Drug Utilization Suggests Bundles Payment is Too High"(GAO-13-190R).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "END STAGE RENAL DISEASE: REDUCTION IN DRUG UTILIZATION SUGGESTS BUNDLED PAYMENT IS TOO HIGH" (GAO-13-190R)

The Department appreciates the opportunity to review and comment on this draft report.

GAO Recommendation

GAO recommends that the Secretary of Health and Human Services direct CMS to rebase the bundled payment rate to account for changes in the utilization of ESRD drugs as soon as possible and periodically thereafter and, if necessary, GAO recommends that CMS seek authority to do so from the Congress.

HHS Response

HHS acknowledges this recommendation and agrees with GAO that the ESRD bundled payment rate should reflect accurate data on utilization of ESRD services, however, we note that the statute does not provide explicit rebasing authority for the ESRD bundled payment rate. We believe that such authority would help further ensure that payments are established accurately and support access to high quality care for Medicare beneficiaries with ESRD.

1

(291035)