

GAO

Report to the Chairman, Committee on
Ways and Means, House of
Representatives

November 2006

END-STAGE RENAL DISEASE

Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility





Highlights of [GAO-07-77](#), a report to the Chairman, Committee on Ways and Means, House of Representatives

Why GAO Did This Study

Medicare covers dialysis—a process that removes excess fluids and toxins from the bloodstream—for most individuals with end-stage renal disease (ESRD), a condition of permanent kidney failure. CMS pays for certain dialysis services under a type of bundled rate, called a composite rate, and, for certain dialysis-related drugs, pays a separate rate per dose each time the drug is administered. These drugs are referred to as “separately billable” and are paid at 6 percent above manufacturers’ average sales price (ASP). Recently, the Congress required CMS to explore the creation of a bundled payment for all ESRD services, including separately billable drugs. GAO was asked to examine (1) recent changes in payments for ESRD services, (2) the ASP payment method of setting rates for separately billable ESRD drugs, and (3) CMS efforts to develop a bundled payment method that includes all ESRD drugs. GAO obtained information for this study from CMS, the U.S. Renal Data System, ESRD experts, and previously issued GAO reports.

What GAO Recommends

The Congress should consider establishing a bundled payment system for all ESRD services, including drugs, as soon as possible. CMS generally agreed with GAO’s view, but said it needed to finalize, among other things, the development of a sound case-mix adjuster before bundling payment for all ESRD services.

www.gao.gov/cgi-bin/getrpt?GAO-07-77.

To view the full product, including the scope and methodology, click on the link above. For more information, contact A. Bruce Steinwald at (202) 512-7101 or steinwalda@gao.gov.

END-STAGE RENAL DISEASE

Bundling Medicare’s Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility

What GAO Found

The effect of several legislative and regulatory changes since 2003 has been to raise the composite rate while reducing Medicare’s pre-2005 generous payments for separately billable ESRD drugs. In 2005, when the first legislative change was implemented, Medicare expenditures for certain separately billable drugs dropped 11.8 percent. In 2006, Medicare regulation changed the payment for these drugs to a method based on ASP. Since then, Medicare’s payment rates have varied from quarter to quarter but have remained relatively consistent with the lower 2005 payment rates. Medicare’s cost containment efforts have targeted the most expensive of the separately billable drugs—Epogen®—for which program spending totaled \$2 billion in 2005. Epogen is used to treat anemia in ESRD patients; most patients receive this drug at nearly every dialysis session. Recent data indicate that Epogen use per patient continues to rise, although more slowly than in previous years.

Several unknowns about the composition of ASP and the lack of empirical evidence for the percentage level added to ASP make it difficult for CMS to determine whether the ASP-based payment rates are no greater than necessary to achieve appropriate beneficiary access. Paying for Epogen under the ASP method is of particular concern. The ASP method relies on market forces to moderate manufacturers’ prices; but Epogen is the product of a single manufacturer and has no competitor products in the ESRD market. Without competition, the power of market forces to moderate price is absent. For rarely used products, the lack of price competition may be financially insignificant, but for Epogen, which is pervasively and frequently used, the lack of price competition could be having a considerable effect on Medicare spending.

In 2003, the Congress required CMS to issue a report and conduct a demonstration of a system that would bundle payment for ESRD services, including drugs that are currently billed separately, under a single rate. The bundled payment approach, used to pay for most Medicare services, encourages providers to operate efficiently, as they retain the difference if Medicare’s payment exceeds the costs they incur to provide the services. GAO and others have found that a bundled rate for all ESRD services would have advantages for achieving efficiency and clinical flexibility in treating ESRD patients. CMS’s demonstration testing the feasibility of a bundled rate, mandated to start in January 2006, is delayed, as is the completion of the agency’s mandated report to the Congress on bundling. The report was due in October 2005; as of November 2006, CMS officials could not tell us when the report would be available.

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Abbreviations

ASP	average sales price
AWP	average wholesale price
CMS	Centers for Medicare & Medicaid Services
CHOIR	Correction of Hemoglobin and Outcomes in Renal Insufficiency Trial
CREATE	Cardiovascular Risk Reduction by Early Anemia Treatment with Epoetin Beta Trial
ESRD	end-stage renal disease
FDA	Food and Drug Administration
Hct	hematocrit
HHS	Department of Health and Human Services
KCC	Kidney Care Council
KDOQI	Kidney Disease Outcomes Quality Initiative
MedPAC	Medicare Payment Advisory Commission
MMA	The Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NRAA	National Renal Administrators Association
OIG	Office of the Inspector General
RPA	Renal Physicians Association
USRDS	United States Renal Data System

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United States Government Accountability Office
Washington, DC 20548

November 13, 2006

The Honorable William M. Thomas
Chairman
Committee on Ways and Means
House of Representatives

Dear Mr. Chairman:

Regardless of age, most individuals with end-stage renal disease (ESRD), a condition of permanent kidney failure, are eligible for health care coverage under Medicare.¹ Since the implementation of the ESRD benefit in 1973, hundreds of thousands of lives have been extended through Medicare-covered dialysis treatment—a process that removes excess fluids and toxins from the bloodstream. Patients receive additional items and services related to their dialysis treatments, such as laboratory tests, clinical services, and drugs to treat conditions resulting from the loss of kidney function, such as anemia and low blood calcium. In 2005, Medicare’s ESRD population was about 390,000 and program expenditures for dialysis and dialysis-related drugs totaled \$7.9 billion.²

The Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Human Services (HHS), which has the responsibility for administering the Medicare program, divides ESRD items and services into two groups for payment purposes. In the first group are dialysis and associated routine services—such as nursing, supplies, equipment, and certain laboratory tests. These items and services are paid for under a composite rate—that is, one rate for a defined set of services. Paying under a composite rate is a common form of Medicare payment also known as bundling. In the second group are primarily injectable drugs and certain laboratory tests that were either not routine or not available in 1983 when Medicare implemented the composite rate. These items and

¹In addition to being diagnosed with ESRD, individuals generally must meet one of the following requirements to receive Medicare coverage: obtain the required work credits under the Social Security program, receive Social Security benefits, or be the spouse or dependent child of a person who has met the required work credits or is receiving Social Security benefits. 42 U.S.C. § 426-1 (2000).

²For the purposes of this report, Medicare expenditures include the 20 percent coinsurance paid by the beneficiary, unless otherwise noted.

services, which are paid for separately on a per-service basis, are referred to as “separately billable.” Over time, Medicare’s composite rate, which was not automatically adjusted for inflation, covered progressively less of the costs to provide routine dialysis services, while program payments for the separately billable drugs generally exceeded providers’ costs to obtain these drugs.³ As a result, dialysis facilities relied on Medicare’s generous payments for separately billable drugs to subsidize the composite rate payments that had remained nearly flat for two decades.⁴ In addition, the use of the separately billable drugs by facilities became routine, and program payments for these drugs grew substantially. In 2005, program spending for the separately billable ESRD drugs accounted for about \$2.9 billion.

Medicare’s payment method for separately billable ESRD drugs has changed several times in the last few years. Currently, each of these drugs is paid for on a per administration basis equal to 6 percent above manufacturers’ average sales price (ASP), referred to as ASP+6; this payment rate went into effect in 2006.⁵ In 2005, Medicare spending for one of these drugs, Epogen®,⁶ was \$2 billion, accounting for more than two-thirds of Medicare payments for all separately billable ESRD drugs. Introduced in 1989, Epogen was an expensive breakthrough drug used to

³These drugs are covered under Medicare Part B, the part of Medicare that covers a broad range of medical services, including physician, laboratory, hospital outpatient department services, and durable medical equipment. Part B-covered drugs are typically administered by a physician or other medical professional rather than by patients themselves. In contrast, drugs covered under the new prescription drug benefit, known as Part D, are generally self-administered by patients.

⁴Dialysis facilities can be hospital-based or freestanding, part of a chain or independent, and for-profit or not-for-profit; 60 percent of dialysis facilities in the United States are owned by two for-profit chains. Large chains tend to receive volume discounts on ESRD drugs, whereas smaller, independent facilities may not have the same negotiating power; thus smaller facilities may pay higher prices for ESRD drugs.

⁵The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 defined ASP as manufacturer’s average sales price for all U.S. purchasers of a drug, net of volume, prompt pay, and cash discounts, and charge-backs and rebates. Certain prices, including prices paid by certain federal purchasers, are excluded, as are prices for drugs furnished under Medicare Part D. Pub. L. No. 108-173, sec. 302(c), § 1847(c), 117 Stat. 2066, 2240-41 (to be codified at 42 U.S.C. § 1395w-3a(c)).

⁶Epogen, which is a brand name for epoetin alfa, is a synthetic version of erythropoietin—a protein made by the kidney that stimulates the production of red blood cells. The drug was developed in the 1980s by Amgen, a biologicals manufacturing company that markets the drug for use in the ESRD setting.

treat anemia in patients with ESRD.⁷ Over time, policymakers have raised concerns about incentives in the Medicare payment system for dialysis facilities to use Epogen more than necessary because Medicare payments for the drug substantially exceeded facilities' costs of acquiring it.⁸ In principle, these incentives existed for all of the separately billable drugs, but the attention to Epogen stems from its pervasive, frequent use: that is, most ESRD patients receive injections of Epogen at nearly every dialysis treatment.⁹

In recent years, CMS has been exploring, as required by the Congress, the creation of a bundled payment for all ESRD services, including the drugs that facilities currently bill for separately. In response to a mandate that CMS study the feasibility of creating a bundled payment,¹⁰ the agency issued a study in 2003 concluding that developing a bundled ESRD payment rate was feasible and that further study of case-mix adjustment—that is, a mechanism to account for differences in patients' use of resources—was needed. In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Congress required that CMS report on the design of a bundled prospective payment system for ESRD services, including a case-mix adjustment methodology, and conduct a

⁷In examining Medicare's payment options in 1990 to cover this drug, the Office of Technology Assessment noted that Epogen not only reduces dialysis patients' need for blood transfusions but also alleviates symptoms of anemia and improves the quality of patients' lives. See U.S. Congress, Office of Technology Assessment, *Recombinant Erythropoietin: Payment Options for Medicare*, OTA-H-451 (Washington, DC: May 1990).

⁸Unlike the method Medicare used to pay for other separately billable drugs, the method Medicare used to pay for Epogen was an amount set in statute for a single year—\$10.00 per 1,000 units in 1994; CMS continued to pay this rate at its discretion until 2005. Most patients receive Epogen three times a week; the dose is based on the patient's body weight among other things. A typical starting dose is 50-100 units per kilogram or per 2.2 pounds. For example, a patient weighing 150 pounds may receive a dose of between 3,400 units and 6,800 units three times a week. The dose is then titrated based on the patient's response to the therapy.

⁹Whether Epogen has been overused has not been determined conclusively but research currently being conducted is shedding light on this issue. Evidence of systematic overuse is difficult to establish, as needed amounts can vary across patients and across treatments for the same patient. See for example, Onyekachi Ifudu, "Controversies in Renal Anemia Management," *Dialysis and Transplantation*, vol. 35, no. 3 (2006) and Dennis Cotter et al., "Translating Epoetin Research Into Practice: the Role of Government and the Use of Scientific Evidence," *Health Affairs*, vol. 25, no. 5 (2006).

¹⁰Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub L. No. 106-554, app. F, § 422(b)-(c), 114 Stat. 2763A-463, 2763A-516-2763A-517.

3-year demonstration to test the design of a bundled ESRD payment system.¹¹

You asked us to report on issues related to payment for separately billable ESRD drugs. This report examines the (1) potential for recent payment changes to address the subsidization issue and eliminate incentives to overuse separately billable ESRD drugs, (2) appropriateness of the ASP payment method to set rates for separately billable ESRD drugs, and (3) rationale for developing, and the status of CMS's efforts to develop, a bundled payment method that includes all ESRD drugs.

To examine the effect of recent payment changes, we reviewed legislation and regulations relevant to the payment system for ESRD drugs and services. We also reviewed publicly available information from CMS on prices for drugs used in ESRD facilities. We reviewed data for the first 6 months of each year from 1991 to 2005 and preliminary data from the first 6 months of 2006 on the utilization of Epogen from the United States Renal Data System (USRDS).^{12,13} We assessed the reliability of these data by interviewing officials responsible for producing these data, reviewing relevant documentation, and examining the data for obvious errors. We determined that the data were sufficiently reliable for the purposes of our study. To determine the appropriateness of the ASP payment method, we reviewed our previously issued products on this method and interviewed CMS officials, dialysis facility representatives, nephrologists, drug manufacturers, and other experts on ESRD.¹⁴ To explore the rationale for and efforts to design a payment bundle for ESRD services, we reviewed the clinical literature on dialysis and injectable drugs and information

¹¹Pub. L. No. 108-173, § 623(e)–(f), 117 Stat. 2066, 2315-17.

¹²We restricted the utilization data to the first half of the year to make our comparisons consistent with preliminary 2006 data, for which we have the first 6 months of the year.

¹³USRDS is a national data system that collects, analyzes, and distributes information about ESRD in the United States and is funded by the National Institute of Diabetes and Digestive and Kidney Diseases in conjunction with CMS. The data for 2006 may change as more Medicare claims for ESRD services are submitted.

¹⁴GAO, *Medicare Part B Drugs: CMS Data Source for Setting Payments Is Practical but Concerns Remain*, [GAO-06-971T](#) (Washington, D.C.: July 13, 2006); *Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS*, [GAO-06-372](#) (Washington, D.C.: Apr. 28, 2006); and *Medicare: Comments on CMS Proposed 2006 Rates for Specified Covered Outpatient Drugs and Radiopharmaceuticals Used in Hospitals*, [GAO-06-17R](#) (Washington, D.C.: Oct. 31, 2005).

from CMS on its ESRD bundling demonstration. We performed this work from April 2006 through November 2006 in accordance with generally accepted government auditing standards.

Results in Brief

Since 2003, several legislative and regulatory changes have been implemented to adjust Medicare's composite rate and lower payment rates for separately billable ESRD drugs. The effect of these changes has been to raise the composite rate while reducing the subsidy from generous Medicare payments for the separately billable drugs under pre-MMA payment rates. In 2005, when the first MMA change to Medicare's payment method for these drugs was implemented, Medicare expenditures for certain separately billable ESRD drugs dropped 11.8 percent. Since 2006, when payment for these drugs changed to a method based on ASP, Medicare's payment rates have varied from quarter to quarter but have remained relatively consistent with the lower 2005 payments. Medicare's cost containment efforts have targeted Epogen, because most of the program's spending for ESRD drugs outside the composite rate is for Epogen alone. Several months of data suggest that, although the growth in Epogen use per patient has slowed, the use of this drug continues to rise.

Medicare's ASP method of paying for Part B drugs—which include the ESRD drugs outside the composite rate—may not be sufficient for achieving Medicare's rate-setting goals. Several unknowns about the composition of ASP and the lack of empirical evidence for the percentage level added to ASP make it difficult for CMS to determine whether the ASP-based payment rates are no greater than necessary to achieve appropriate beneficiary access. Paying for Epogen under the ASP method is of particular concern. The ASP method relies on market forces to moderate manufacturers' prices; however, Epogen is the product of a single manufacturer and has no competitor products in the ESRD market. In principle, ASPs are lower than they would otherwise be when two or more manufacturers of similar products compete on price for market share. However, when no competition exists, as is the case for Epogen, the power of market forces to moderate price is absent. For rarely used products, the lack of price competition may be financially insignificant, but for Epogen, which is pervasively and frequently used, the lack of price competition could be having a considerable effect on Medicare spending.

Bundling services under a single payment rate is a fundamental principle of Medicare payment policy for most types of services. The composite rate for routine dialysis-related services was the first of Medicare's several payment systems that, in broad terms, sets a fixed, prospective rate for a

set of clinically related services. Under Medicare's current payment policy for ESRD services, the composite rate excludes drugs that have become routine in treating ESRD patients. In 2003, the MMA required CMS to design a system that would no longer pay for each injectable ESRD drug under a separate rate but would bundle payment for these drugs together with other ESRD items and services under a single rate. We and others have noted that a bundled rate would have advantages for achieving efficiency and clinical flexibility.¹⁵ For example, a bundled rate would remove the financial incentive for facilities to choose one treatment over another, allowing the flexibility to choose treatments that are clinically effective but may require less use of Epogen. Interested parties we spoke with, including facility representatives and ESRD experts, also supported a bundled payment for dialysis-related items and services for similar reasons. In addition, they noted the importance of designing a sound case-mix adjuster to account for the differences across facilities in the mix of patients using more or less resources than average and the need for an automatic payment update to adjust the bundled rate for inflation. CMS's report designing a model for a bundled ESRD payment system was due in October 2005; however, as of November 2006, CMS officials could not tell us when the report would be issued. The demonstration testing the feasibility of a bundled rate, mandated to start in January 2006, is also delayed.

In light of the uncertain timeline necessary for CMS to test bundling and the potential for bundling to eliminate financial incentives to overuse separately billable drugs, the Congress should consider establishing a bundled payment system for all ESRD services as soon as possible.

In commenting on a draft of this report, CMS generally agreed with our view that all ESRD services be included under a bundled payment system but expressed the need to resolve implementation issues, primarily that the development of a sound case-mix adjuster be finalized. Representatives from ESRD industry groups who reviewed the report

¹⁵See GAO *Medicare Dialysis Facilities: Beneficiary Access Stable and Problems in Payment System Being Addressed*, [GAO-04-450](#) (Washington, D.C.: June 25, 2004); Tommy G. Thompson, Secretary of Health and Human Services, *Report to Congress: Toward a Bundled Outpatient Medicare End Stage Renal Disease Prospective Payment System* (Washington, D.C.: May 2003); and Medicare Payment Advisory Commission (MedPAC), *Report to the Congress, Medicare Payment Policy* (Washington, D.C.: March 2006) and *Report to the Congress, Medicare Payment Policy* (Washington, D.C.: March 2001). MedPAC is an independent federal body established by law to advise the Congress on issues affecting the Medicare program.

echoed CMS's concerns regarding the development of an adequate case-mix adjuster and expressed other concerns associated with bundled payments, such as the need to account for the costs of technology innovation and treatment protocols.

Background

Most individuals diagnosed with ESRD are eligible to receive Medicare benefits under both Medicare Parts A and B.¹⁶⁻¹⁷ Medicare covers over 80 percent of all individuals with the disease.

Treatment of ESRD

ESRD treatment options include kidney transplantation and maintenance dialysis. The latter removes substances that would otherwise be filtered through the kidney from the individual's blood. Kidney transplants are not a practical option on a wide scale, as not all patients are candidates for transplant and suitable donated organs are scarce. In contrast, dialysis is the treatment used by most ESRD patients. Dialysis can be administered through two methods: hemodialysis and peritoneal dialysis. During hemodialysis, a machine pumps blood through an artificial kidney, called a hemodialyzer, and returns the cleansed blood to the body. Hemodialysis, the most prevalent treatment method,¹⁸ is generally administered at

¹⁶ 42 U.S.C. § 426-1(b) (2000).

¹⁷ Medicare Part A covers inpatient hospital, skilled nursing facility, and hospice care, as well as some home health care. Medicare Part B covers physician services, hospital outpatient services, and certain other services, such as physical therapy. Medicare coverage generally begins the third month after the month dialysis begins. For individuals who have employer group coverage, Medicare is the secondary payer for 30 months, after which Medicare becomes the primary payer. 42 U.S.C. § 1395y(b)(1)(B)(iii) (2000). Generally, individuals with ESRD may not join a Medicare Advantage Plan. 42 U.S.C. § 1395w-21(a)(3)(B) (2000).

¹⁸ In 2003, about 91 percent of all dialysis patients underwent in-facility hemodialysis, and about 8 percent of the dialysis population utilized peritoneal dialysis.

freestanding facilities that provide dialysis services.¹⁹ The conventional regimen includes hemodialysis three times a week.²⁰

Peritoneal dialysis—which is generally done in the home—utilizes the peritoneal membrane, which surrounds the patient’s abdomen, as a natural blood filter. Patients remove wastes and excess fluids from their abdomen manually throughout the day, or a machine automates the process while they sleep at night. This procedure eliminates the need for the blood to leave the body of the patient and filter through a machine. The use of peritoneal dialysis has declined as a treatment modality over the last decade.²¹

One of the complications of ESRD is anemia, a condition in which an insufficient number of red blood cells is available to carry oxygen throughout the body. In ESRD patients, this condition is treated by maintaining at an optimal level the percentage of red blood cells relative to all cells in whole blood (by volume). This measure is known as the hematocrit (Hct) level. The Kidney Disease Outcomes Quality Initiative (KDOQI), established by the National Kidney Foundation, has set the minimum target for ESRD patients’ Hct levels at 33 percent and has found insufficient evidence to recommend routinely maintaining Hct levels at 39 percent or greater.²² ESRD patients receive Epogen to keep their Hct above a minimum level.²³ The Food and Drug Administration (FDA)

¹⁹In 2003, fewer than 1 percent of patients received hemodialysis at home with the assistance of a caregiver.

²⁰This frequency is consistent with Medicare’s coverage of three hemodialysis treatments a week. Some experts contend that daily hemodialysis—five to seven times a week—is clinically preferable, as this frequency more closely approximates the body’s continuous cleansing of the blood. Proponents assert that daily hemodialysis leads to fewer hospitalizations and a reduction in the use of medications. In addition, the National Institutes of Health is currently sponsoring a study of nocturnal dialysis—a form of hemodialysis that can be done at home while the patient is asleep, six nights a week.

²¹The percentage of patients undergoing peritoneal dialysis has steadily decreased since its peak of 15 percent in 1990.

²²See National Kidney Foundation, “KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease,” *American Journal of Kidney Diseases*, vol. 47, no. 5, supp. 3 (2006).

²³According to the 18 ESRD networks that serve as the liaison between the federal government and dialysis providers, the percent of patients with a mean Hct greater than or equal to 33 has increased from 43 percent in 1997 to 80 percent in 2003. See The Forum of ESRD Networks *Summary Report of the ESRD Networks’ Annual Reports 2004*, (Baltimore, Md: December 2005).

labeled Epogen for use encompassing a somewhat lower Hct target level ranging from 30 to 36 percent. Recent clinical studies cited by KDOQI indicate that there may be increased patient mortality and morbidity if Hct levels are much higher than 39 percent.²⁴ Epogen is typically administered to Medicare ESRD patients intravenously. Epogen can also be administered subcutaneously, that is, through an injection under the skin.²⁵ The subcutaneous method requires less epoetin, but experts note that, because some pain is associated with this method, patients generally prefer intravenous delivery.²⁶

Medicare Payment for ESRD Services

Medicare's composite rate is designed to cover the cost of services associated with a single dialysis treatment, including nursing and other clinical services, social services, supplies, equipment, and certain laboratory tests and drugs. Under the composite rate, facilities receive a fixed payment, regardless of their actual costs to deliver these services. In 2006, the composite base rate is about \$130 for freestanding dialysis facilities.²⁷

Medicare pays separately for certain drugs and laboratory tests that have become routine treatments since 1983. These drugs include, but are not limited to, epoetin (brand name, Epogen), injectable vitamin D, and

²⁴See 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," *New England Journal of Medicine*, vol. 339, no. 9 (1998). Two clinical trials, Cardiovascular Risk Reduction by Early Anemia Treatment with Epoetin Beta Trial (CREATE) and Correction of Hemoglobin and Outcomes in Renal Insufficiency Trial (CHOIR) compared the efficacy and safety of higher Hct targets in patients with non-dialysis dependent chronic kidney disease. The target Hct level was between 39 and 45 percent in the CREATE treatment group. The CREATE trial did not achieve its goal of reducing risk for certain cardiac events. In the CHOIR trial, the incidence of adverse events, including mortality, was higher in the treatment group, with a target Hct of 40.5 percent, than in the control group, with a target of 33.9 percent. The CHOIR trial was stopped because of safety concerns.

²⁵At Department of Veterans Affairs facilities, subcutaneous administration of epoetin is the predominant delivery method.

²⁶See Denise Hynes et al., "Adherence to Guidelines for ESRD Anemia Management," *American Journal of Kidney Diseases*, vol. 47, no. 3 (March 2006) and James Kaufman et al., "Subcutaneous Compared with Intravenous Epoetin in Patients Receiving Hemodialysis," *The New England Journal of Medicine*, vol. 339, no. 9 (1998).

²⁷Additional adjustments to the rate account for, among other things, differences in providers' costs associated with location, based on a geographic wage index, and differences in facilities' mix of patients, who vary in their clinical resource needs.

injectable iron. Epogen is generally administered to most patients at every dialysis treatment, whereas the other drugs, although routinely provided, are not administered as frequently. Table 1 highlights three separately billable prescription drugs provided routinely to dialysis patients.

Table 1: Separately Billable Injectable ESRD Drugs Used by Dialysis Facilities in 2005

Separately billable drugs used in dialysis treatments	Compound	Number of manufacturers	Percentage of Medicare expenditures for separately billable ESRD drugs
Injectable iron ^a	Iron sucrose	1	5.3
	Sodium ferric gluconate complex	1	3.3
	Iron dextran	3	0.1
Injectable vitamin D ^b	Paricalcitol	1	11.4
	Doxercalciferol	1	2.8
	Calcitriol	8	0.4
Epoetin ^c	Epoetin alfa	1	70.0
	Darbepoetin alfa	1	3.7
Other separately billable drugs used in dialysis facilities	Levocarnitine, Alteplase, Vancomycin, vaccines, etc.	N/A	3.0
Total			100.0

Source: GAO analysis of CMS data and drug information from FDA.

^aIron is used in the treatment of anemia in conjunction with epoetin.

^bVitamin D is used to prevent osteomalacia by promoting bone mineralization.

^cEpoetin is used in the treatment of anemia by promoting the formation of red blood cells by the bone marrow.

As table 1 shows, three drugs—iron sucrose, paricalcitol, and epoetin alfa—account for about 87 percent of Medicare spending on separately billable ESRD drugs. Although each of these three drugs is a “sole-source” product—that is, produced by a single manufacturer—two of the three

have pharmaceutical alternatives available, whereas the third, epoetin, has no available alternatives in the ESRD market.²⁸

In recent years, Medicare's method of paying for separately billable ESRD drugs has changed several times. Beginning in 1998, Medicare law required that payment for drugs covered under Part B equal 95 percent of the drug's average wholesale price (AWP).²⁹ Despite its name, however, AWP was neither an average price nor the price wholesalers charged. It was a price that manufacturers derived using their own criteria; there were no requirements or conventions that AWP reflect the price of an actual sale of drugs by a manufacturer.³⁰ An analysis we conducted in 2001 on Part B drug prices found that Medicare's AWP-based payments often far exceeded market prices that were widely available to health care providers.³¹

The MMA mandated that in 2005 Medicare pay for separately billable ESRD drugs based on their acquisition costs, as determined by the HHS Office of the Inspector General (OIG).³² Since acquisition costs were not defined in the MMA, the OIG determined a drug's average acquisition cost based on a survey of prices providers paid for the top 10 ESRD drugs,

²⁸Although darbepoetin alfa, or Aranesp®, is an alternative to Epogen and is approved for use in ESRD patients, it is not generally marketed to freestanding dialysis facilities. It is, however, marketed to hospitals, which purchase the drug to treat anemia in patients with chronic kidney disease, certain types of cancer, and ESRD patients receiving dialysis at the hospital's facility.

²⁹The Balanced Budget Act of 1997 required that payment for drugs and biologicals furnished on or after January 1, 1998, equal 95 percent of the drug's AWP if the drug is not otherwise paid on a cost or prospective payment basis. Pub. L. No. 105-33 § 4556, 111 Stat. 251, 462-63. Until 2004, Medicare paid physicians 95 percent of AWP for Part B drugs. The MMA changed this to 85 percent of AWP for 2004. MMA sec. 303(b), § 1842(o)(4)(A), 117 Stat. 2238 (to be codified at 42 U.S.C. § 1395u(o)(4)(A)).

³⁰AWPs are published in commercial drug price compendia, based on data obtained from manufacturers, distributors, and other suppliers; the Medicare claims administration contractors that pay claims for Part B drugs based providers' payments on the published AWP.

³¹GAO, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs*, [GAO-01-1118](#) (Washington, D.C.: Sept. 21, 2001).

³²MMA sec. 623(d)(1), § 1881(b)(13)(A)(ii), 117 Stat. 2314 (to be codified at 42 U.S.C. § 1395rr(b)(13)(A)(ii)).

ranked by Medicare expenditures.³³ For 2005, Medicare paid the OIG-determined average acquisition cost for the top 10 ESRD drugs.³⁴ For 2006, the MMA gave the HHS Secretary discretion to alter the basis of payment for separately billable ESRD drugs.³⁵ Under this authority, CMS determined that Medicare would pay for the separately billable ESRD drugs using the method required by the MMA to pay physicians for these drugs—that is, 106 percent of the drug’s ASP.³⁶

CMS instructs pharmaceutical manufacturers to report data to CMS on the ASP for each Part B drug sold by the manufacturer, within 30 days after the end of the quarter. For drugs sold at different strengths and package sizes, manufacturers are required to report price and volume data for each product, after accounting for price concessions. CMS then aggregates the manufacturer-reported ASPs to calculate a national ASP for each drug category.³⁷ ASP rates are calculated and posted every quarter. The rates reflect the sales price on average from 6 months earlier.

³³These prices were net of rebates and discounts providers received. See Department of Health and Human Services Office of the Inspector General, *Medicare Reimbursement for Existing End-Stage Renal Disease Drugs*, OEI-03-04-00120 (Washington, D.C.: May 2004).

³⁴For the drugs representing 2 percent of Medicare spending not accounted for by the top 10 ESRD drugs, Medicare paid ASP+ 6 percent in 2005.

³⁵MMA sec. 623(d)(1), § 1881(b)(13)(A)(iii), 117 Stat. 2314 (to be codified at 42 U.S.C. § 1395rr(b)(13)(A)(iii)).

³⁶70 *Fed. Reg.* 70,116, 70,162 (Nov. 21, 2005).

³⁷Manufacturers’ reported price data are based on FDA’s system of National Drug Codes, while the ASP that CMS calculates for each drug is based on the agency’s Healthcare Common Procedure Coding System, which uses categories that are broader than the FDA’s coding system.

New Payment Provisions Reduced Subsidy from Separately Billable Drugs but Did Not Eliminate Incentives to Overuse These Drugs

Since 2003, several legislative and regulatory changes have been implemented affecting Medicare's composite rate for routine ESRD services and payment rates for separately billable ESRD drugs. The changes have increased the composite rate and reduced the subsidy facilities obtained from generous Medicare payments for the separately billable drugs under pre-MMA payment rates. Nevertheless, as long as facilities receive a separate payment for each administration of each drug and the payment exceeds the cost of acquiring the drug, an incentive remains to use more of these drugs than necessary. For Epogen, the most frequently used drug, several months of data indicate that the per-patient use of this drug continues to rise, although at a slower rate than under pre-MMA payment rates.

New Payment Provisions Increased Composite Rate and Reduced Subsidy from Separately Billable Drugs

The MMA initiated new Medicare payment provisions addressing the composite rate and payment for separately billable drugs. Prior to the MMA's payment changes, facilities relied on payments for separately billable drugs to subsidize the cost of providing dialysis services covered under the composite rate. In a 2004 report, we found that, in 2001, Medicare's payment for the composite rate was 11 percent lower on average than facilities' average costs to provide the items and services included in the composite rate, whereas Medicare's payment for separately billable drugs was 16 percent higher than facilities' average costs of acquiring these drugs.³⁸ We concluded that this payment disparity created an incentive for facilities to overuse separately billable drugs, as payments for them compensated for losses on items and services included in the composite rate.

Together with the MMA provisions, more recent legislative and regulatory changes have reduced the disparity between Medicare's payments and facilities' average costs for both composite rate services and separately billable drugs. Essentially, these changes lowered payments for separately billable drugs from their pre-MMA amounts, and raised payments for the composite rate. The base composite rate was increased by 1.6 percent in 2005 and 2006 and the composite rate total was further increased through a "drug add-on" payment, which shifted some of the payments for

³⁸See [GAO-04-450](#). Because composite rate payments represent a larger share of Medicare spending than payments for separately billable drugs, these percentage differences in costs and payments are not directly comparable.

separately billable drugs to the composite rate.³⁹ In 2005, the add-on equaled 8.7 percent of the updated composite rate. In 2006, the 8.7 percent was replaced with a drug add-on payment of 14.5 percent of the 2006 updated composite rate.⁴⁰ (See table 2.)

Table 2: Recent Legislative and Regulatory Changes to ESRD Payments

	Changes in composite rate	Changes in payment for separately billable drugs
MMA	Increase in the base composite rate of 1.6 percent in 2005. Creation of a “drug add-on” adjustment to the composite rate in order to maintain budget neutrality, starting in 2005. Adjustment of drug add-on payment made yearly to reflect annual growth of drug expenditures, starting in 2006.	Payment rates based on average acquisition cost as determined by the OIG for 2005.
CMS regulation	Drug add-on payment equaled 8.7 percent of the updated 2005 base composite rate. Drug add-on payment of 8.7 percent was replaced with an add-on equal to 14.5 percent of the updated 2006 base composite rate.	Payment rates based on ASP + 6 percent for 2006.
Deficit Reduction Act of 2005	Increase in the base composite rate of 1.6 percent in 2006.	

Source: GAO analysis of laws and regulations.

Note: The HHS OIG developed the methodology to determine average acquisition cost of ESRD drugs.

The most significant changes to the ESRD payment system are the changes in payment rates for separately billable drugs. In 2005, Medicare’s payment rates based on average acquisition costs were lower than its previous payment rates based on 95 percent of AWP. For example, from

³⁹These add-on payments—the difference between the rates Medicare paid under pre-MMA provisions and the rates paid each year from 2005 on—are designed to maintain budget neutrality as a result of payment reductions for separately billable drugs, beginning in 2005.

⁴⁰The MMA required CMS to annually update the drug add-on payment to account for changes due to increased utilization and prices. MMA sec. 623(d)(1), § 1881(b)(12)(F), 117 Stat. 2314 (to be codified at 42 U.S.C. § 1395rr(b)(12)(F)).

2004 to 2005, the per-unit rate for iron dextran decreased from \$17.91 to \$10.94 and the per-unit rate for paricalcitol decreased from \$5.33 to \$4.00. (See table 3.) Since 2006, when the payment method for separately billable drugs changed to ASP + 6 percent, Medicare's payment rates have varied from quarter to quarter but have remained relatively consistent with the lower 2005 payments based on average acquisition costs.

Table 3: Medicare Reimbursement Rates for Certain Separately Billable ESRD Drugs

		2004 95% AWP	2005 Average acquisition cost	January 2006 ^a ASP+6%	April 2006 ^a ASP+6%	July 2006 ^a ASP+6%	October 2006 ^a ASP+6%
Iron	Iron dextran (50.0 mg)	\$17.91	\$10.94	n/a	n/a	n/a	n/a
	Iron dextran ^b (165 injection) (50.0 mg)	n/a	n/a	\$12.25	\$12.42	\$11.69	\$11.78
	Iron dextran ^b (267 injection) (50.0 mg)	n/a	n/a	\$10.24	\$10.27	\$10.34	\$10.38
	Iron sucrose (1.0 mg)	\$0.66	\$0.37	\$0.36	\$0.36	\$0.37	\$0.36
	Sodium ferric gluconate complex (12.5 mg)	\$8.17	\$4.95	\$4.90	\$5.06	\$4.75	\$4.81
Vitamin D	Calcitriol (0.1 mcg)	\$1.38	\$0.96	\$0.71	\$0.46	\$0.51	\$0.53
	Paricalcitol (1.0 mcg)	\$5.33	\$4.00	\$3.81	\$3.80	\$3.81	\$3.81
	Doxercalciferol (1.0 mcg)	\$5.50	\$2.60	\$2.69	\$3.17	\$3.16	\$2.88
Epoetin	Epogen (1,000 units)	\$10.00 ^c	\$9.76	\$9.57	\$9.33	\$9.48	\$9.45

Source: GAO analysis of CMS information.

^aPayments under ASP + 6 percent are based on quarterly data and rounded to the nearest cent.

^bThe different doses of iron dextran were paid separately under the ASP + 6 percent methodology.

^cThe payment for Epogen does not represent 95 percent of AWP.

Since the implementation of these changes, Medicare spending for individual separately billable ESRD drugs has decreased to varying degrees. Beginning in 2005, when Medicare's payment method for these drugs changed from AWP to average acquisition cost, Medicare expenditures for several separately billable drugs decreased 11.8 percent

from 2004. (See table 4.) Specifically, the average payments for iron sucrose and paricalcitol decreased by almost 35 percent and 25 percent, respectively.⁴¹ Similarly, payment for Epogen was lower than it had been for the previous decade, when it was set statutorily at \$10 per unit, but the reduction—3.2 percent—was significantly less compared with the other drugs.

Table 4: Percentage Change in Medicare Expenditures for Certain Separately Billable ESRD Drugs from 2004 to 2005

Dollars in millions				
		2004 Medicare expenditures	2005 Medicare expenditures	Percentage change ^a
Iron	Iron dextran (50.0 mg)	5.0	2.3	-54.4
	Iron sucrose (1.0 mg)	237.3	154.8	-34.8
	Sodium ferric gluconate complex (12.5 mg)	159.6	96.2	-39.7
Vitamin D	Calcitriol (0.1 mcg)	20.9	10.9	-48.1
	Paricalcitol (1.0 mcg)	439.4	331.3	-24.6
	Doxercalciferol (1.0 mcg)	112.8	81.9	-27.4
Epoetin	Epogen (1,000 units)	2,107.2	2,039.6	-3.2
Total		3,082.2	2,716.9	-11.8

Source: GAO analysis of CMS data.

Note: Total includes Medicare expenditures from all facility types and the 20 percent coinsurance the beneficiary pays.

^aTotals and percentage change were calculated prior to rounding.

Because payments to facilities for separately billable drugs are closer to the cost of acquiring these drugs and because composite rate payments have increased, the degree of cross-subsidization to support services

⁴¹After epoetin, the next highest Medicare expenditures are for iron sucrose and paricalcitol in the ESRD setting.

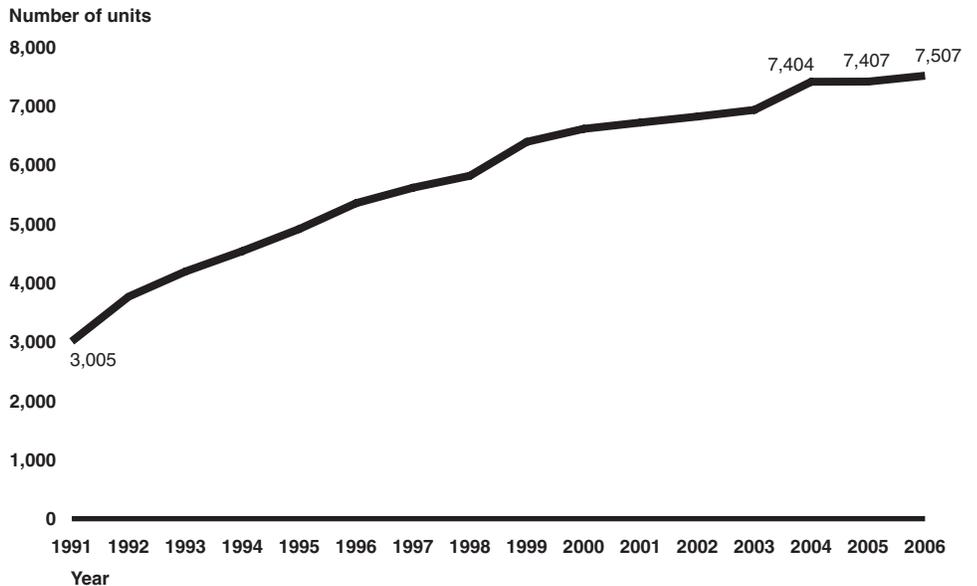
provided under the composite rate has diminished, but the incentive to overuse these drugs has not been eliminated. To the extent that facilities can obtain the drugs for less than Medicare's payment rates and that the volume of drugs billed for separately increases facilities' revenue, an incentive remains for facilities to overuse these drugs to maximize revenues.

Preliminary Data Suggest that Epogen Use Continues to Grow, Though More Slowly than Before MMA Provisions Took Effect

Utilization of Epogen—a major spending driver for ESRD services—has been and remains a focus of Medicare's ESRD cost containment efforts. Preliminary data show that Epogen use—as measured by average dose per administration—continues to increase, although at a much slower rate than in previous years.⁴² Specifically, using data for the first 6 months of each year, we found that from 1991 through 2004, before the MMA provisions took effect, Epogen use increased at an average annual rate of 6.7 percent, rising from about 3,000 units per administration to about 7,400 units (see fig. 1). In 2005, Epogen use remained virtually unchanged; in 2006, the average monthly Epogen dose per administration increased slightly from about 7,400 units to about 7,500 units, an increase of about 1.4 percent.

⁴²We restricted the data to the first half of the year to increase the validity of our comparison of previous years to 2006, for which we have only partial data.

Figure 1: Average Epogen Dose per Administration in the First 6 Months of Each Year, 1991-2006

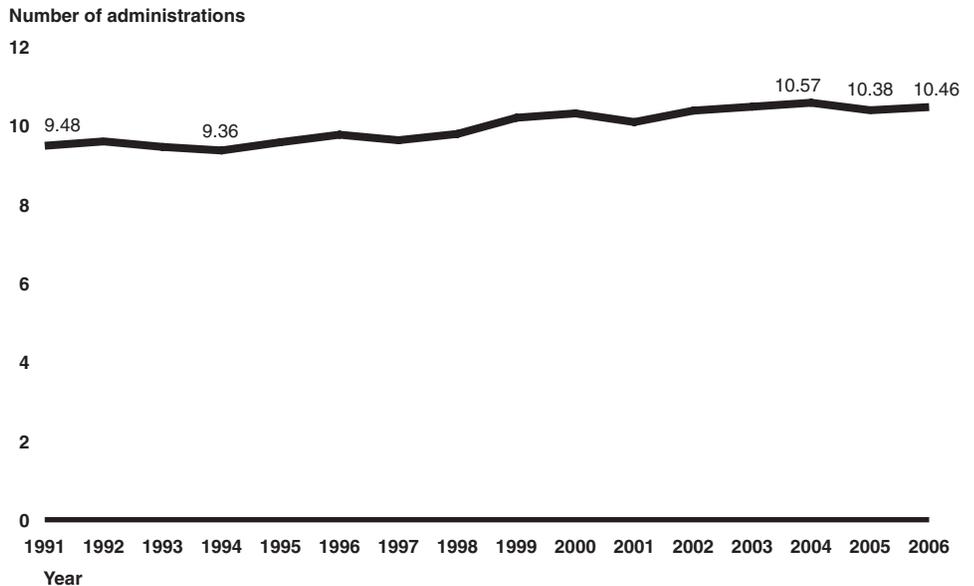


Source: GAO analysis of data from the USRDS.

Note: Data are per ESRD patient with at least one Epogen claim in the first 6 months. We restricted the utilization data to the first half of the year to make our comparisons consistent with 2006 data, which we only have for the first 6 months of the year.

Another measure of Epogen use—the average number of Epogen administrations per month per patient—also has not changed significantly since the implementation of the MMA. Between the first 6 months of 1994 and the first 6 months of 2004, the average number of monthly Epogen administrations per patient increased from about 9.4 to about 10.6 (see fig. 2). Although the average number of monthly administrations was lower in both 2005 and 2006—at about 10.4 and 10.5 per patient, respectively—the average number of administrations per patient in 2006 was about 10 percent higher than in 1991, when the number was about 9.5.

Figure 2: Average Number of Monthly Epogen Administrations in the First 6 Months of Each Year, 1991-2006



Source: GAO analysis of data from the USRDS.

Note: Data are per ESRD patient with at least one Epogen claim in the first 6 months. We restricted the utilization data to the first half of the year to make our comparisons consistent with 2006 data, which we only have for the first 6 months of the year.

In addition to payment changes, CMS has sought over time to limit expenditures for Epogen by issuing policies that link payment to utilization. That is, Medicare reduces payments when a patient's Hct level reaches a certain percentage. Since 1997, CMS has created three different monitoring policies to encourage the efficient use of Epogen for ESRD patients. Each of these policies has been closely aligned with the clinical guidelines for Hct levels endorsed by the National Kidney Foundation. In 1997, the first policy denied payment when a patient's 3-month rolling average Hct level exceeded 36.5 percent. In 1998, CMS revised the policy so that the maximum level for the 3-month rolling average Hct was 37.5 percent; if a patient exceeded that level, payments were not denied as long as the Epogen dose was reduced 20 percent. In July 2004, CMS issued a proposal for a new monitoring policy. After consultation with the dialysis community, the final policy took effect on April 1, 2006. Under this policy, when a patient's Hct level is above 39.0 percent, the facility must reduce the Epogen dosage by 25 percent of the preceding month's

administered amount.⁴³⁻⁴⁴ Whether or not the facility reduces the dosage, Medicare pays the facility as though the reduction has occurred—in effect, not rewarding the facility for overutilization.

ASP Payment Method, While Administratively Practical, May Not Help Medicare Foster Efficient Provider Goals

In broad terms, Medicare’s policy is to set payment rates that are adequate to ensure beneficiary access to services but do not exceed the costs efficient providers incur to furnish needed care. In prior work on Medicare payment for Part B drugs, which include separately billable ESRD drugs, we noted that the ASP method was practical for setting payment rates compared with Medicare’s previous methods to pay for these drugs, but we remained concerned about the appropriateness of the rates set under ASP.⁴⁵ The practical aspects of ASP are several: it is based on actual transactions and is a better proxy for providers’ acquisition costs than Medicare’s previous methods to pay for these drugs; ASP is the most recent publicly available price information, as it is updated quarterly, and is therefore timely for rate-setting purposes; and price data from manufacturers are administratively easier for CMS to collect than obtaining such data from health care providers.

However, we also observed that CMS is not well-positioned to validate the accuracy or appropriateness of its ASP-based payment rates. Significantly, CMS lacks sufficient information on how manufacturers allocate rebates to individual drugs sold in combination with other drugs or products. In addition, CMS does not instruct manufacturers to provide a breakdown of price and volume data by purchaser type—that is, by physicians, hospitals, other health care providers, and wholesalers, which purchase drugs for resale to health care providers. As a result, CMS cannot determine how well average price data represent acquisition costs for different purchaser types.⁴⁶ Additionally, a sufficient empirical foundation does not exist for

⁴³Medicare has a process under which facilities can appeal the denial of a claim by showing that it is medically necessary. 42 U.S.C. § 1395ff (2000).

⁴⁴Effective October 2006, CMS revised the monitoring policy to, among other things, clarify its policy for reporting dosage reductions.

⁴⁵[GAO-06-971T](#), [GAO-06-372](#), and [GAO-06-17R](#).

⁴⁶In a report to the Congress, CMS stated that it was unable to obtain net acquisition cost data and average sales price data by purchaser type due to the proprietary nature of drug pricing information. See HHS, *Report to Congress—Report on Sales of Drugs and Biologicals to Large Volume Purchasers* (Washington, D.C.: 2006).

setting the payment rate for Medicare Part B drugs at 6 percent above ASP, further complicating efforts to determine the appropriateness of the rate.

The ASP payment method is of particular concern with respect to Epogen because it is the only product available in the ESRD market for anemia management. The ASP method relies on market forces to achieve a favorable payment rate for Medicare—that is, one that is sufficient to maintain beneficiary access but not overly generous for providers and therefore wasteful for taxpayers. In principle, under ASP, when two or more clinically similar products exist in a market, market forces could serve to bring prices down, as each manufacturer competes for its own product's market share. In contrast, when a product is available through only one manufacturer, Medicare's rate lacks the moderating influence of competition. For this reason, Medicare's ASP method may not be appropriate for Epogen, which is the product of a single manufacturer and has no competitor products in the ESRD market. The lack of price competition may be financially insignificant for noncompetitive products that are rarely used, but for Epogen, which is pervasively and frequently used, the lack of price competition could be having a considerable effect on Medicare spending.

Since the introduction of Epogen in the ESRD anemia management market, it has been difficult for competitor products to enter this market. Amgen, Epogen's manufacturer, has held seven patents on Epogen, the first of which was granted in 1987 and the last of which expires in 2015; Amgen has obtained injunctions against pharmaceutical firms seeking to market their anemia management drugs in the United States. However, competitor products may enter the U.S. market in the near future. There are three potential sources of future competition: a drug that currently exists, drugs that are likely to enter the market soon, and products that are under development. Aranesp is a drug that Amgen manufactures and markets to hospitals and physicians to treat anemia in patients with cancer and chronic kidney disease but generally does not market to ESRD facilities. CERA is a drug that the manufacturer—F. Hoffmann LaRoche—hopes to introduce in the United States sometime in 2007.⁴⁷ Certain

⁴⁷Amgen has filed suit in U.S. District Court against F. Hoffmann LaRoche to prevent it from marketing CERA in the United States on the grounds that CERA violates Amgen's patents. Although the patent infringement case has not been resolved, industry analysts expect that F. Hoffmann LaRoche will launch CERA "at risk" in 2007, after getting approval from FDA. Launching at risk here means marketing the product at the risk of incurring damages for patent infringement.

products currently in development, which are several years away from entering the market, could have a distinct advantage over injectable products, as they are expected to be long-lasting oral therapies.^{48,49}

Bundling Is Fundamental to Medicare Payment Policy, but System to Expand Composite Rate Bundle to Include All ESRD Drugs Remains in Design Phase

The composite rate for routine dialysis-related services was the first of Medicare's several payment systems that, in broad terms, sets a fixed, prospective rate for a set of clinically related services. Consistent with this payment policy, the Congress has required CMS to develop a system that would no longer pay for each injectable ESRD drug under a separate rate but would bundle payment for these drugs together with other ESRD services under a single rate. A bundled rate would have advantages for achieving efficiency and greater clinical flexibility. CMS's design of a bundled rate is under way but behind schedule, making the implementation of a fully bundled payment system, based on this design, at least several years away. Any payment system changes based on CMS's report or demonstration would require legislation.

Bundling Intended to Encourage Efficiency and Clinical Flexibility While Discouraging Unnecessary Use

Medicare's approach to paying for most services provided by facilities is to pay for a group—or bundle—of services using a prospectively set rate. For example, under prospective payment systems, Medicare makes bundled payments for services provided by acute care hospitals, skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities. In creating one payment bundle for a group of associated items and services provided during an episode of care,⁵⁰ Medicare encourages providers to operate efficiently, as providers retain the difference if Medicare's payment exceeds the costs they incur to provide the services. Medicare's

⁴⁸For example, FibroGen recently developed FG-2216 and FG-4592, which are currently in exploratory clinical trials in Europe.

⁴⁹Oral products could be covered under Part D—Medicare's new prescription drug benefit. In this case, payments for them would not be made to dialysis facilities under Medicare Part B.

⁵⁰For example, Medicare's bundled payment for home health services covers a 60-day episode of care.

composite rate for routine dialysis-related services was introduced in 1983 and was the program's first bundled rate.⁵¹

In recent years, we, the Medicare Payment Advisory Commission (MedPAC), and CMS have recommended expanding the bundled payment for ESRD services to include not only the services paid under the composite rate but also the drugs that facilities currently bill for separately.⁵² Experts contend that a bundled payment for dialysis-related services would have two principal advantages. First, it would encourage facilities to provide services efficiently; in particular, under a fixed, bundled rate for a defined episode of care,⁵³ facilities would no longer have an incentive to provide more ESRD drugs than clinically necessary. Second, bundled payments would afford clinicians more flexibility in decision making because incentives to prescribe a particular drug or treatment are reduced.

For example, certain clinical alternatives are, according to some ESRD experts, advantageous to patients and could result in the use of less Epogen, but these alternatives are not encouraged under the current payment system. Studies have shown that daily hemodialysis—which some experts contend is clinically preferable—reduced the need for Epogen in some ESRD patients with anemia.⁵⁴ However, Medicare coverage is limited to three dialysis treatments a week. Under a bundled payment, facilities would have the flexibility to increase the number of

⁵¹In 1978, the Secretary of HHS was required to prescribe methods and procedures for determining the amount Medicare should pay for ESRD services and to provide appropriate incentives to encourage more efficient and effective delivery of services including, to the extent feasible, prospectively set payment rates. Pub. L. No. 95-292, sec. 2, § 1881(b)(2)(B), 92 Stat. 307, 309 (codified as amended at 42 U.S.C. § 1395rr(b)(2)(B) (2000)).

⁵²See [GAO-04-450](#), MedPAC (March 2006) and (March 2001), and HHS (May 2003).

⁵³In the case of the composite rate, one dialysis session constitutes an episode of care. Unlike the current composite rate payment method, a newly designed payment bundle could define the episode of care more broadly. For example, the new payment bundle could cover dialysis and related items and services for 1 month.

⁵⁴See Francesco Locatelli and Lucia Del Vecchio, "Dialysis Adequacy and Response to Erythropoietic Agents: What is the Evidence Base?" *Nephrology Dialysis Transplantation*, vol. 18, supp. 8 (2003), Ezio Movilli et al., "Adequacy of Dialysis Reduces the Doses of Recombinant Erythropoietin Independently from the Use of Biocompatible Membranes in Haemodialysis Patients," *Nephrology Dialysis Transplantation*, vol. 16, no.1 (2001), and Onyekachi Ifudu et al., "The Intensity of Hemodialysis and the Response to Erythropoietin in Patients with End-Stage Renal Disease," *The New England Journal of Medicine*, vol. 334, no. 7 (1996).

weekly dialysis treatments and reduce their use of Epogen. Studies have also shown that patients who receive subcutaneous instead of intravenous injections of epoetin and patients undergoing peritoneal dialysis instead of hemodialysis need less epoetin to manage their anemia.^{55,56} Under the current payment system, which pays facilities for epoetin on a per administration basis, facilities have an incentive to select the epoetin delivery method and the dialysis modality that maximize their Medicare revenue. Under a bundled payment, facilities would have less incentive to choose the costlier intravenous over subcutaneous injections of epoetin or the costlier hemodialysis over peritoneal dialysis.

Facility representatives, ESRD experts, and other interested parties we spoke with generally supported a bundled payment for dialysis-related items and services while underscoring the importance of certain elements as part of the bundled payment system. First, facility representatives noted that bundled payments called for a case-mix adjuster—that is, a mechanism to account for the differences in the mix of more expensive and less expensive patients across facilities. Without accounting for these differences, facilities that treated a disproportionate share of costly patients would be financially disadvantaged.

Second, some facility representatives noted that an automatic payment update would be needed to adjust the bundled rate for inflation, consistent with Medicare's other bundled payment systems that are updated automatically on an annual basis. They pointed out that the current ESRD

⁵⁵In recent studies, researchers have determined that subcutaneous delivery of epoetin, compared with intravenous delivery, could result in significant cost savings to Medicare. See Denise Hynes et al., "Potential Cost Savings of Erythropoietin Administration in End-Stage Renal Disease," *The American Journal of Medicine*, vol. 112, no. 3, (2002), Anatole Besarab et al., "Meta-Analysis of Subcutaneous Versus Intravenous Epoetin in Maintenance Treatment of Anemia in Hemodialysis Patients," *American Journal of Kidney Diseases*, vol. 40, no. 3 (2002), and Laura Pizzi et al., "Economic Implications of Non-Adherence to Treatment Recommendations for Hemodialysis Patients with Anemia," *Dialysis and Transplantation*, vol. 35, no. 11 (2006).

⁵⁶See Francisco Coronel et al., "Erythropoietin Requirements: A Comparative Multicenter Study Between Peritoneal Dialysis and Hemodialysis," *Journal of Nephrology*, vol 16, no. 5 (2003) and Jon Snyder et al., "Hemoglobin Levels and Erythropoietin Doses in Hemodialysis and Peritoneal Dialysis Patients in the United States," *Journal of the American Society of Nephrology*, vol. 15, no. 1 (2004).

composite rate is Medicare's only payment bundle that does not receive an automatic update.⁵⁷

Third, ESRD experts we spoke with noted that, under bundling, the incentive to overuse services is blunted, but the incentive to underuse services is present. For example, facilities could choose to provide too little Epogen to patients with anemia because they would save money providing less of this costly drug. These individuals commented that CMS's monitoring policy, which currently focuses on overutilization of Epogen, would need to refocus its attention on underutilization to ensure that under a bundled payment system ESRD patients received appropriate levels of Epogen and other dialysis-related drugs and services.

Implementation of Bundled Payment System for ESRD Services Could Be Years Away

The MMA mandated a two-pronged approach for CMS to study the creation of a bundled payment method. It required CMS to submit a report to the Congress on a bundled payment system design in October 2005 and start a 3-year bundling demonstration in January 2006.⁵⁸ The legislation linked the two requirements by directing CMS to base the design of the bundling demonstration on the content of the mandated report. It also required CMS to obtain input on the demonstration's design and implementation from an advisory panel that included industry and government experts. The report had not been issued nor had the demonstration been launched as of November 2006. Any payment system changes based on CMS's report or demonstration would require legislation.⁵⁹

The report and demonstration efforts, led by two different organizational units in CMS, face similar design considerations. Both must define the ESRD services to be included in a payment bundle, design a case-mix adjustment model to account for differences in patients' use of resources, and develop a payment policy for exceptional cases, known as an outlier policy. However, despite similar goals, each unit has a different focus.

⁵⁷Since the MMA provisions became effective, the drug add-on payment to the composite rate is updated annually, but adjustments to the base rate are not automatic; only seven adjustments have been made in the last 23 years.

⁵⁸MMA § 623(e)–(f), 117 Stat. 2315-16.

⁵⁹The MMA specified that drugs billed separately when it was enacted continue to be billed separately and not bundled into the composite rate. MMA sec. 623(d)(1), § 1881(b)(13)(B), 117 Stat. 2314-15 (to be codified at 42 U.S.C. § 1395rr(b)(13)(B)).

Essentially, the unit responsible for the report is designing a bundled payment system that is intended to be implemented programwide and expeditiously, following congressional approval. In contrast, the unit responsible for the demonstration is designing a bundled payment system that is intended to be implemented on a limited and self-selective basis—that is, through facilities’ voluntary participation in the demonstration.

The time frame for implementing a bundled payment system based on CMS’s report is uncertain. Officials could not tell us when the report would be available. Furthermore, additional time is needed for the Congress to review the report and possibly pass legislation based on the report. CMS officials predict that it would take a minimum of 18 months to fully implement the system, once legislation had been enacted.

The start of the bundled payment demonstration is similarly subject to an uncertain chain of events. Specifically, under MMA, CMS cannot launch its demonstration before considering the information in its mandated report.⁶⁰ However, once demonstration staff are able to consider the report’s information, CMS can begin taking steps to solicit proposals for participation by dialysis facilities. The selection process involves screening applications for conformance with the demonstration’s criteria and the awarding of contracts. This process can take a minimum of several months. Demonstration staff anticipate that the demonstration will start in October 2007. Under this time line, they expect that the first useable results will be available 12 months later, or October 2008. On the basis of these results, the Congress could choose to pass legislation to change the ESRD payment system. Because CMS typically makes mandated payment changes effective at the beginning of calendar years, and because such changes require a several-month period of rulemaking and public comment, the earliest payment year that could be informed by demonstration results is 2010.

⁶⁰A step toward implementing the demonstration has already been taken. Largely as an incentive for facilities to participate, CMS is incorporating “pay for performance” in its bundled payment design—that is, a mechanism that would link a facility’s conformance to ESRD quality standards to Medicare’s payment rate. In July 2006, CMS solicited proposals for a contractor to develop the pay-for-performance component of the bundling demonstration; subsequently, CMS awarded a contract.

Conclusions

The rationale for Medicare to continue paying for Epogen and other ESRD drugs outside of a payment bundle has diminished over time. Composite rate updates and add-ons, coupled with the overhaul of payment for Part B drugs, have moved Medicare toward paying more appropriately for ESRD services. Nevertheless, under the ASP payment method—which pays for separately billable ESRD drugs on a per administration basis—facilities continue to have an incentive to use these drugs more than may be necessary. Paying for Epogen under ASP presents an additional dilemma: as a single-source drug in a market with no competitor products, Epogen is not subject to the moderating effects that competition can have on price.

In our view, Medicare could realize greater system efficiency if all ESRD services, including drugs, were bundled under a single payment. A bundled payment—suitably adjusted for differences across facilities in their mix of patients—would encourage facilities to use drugs more prudently, as they would have no financial incentive to use more than necessary and could retain the difference between Medicare’s payment and their costs. At the same time, because treatment choices would be payment neutral, clinicians would have more flexibility to try different treatment combinations of items and services paid for in the bundle. To account for facilities’ increased or decreased costs over time, a reexamination of the bundled rate may be necessary periodically. In the case of Epogen, for example, if other competitor products entered the market in the future, the costs facilities would incur to treat anemia could decline. By adjusting the payment bundle accordingly, Medicare could realize the benefits of such cost reductions.

CMS’s time line is considerably protracted for issuing the mandated report on a bundled ESRD payment system and conducting a demonstration that remains under development. The time needed to complete these steps makes the prospect of implementing such a system several years away.

Matter for Congressional Consideration

In light of the uncertain time frame for CMS’s test of bundling and the potential for bundling to eliminate financial incentives to overuse separately billable drugs, the Congress should consider establishing a bundled payment system for all ESRD services as soon as possible.

Agency and Industry Comments and Our Evaluation

Comments from CMS

In written comments on a draft of this report, CMS noted its appreciation of our interest in ensuring an appropriate payment system for all ESRD services and stated that our findings will be useful to the agency in fulfilling its commitment to reform the ESRD payment system. The agency generally agreed with our view that all ESRD services should be included under a bundled payment system but expressed the need to resolve implementation issues, primarily that the development of a sound case-mix adjuster be finalized. It stated that such a system should also promote efficiency and clinical flexibility for ESRD facilities and should guard against incentives to undertreat ESRD patients in order to maximize profits. We agree that a fully bundled system will require an adequate case-mix adjuster and a monitoring system to ensure patients receive adequate care. At the same time, we are asking the Congress to consider acting as soon as possible, acknowledging that the Congress would likely want to receive and consider CMS's research findings and recommendations before establishing a new payment system.

CMS observed that it has devoted considerable time and resources to developing an appropriate ESRD payment system, including research on case-mix adjusters and quality incentives. Specifically, the agency noted that the implementation in April 2005, of the case-mix adjusted composite rate as required by the MMA of 2003 was a significant accomplishment. CMS has also pursued several research approaches in its efforts to create a demonstration of a fully bundled ESRD payment system and expects to build on these prior efforts to form the basis for ESRD payment reform. We commend CMS for its attention to research on ESRD payment and encourage the agency to expedite the completion of its report to the Congress. CMS also mentioned the importance of collecting data on patient outcomes. We appreciate the importance of collecting these data, but this issue was beyond the scope of this report. CMS provided technical comments, which we incorporated as appropriate. We have reprinted CMS's letter in appendix I.

Comments from Industry Representatives

We invited representatives of drug manufacturers, large and small dialysis facility organizations, and a nephrologist specialty association to review and comment on the draft report. The groups represented were Amgen Inc. (Amgen), F. Hoffmann-La Roche Ltd. (Roche), the Kidney Care Council (KCC), the National Renal Administrators Association (NRAA), and the Renal Physicians Association (RPA). Several of the industry groups noted that the report was well written, thorough, and covered many of the issues affecting dialysis providers. The bulk of the groups' comments focused on three general issues central to the message of our report: the increase in utilization of Epogen over time, the current ASP-based payment system for ESRD drugs, and the implementation of a fully bundled ESRD payment system.

First, Amgen, KCC, Roche, and NRAA noted that the report did not fully explain why utilization of Epogen has grown over time or why the growth rate has slowed in recent years. Amgen stated that the draft report did not sufficiently cover the goal of Epogen therapy—which is to increase patient Hct levels—and its link to improved quality of life for dialysis patients. KCC noted that while the average Epogen dose has increased over time, patient outcomes—as measured by average Hct levels—have also improved. KCC further contended that because Epogen utilization has remained relatively flat in recent years, providers are not responding to the incentive to overuse ESRD drugs. Roche maintained that the slow growth in Epogen use over the past few years is attributable to more patients' having achieved Hct levels within the target range. NRAA added that the slower growth of Epogen use is positive because it demonstrates that providers use less Epogen as more patients reach the target Hct range.

In our report, we discuss the utilization of Epogen rather than the clinical outcomes associated with that utilization. In response to the groups' comments, we have added information that describes the benefits of Epogen therapy as well as data on patient Hct levels prior to the MMA payment changes. Although we do not take a position on whether the drug is overutilized at the levels we report, we stand by our contention that an inherent incentive to maximize revenues exists when items are paid for on a cost-plus (e.g., ASP+6 percent), fee-for-service basis. It is because of the inherent nature of this incentive that we recommend combining payment for ESRD drugs with all dialysis services under a single bundled rate.

Second, all of the groups commented on our discussion in the report of the current ASP-based payment method for separately billable ESRD drugs, with some groups expressing concerns about an abrupt movement to a fully bundled rate. Amgen noted that the ASP method is relatively new and that it is too early to decide whether to move to a fully bundled rate. In addition, Amgen was concerned with our characterization of ASP payment issues associated with Epogen and stated that the entry of a new anemia management product may not necessarily result in reduced prices. Two of the organizations noted that, prior to moving to a bundled rate, a transitional system—one that encourages price competition for anemia management drugs—may be desirable. Roche stated that continuing to use the ASP-based payment system for Epogen could have negative downstream effects on a fully bundled ESRD payment system, as any price increases prior to bundling would be captured in the dollar amounts allocated for anemia management drugs included in the bundle. Similarly, KCC stated that an alternative payment system should be explored prior to bundling. KCC also stated that, as long as there is no viable clinical alternative to Epogen, bundling by itself would not provide for clinical flexibility, nor would bundling alone ensure drug price stability. KCC suggested that a transitional system could involve paying for drugs at ASP and transferring the rate's current 6 percent add-on to the composite rate. In general, both RPA and NRAA viewed the ASP-based payment method for ESRD drugs favorably. RPA specifically referred to the recent legislative and regulatory actions, including the move to an ASP-based rate, as "responsible," because payments for separately billable drugs were lowered while the composite rate was increased.

Our discussion of the ASP-based payment method focuses on payment for separately billable drugs in general and on Epogen in particular because of its market domination and the high Medicare expenditures associated with it. We agree that the introduction of a competitor product may not result in immediate price reductions, but note that, in principle, competition tends to lower prices over time. Although we acknowledge that there may be a better way to pay for separately billable drugs than ASP+6 percent, our focus is on the need to mitigate the incentives that can undermine the efficient use of resources in ESRD care. Any transitional system that allows separate billing for individual drugs perpetuates the incentive to maximize revenues through utilization of these drugs. We agree that bundling by itself cannot solve problems resulting from the lack of price competition. However, as noted in our draft report, if price competition were introduced under a bundled payment system, it could result in lower treatment costs for providers and—after adjustments to the bundle for these lower costs—could result in savings for Medicare.

Finally, representatives from four of the groups expressed concerns about implementation challenges associated with a payment bundle. Consistent with CMS's position and the position of experts cited in our draft report, Amgen and KCC emphasized the importance of appropriate case-mix adjustment in a bundled payment system. KCC underscored the considerable variation in patients' need for Epogen and the role of the case-mix adjuster to ensure adequate compensation for providers treating patients needing unusually high levels of the drug. RPA, NRAA, and KCC were concerned that bundling could limit innovation in the ESRD market or that physicians would be reluctant to use any new ESRD drugs that facilities would find to costly to cover within the payment bundle. Consistent with this concern, NRAA noted that the payment bundle methodology should have a mechanism to ensure the appropriate incorporation of new technologies and treatment protocols.

We agree that an appropriate case-mix adjuster is important to a bundled payment system and noted in the draft report that adjusting for differences in patients' needs was a key point made by interested parties we contacted. We acknowledge that if the payment bundle does not account for patient differences, facilities that treat a disproportionate share of costly patients would be financially disadvantaged. We note that CMS has done extensive research on case-mix adjustment in a fully bundled ESRD payment system and believe that any new system will benefit from these efforts. We also agree that a new payment bundle should be periodically updated to reflect the costs of current technologies and treatment protocols. Specific details on the contents of a bundle, its implementation, and evaluation over time were beyond the scope of this report.

As we agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this letter. At that time, we will send copies of this report to the appropriate congressional committees and other interested parties. We will also make copies available to others upon request. This report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staff have questions about this report, please contact me at (202) 512-7101 or steinwalda@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

Sincerely yours,

A handwritten signature in black ink that reads "A. Bruce Steinwald". The signature is written in a cursive style with a large, stylized "S" at the end.

A. Bruce Steinwald
Director, Health Care

Appendix I: Comments from the Centers for Medicare & Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: NOV 9 2006

TO: A. Bruce Steinwald
Director, Health Care

FROM: Leslie V. Norwalk, Esq.
Acting Administrator

SUBJECT: Government Accountability Office's Draft Report: "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)

Thank you for the opportunity to review and comment on the Government Accountability Office's (GAO) draft report entitled, "END-STAGE RENAL DISEASE: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility." We appreciate the GAO's interest in ensuring an appropriate payment system for all end-stage renal disease (ESRD) services and thank you for your efforts on this report.

The GAO's findings provide useful information that will help us fulfill our commitment to reform the ESRD payment system in a way that supports high quality care and appropriate payment for services. The report recommends, in light of the uncertainties concerning the timing of the Report to Congress and demonstration, that Congress consider establishing a bundled payment system for all ESRD services as soon as possible.

Specifically, it recommends the immediate implementation of a bundled payment system suitably adjusted for differences across facilities in their mix of patients, and notes that facility representatives generally support bundled payment. This support for bundled payment would appear to be conditioned on: (1) the implementation of an acceptable method of case mix adjustment, without which facilities treating a disproportionate number of costly patients would be disadvantaged; (2) establishing an annual update factor to adjust the bundled payment for inflation; and (3) implementation of safeguards to protect against potential underutilization of services.

GAO Recommendation:

Congress should consider establishing a bundled payment system for all ESRD services as soon as possible.

Page 2 – A. Bruce Steinwald

CMS Response:

We appreciate the GAO's support of Medicare payment reform in recommending that Congress take action to implement a fully bundled prospective payment system (PPS) for dialysis services provided by ESRD facilities. The Centers for Medicare & Medicaid Services (CMS) agrees with the GAO that reforms in this area should move forward "as soon as possible." However, CMS also believes the timeframe should ensure adequate research and development to support implementation of a system that pays fairly while supporting high quality care through mechanisms such as pay-for-performance.

We also agree that such a system should promote efficiency and clinical flexibility for ESRD facilities. We believe the system should guard against incentives to under-treat or "cherry-pick" ESRD patients in order to maximize profits. While the report briefly addresses this concern, we would like to emphasize that accomplishing these goals will require that (1) research be complete to ensure an adequate case mix adjustment system for a fully bundled system and (2) prior to implementation, mechanisms be in place to ensure beneficiary protections with respect to quality of care.

We also wish to note CMS' significant accomplishments in implementing the basic case mix adjusted composite rate system required by the MMA. After enactment of the new law, CMS funded research activities to develop new case-mix adjustments that were implemented in April 2005. Since then, CMS has pursued several research approaches that could be used in a demonstration of a bundled PPS. However, we are not yet satisfied that the results achieve our goals related to quality and payment accuracy. Thus, we have devoted a considerable amount of time and resources to developing an appropriate ESRD payment system including research targeted on case mix adjusters and quality incentives. We expect our current efforts, building on the prior research, will provide the basis for payment reform in this area.

While the report does not make a specific recommendation on the issue, GAO might consider the benefits of linking a bundled payment system with a requirement that ESRD facilities report outcomes data for 100 percent of their patients. Such data would allow monitoring quality of care under a bundled PPS that could address potential concerns about ESRD beneficiaries being vulnerable to substandard care. CMS is in the process of developing a Web-based ESRD data system that could be used to collect such data electronically by 2009.

The CMS would like to thank the GAO for their efforts on this report. These findings provide us with useful information that will assist us in moving forward with development of a bundled payment system for all ESRD services. We look forward to working collaboratively in the future to address the recommendations in this report.

We have also provided technical comments for your consideration.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

A. Bruce Steinwald (202) 512-7101 or steinwalda@gao.gov.

Acknowledgments

Phyllis Thorburn, Assistant Director; Jessica Farb; Hannah Fein; Zachary Gaumer; and Shivani Sharma made key contributions to this report.

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