United States Government Accountability Office

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Report to Congressional Requesters

March 2010

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

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Highlights

Highlights of GAO-10-295, a report to congressional requesters

Why GAO Did This Study

Medicare covers dialysis for most individuals with end-stage renal disease (ESRD). Beginning in January 2011, the Centers for Medicare & Medicaid Services (CMS) is required to use a single payment to pay for dialysis and related services, which include injectable ESRD drugs. Questions have been raised about this new payment system's effects on the access to and quality of dialysis care for certain groups of beneficiaries, such as those who receive above average doses of injectable ESRD drugs. GAO examined (1) Medicare expenditures for injectable ESRD drugs, by demographic characteristics; (2) factors likely to result in above average doses of these drugs; (3) CMS's approach for addressing beneficiary differences in the cost of dialysis care under the new payment system; and (4) CMS's plans to monitor the new payment system's effects. GAO analyzed 2007 data—the most recent available—on Medicare ESRD expenditures and input from 73 nephrology clinicians and researchers collected using a Web-based data collection instrument. GAO also reviewed reports and CMS's proposed rule on the payment system's design and interviewed CMS officials.

What GAO Recommends

GAO recommends that CMS begin monitoring access to and quality of dialysis care for certain beneficiary groups as soon as possible after implementation of the new payment system. CMS agreed with this recommendation.

View GAO-10-295 or key components.
For more information, contact James C. Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

Certain demographic groups had above average Medicare expenditures for injectable ESRD drugs in 2007. For example, Medicare spent $782 per month on injectable ESRD drugs per African American beneficiary, which was about 13 percent more than the average across all beneficiaries on dialysis and was also higher than for other racial groups. Similarly, monthly Medicare spending per beneficiary with additional coverage through Medicaid was about 6 percent higher than the average across all beneficiaries on dialysis.

Although GAO did not identify the factors that led to the differences described above, it did obtain information from 73 nephrology clinicians and researchers, selected through referrals from dialysis-related professional organizations and a literature review, on the factors that they consider likely to result in above average doses of injectable ESRD drugs. A majority of these experts identified primarily clinical factors as likely to result in above average doses of these drugs. For example, at least 50 percent of the 73 clinicians and researchers from whom GAO obtained information identified 14 factors (including chronic blood loss and low iron stores) as likely to result in above average doses of erythropoiesis stimulating agents, which accounted for about 75 percent of expenditures on injectable ESRD drugs in 2007.

CMS's proposed design for the new payment system for dialysis care includes, as required by law, two payment mechanisms to address differences across beneficiaries in their costs of dialysis care. Under the first payment mechanism—a case-mix adjustment—CMS proposed to adjust payments based on characteristics such as age, sex, and certain clinical conditions that are associated with beneficiaries' costs of dialysis care. The second proposed payment mechanism—an outlier policy—involves making additional payments to providers when they treat patients whose costs of care are substantially higher than would be expected.

CMS's preliminary plans for monitoring the effects of the new payment system build on existing initiatives, but it is unclear whether CMS will monitor the effects on the quality of and access to dialysis care for groups of beneficiaries. In prior work, GAO and others have emphasized the importance of monitoring both the quality of and access to care to ensure that Medicare payment system changes do not result in certain groups of beneficiaries experiencing poor care quality or problems accessing services. CMS intends to monitor the quality of dialysis care under the new payment system, but the extent to which CMS will conduct such monitoring for various groups of beneficiaries is currently unclear because CMS's plans are preliminary. Furthermore, CMS's preliminary plans for monitoring access to dialysis care are limited. However, CMS has stated that it will have a comprehensive monitoring strategy in place by January 2011.

GAO obtained comments on a draft of this report from CMS and from industry groups representing both large and small dialysis providers and nephrologists.

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Abbreviations

AV	arteriovenous
BMI	body mass index
CMS	Centers for Medicare & Medicaid Services
CPM	clinical performance measure
CROWNWeb	Consolidated Renal Operations in a Web-Enabled Network
EDB	Enrollment Database
ESA	erythropoiesis stimulating agent
ESRD	end-stage renal disease
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
IV	intravenous
KCC	Kidney Care Council
MedPAC	Medicare Payment Advisory Commission
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
NRAA	National Renal Administrators Association
PTH	parathyroid hormone
QIP	quality incentive program
REMIS	Renal Management Information System
RPA	Renal Physicians Association
UM-KECC	University of Michigan Kidney Epidemiology and Cost Center
USRDS	United States Renal Data System
VA	Department of Veterans Affairs

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United States Government Accountability Office
Washington, DC 20548

March 31, 2010

The Honorable Pete Stark
Chairman
Subcommittee on Health
Committee on Ways and Means
House of Representatives

The Honorable John Lewis
Chairman
Subcommittee on Oversight
Committee on Ways and Means
House of Representatives

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.[1] Since the implementation of Medicare's coverage for dialysis care in 1973, hundreds of thousands of lives have been extended through Medicare-covered dialysis treatment. In 2007, Medicare's dialysis population numbered about 414,000, and program expenditures for dialysis and injectable ESRD drugs were about $6.8 billion.[2] Beginning in 2011, the Centers for Medicare & Medicaid Services (CMS), the agency within the Department of Health and Human Services (HHS) that administers Medicare, will change how Medicare pays for dialysis and related services to better encourage the

[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 both Medicare Parts A and B. 42 U.S.C. § 426-1. Medicare Part A covers inpatient hospital, skilled nursing facility, and hospice care, as well as some home health care. Medicare Part B covers outpatient dialysis services, injectable ESRD drugs, physician services, hospital outpatient services, and certain other services, such as physical therapy. Medicare Part D covers outpatient prescription drugs.

[2]Medicare beneficiaries generally are responsible for a portion of the cost of Medicare-covered services they receive. For the purposes of this report, we exclude beneficiary cost-sharing amounts from Medicare expenditures.

efficient provision of care.[3] Policymakers and others have raised questions about how this change could affect ESRD beneficiaries.[4]

For payment purposes, CMS currently divides dialysis and related services into two groups—one group that is paid for under a single payment and a second group in which services are paid for on a per-service basis. The first group includes dialysis treatment and associated routine services such as nursing, supplies, and equipment. Medicare pays for services in this group under a single payment—referred to as the composite rate—which is a common form of Medicare payment also known as bundling.[5] Medicare uses bundled payments in order to give providers a financial incentive to furnish care efficiently, as providers retain the difference if Medicare's payment exceeds the costs of providing services. On the other hand, providers bear financial liability if the cost of beneficiaries' care exceeds Medicare's payment. Under the current payment system for dialysis care, Medicare uses what is known as a case-mix adjustment to adjust the composite rate in order to account for basic differences in beneficiaries' expected care needs and therefore in the cost of their dialysis care.[6] These differences can be related to beneficiaries' demographic and clinical characteristics. Medicare pays for a second group of dialysis-related services, which were either not routine or not available in 1983 when Medicare implemented the composite rate, on a per-service basis. These separately billable services include injectable ESRD drugs as well as services such as laboratory tests and supplies that are used during the course of dialysis. Injectable ESRD drugs accounted for about 86 percent of Medicare expenditures on all separately billable ESRD services in 2007.

[3]See Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 153, 122 Stat. 2494, 2553-59 (codified at 42 U.S.C. § 1395rr).

[4]See for example, Amar A. Desai et al., "Is there 'Cherry Picking' in the ESRD Program? Perceptions from a Dialysis Provider Survey," *Clinical Journal of the American Society of Nephrology*, vol. 4, no. 4 (2009), and Areef Ishani et al., "Possible Effects of the New Medicare Reimbursement on African Americans with ESRD," *Journal of the American Society of Nephrology*, vol. 20, no. 7 (2009).

[5]In addition to dialysis, Medicare makes bundled payments for services such as home health, skilled nursing, inpatient hospital, and inpatient rehabilitation care.

[6]The composite rate for dialysis services is adjusted based on beneficiaries' age, body surface area, and body mass index (BMI). BMI is based on a person's height and weight and is commonly used to indicate whether he or she is underweight or obese.

Because providers can receive more Medicare payments for prescribing more injectable ESRD drugs, we and others have raised concerns that paying for this care on a per-service basis creates an incentive to use more of these drugs than necessary.[7] Such use could have adverse effects on ESRD patients and contribute to unnecessary Medicare spending. In 2006, we recommended using a single bundled payment for dialysis care because it would improve efficiency by reducing the incentive to use more injectable ESRD drugs than necessary.[8]

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires CMS to implement a new expanded bundled payment system for dialysis care beginning on January 1, 2011.[9] In September 2009, CMS issued a proposed rule that described the design of the expanded bundled payment system in addition to preliminary plans for monitoring the quality of dialysis care beneficiaries receive once the system is implemented.[10] Under this new payment system, CMS will use a single bundled payment to cover all ESRD services that are currently covered under the composite rate or are paid for separately.[11] MIPPA requires that CMS use a case-mix adjustment to account for differences across beneficiaries in the cost of their dialysis care, which could be related to beneficiaries' demographic and clinical characteristics.[12] MIPPA also requires CMS to have an outlier policy, which involves making payments to providers in addition to the bundled payment for beneficiaries whose costs of care are substantially higher than would be expected for these beneficiaries. There are concerns, however, that if the case-mix adjustment and outlier policy do not adequately account for differences

[7]See, for example, 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), and Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C., March 2001).

[8]See GAO-07-77.

[9]Pub. L. No. 110-275, § 153, 122 Stat. at 2553-59.

[10]Medicare Programs; End-Stage Renal Disease Prospective Payment System, 74 Fed. Reg. at 49,922 (proposed Sept. 29, 2009). CMS extended the period for comment on the proposed rule for 30 days on November 4, 2009. Extension of Comment Period, 74 Fed. Reg. at 57,127 (Nov. 4, 2009).

[11]MIPPA also directs GAO to report on the implementation of the expanded bundled payment system by March 1, 2013. Section 153(d), 122 Stat. at 2259-60. We will fulfill this mandate in a future report.

[12]Section 153(b), 122 Stat. at 2253-55 (codified at 42 U.S.C. § 1395rr(b)(14)).

across beneficiaries in the cost of care, some beneficiaries could have their access to or quality of dialysis care adversely affected. Specifically, providers may be discouraged from treating or provide poor quality care to certain groups of beneficiaries. Beneficiaries who require higher-than-average doses, or amounts, of injectable ESRD drugs may be particularly vulnerable to the potential of such adverse effects on access and quality because of their above average costs for these services.

You asked us to report on the characteristics of beneficiaries with above average doses of injectable ESRD drugs who therefore may be particularly vulnerable to adverse effects under the new bundled payment system for dialysis services, and on ways to ensure that such beneficiaries have adequate access to and quality of dialysis care. This report (1) provides information on Medicare expenditures for injectable ESRD drugs, by beneficiaries' demographic characteristics; (2) identifies the factors that clinicians and researchers indicate are likely to result in a higher-than-average dose of injectable ESRD drugs for a dialysis patient; (3) describes CMS's approach for addressing differences among beneficiaries in the cost of dialysis care under the new bundled payment system for these services; and (4) examines CMS's plans for monitoring the effects of the new bundled payment system on beneficiaries.

To provide information on Medicare expenditures for injectable ESRD drugs, by beneficiaries' demographic characteristics, we analyzed the most recent available data from a national data system containing information on beneficiaries with ESRD. Specifically, we obtained 2007 data from the United States Renal Data System (USRDS) for 326,899 of the 413,540 Medicare beneficiaries on dialysis that year.[13,14] We calculated monthly Medicare expenditures per beneficiary on injectable ESRD drugs in 2007.[15,16] We focused our analysis on three types of injectable ESRD

[13]USRDS 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 of the National Institutes of Health in conjunction with CMS.

[14]We excluded beneficiaries (1) who were in Medicare managed care plans, (2) for whom Medicare was not the primary payer, or (3) for whom no claims for Medicare services in 2007 were submitted.

[15]We analyzed monthly expenditures to correspond to Medicare's monthly billing cycle for ESRD services.

[16]We also analyzed data for 2003 through 2006 to determine whether results based on 2007 USRDS data were consistent over time.

drugs—erythropoiesis stimulating agents (ESA), intravenous (IV) iron, and IV vitamin D—because they accounted for about 98 percent of the approximately $2.2 billion in Medicare expenditures for injectable ESRD drugs in 2007. We analyzed these expenditures across the following demographic characteristics available through the USRDS database: age, sex, race, ethnicity, urban/rural residential location, and whether a beneficiary was enrolled in Medicaid.[17] We did not examine the extent to which the associations we report on between demographic characteristics and Medicare expenditures reflect underlying clinical or other factors. The USRDS data we analyzed on race and ethnicity are based on subjective determinations of beneficiaries' racial and ethnic identity. We assessed the reliability of the USRDS data we used by interviewing officials responsible for producing these data, reviewing relevant documentation, comparing the 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. (See app. I for more detail on our scope, methodology, and data reliability.)

To identify the factors that clinicians and researchers indicate are likely to result in a higher-than-average dose of injectable ESRD drugs (specifically, ESAs, IV iron, and IV vitamin D) for a dialysis patient, we developed a structured data collection approach that included interviews with representatives of relevant industry groups, clinicians, and researchers with expertise in ESRD as well as the administration of a Web-based data collection instrument to selected nephrology clinicians and ESRD researchers. Specifically, we conducted 20 structured interviews with representatives of dialysis organizations and dialysis-related professional organizations, nephrology clinicians, and researchers with expertise in ESRD to develop the data collection instrument and provide context for our findings. We also reviewed the clinical literature related to the use of these three types of injectable drugs. We used information from these interviews and our analysis of Medicare expenditures on injectable ESRD drugs to compile a list of factors that may affect the dose of each of the three types of these drugs in our review. Our Web-based data collection instrument asked clinicians and researchers to identify which

[17]Medicaid enrollment is an indicator of socioeconomic status, because beneficiaries' income and asset levels determine their eligibility for financial assistance with the cost of medical care. To be eligible for Medicaid in 2007, an unmarried Medicare beneficiary who was not disabled generally was required to have income of less than 135 percent of the federal poverty level and assets of at most $4,000. The federal poverty level for a single beneficiary in the 48 states and the District of Columbia was $10,210 in 2007.

demographic and clinical factors were more likely to result in a higher-than-average dose for each type of drug. In August and September 2009, we sent our data collection instrument to 131 clinicians and researchers based on referrals from dialysis-related professional organizations and a systematic review of the literature.[18] (See app. I for more information on the criteria used to select potential clinicians and researchers and app. II for the data collection instrument.) Our results represent the opinions of 73 of these selected clinicians and researchers and are not generalizable to a larger population.

To describe CMS's approach for addressing differences among beneficiaries in the cost of dialysis care under the new bundled payment system for these services, we reviewed CMS's proposed rule on the design of this new payment system.[19] We also reviewed reports on the design of this payment system by HHS and the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC), which has assisted CMS with the payment system's design. In addition, we interviewed representatives of the Department of Veterans Affairs (VA) and two large health plans to obtain contextual information about other bundled payment systems.[20,21] Finally, to examine CMS's plans for monitoring the effects of the new bundled payment system on beneficiaries, we interviewed CMS officials and reviewed prior reports as well as CMS's proposed rule on the design of the new bundled payment system.

We conducted this performance audit from November 2008 through March 2010 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

[18]These dialysis-related professional organizations were the American Academy of Nephrology Physician Assistants, the American Nephrology Nurses' Association, the American Society of Nephrology, the American Society of Pediatric Nephrology, the National Kidney Foundation's Council of Advanced Practitioners, the Renal Physicians Association, and Women in Nephrology.

[19]Medicare Programs; End-Stage Renal Disease Prospective Payment System, 74 Fed. Reg. at 49,922 (proposed Sept. 29, 2009).

[20]The two plans whose representatives we interviewed were among the largest in the country with regard to overall plan enrollment.

[21]According to VA officials, VA uses Medicare's current payment system for dialysis care when this care is provided to veterans in non-VA dialysis facilities. The two plans whose representatives we interviewed use bundled payment systems to pay for dialysis care but do not adjust these payments based on demographic or clinical factors.

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.

Background

ESRD is a condition of permanent kidney failure.[22] Treatment options include kidney transplantation and maintenance dialysis. Kidney transplants are not a practical option on a wide scale, as suitable donated organs are scarce. In contrast, dialysis is the treatment used by most beneficiaries with ESRD. Hemodialysis, the most common form of dialysis,[23] is generally administered three times a week at facilities that provide dialysis services.[24,25] During hemodialysis, a machine pumps blood through an artificial kidney, called a hemodialyzer, and returns the cleansed blood to the body. In order to receive hemodialysis treatment, patients must have a vascular access, which is a site on the body where blood is removed and returned during dialysis.[26]

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

[23]In 2007, approximately 93 percent of all dialysis patients underwent hemodialysis therapy. U.S. Renal Data System, *USRDS 2009 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, 2009). Peritoneal dialysis is the other dialysis method and is generally done in the home. Peritoneal dialysis 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.

[24]Dialysis facilities can be freestanding or hospital-based, for-profit or not-for-profit, and part of a chain or independent. Of the approximately 4,800 dialysis facilities in 2007, about 87 percent were freestanding, about 80 percent were for-profit, and 58 percent were affiliated with the two largest dialysis facility chains. Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C., March 2008).

[25]This frequency is consistent with Medicare's coverage of three hemodialysis treatments a week. Medicare currently pays for additional treatments in a given week if they are justified as medically necessary.

[26]The three basic kinds of vascular access for hemodialysis are an arteriovenous (AV) fistula, an AV graft, and a venous catheter. An AV fistula is a connection between a patient's own vein and artery. An AV graft is a vascular access that connects an artery to a vein using a synthetic tube, or graft, implanted under the skin in the arm. The third type of vascular access is a catheter, which is a tube inserted into a vein in the neck, chest, or leg near the groin.

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. A diagnosis of anemia is determined through a measurement of the level of hemoglobin in the blood.[27] To treat anemia, providers may administer ESAs intravenously in conjunction with IV iron.[28,29,30]

Another complication of ESRD is hyperparathyroidism, which can result from a deficiency of vitamin D. Hyperparathyroidism is typically diagnosed based on the level of parathyroid hormone (PTH) in the blood and can lead to elevated phosphorus levels and low calcium levels in the blood as well as softening of the bones.[31] The treatment of hyperparathyroidism includes the administration of IV vitamin D and oral drugs such as phosphate binders and calcimimetics.[32]

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

[28]There are two types of ESAs—epoetin alfa (brand name Epogen®) and darbepoetin alfa (brand name Aranesp®). In 2007, Epogen accounted for about 92 percent of Medicare expenditures on ESAs. Of the approximately $2.2 billion in Medicare expenditures on injectable ESRD drugs in 2007, about 75 percent was spent on ESAs.

[29]Although iron is most commonly administered intravenously, it can also be given orally.

[30]Over the last several years, researchers and clinicians have debated how to best manage anemia in chronic kidney disease patients, including those with ESRD. Some studies have concluded that using ESAs to achieve higher-than-recommended hemoglobin targets does not reduce, and may sometimes result in, adverse cardiovascular events. See Tilman B. Drueke et al., "Normalization of Hemoglobin Level in Patients with Chronic Kidney Disease and Anemia," *The New England Journal of Medicine*, vol. 355, no. 20 (2006), and 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). Based on the results of these studies and other safety concerns, the Food and Drug Administration (FDA) issued a "black box" warning and required labeling changes for ESAs in 2007. FDA recently announced that all patients receiving ESAs must be provided a medication guide that explains the potential for adverse events while using these products. In the case of ESAs, the medication guides warn of "potential death or other serious side effects." Other researchers have suggested that variability in dosing of ESAs across dialysis facilities treating similar patients may be evidence that some utilization of these drugs is not clinically appropriate. See Mae Thamer et al., "Dialysis Facility Ownership and Epoetin Dosing in Patients Receiving Hemodialysis," *The Journal of the American Medical Association*, vol. 297, no. 15 (2007).

[31]PTH is produced by the parathyroid glands, which are located in the neck. PTH controls calcium, phosphorus, and vitamin D levels within the blood and bone.

[32]Phosphate binders are a group of oral medications designed to reduce the absorption of phosphorus from food and drink. Calcimimetics are oral drugs that reduce PTH levels. Both phosphate binders and calcimimetics are oral drugs currently covered under Medicare Part D for beneficiaries with ESRD.

New Bundled Payment System for Dialysis Care

In September 2009, CMS issued its proposed rule for the design of the new bundled payment system for dialysis care, which is required by law for services furnished on or after January 1, 2011.[33] CMS proposed that under the new bundled payment system, Medicare would continue paying dialysis facilities a bundled payment per dialysis treatment for up to three treatments per week as it does under the current system.[34] However, unlike the current payment system, the new bundled payment would cover ESRD drugs and other separately billable services (for example, laboratory tests related to ESRD treatment) in addition to dialysis services currently covered under the composite rate. Under CMS's proposed rule, the ESRD drugs covered under the new bundled payment would include injectable ESRD drugs as well as oral ESRD drugs, such as calcimimetics, that are currently covered under Medicare Part D.

Accounting for Beneficiary Cost Differences under Medicare Bundled Payment Systems

Bundled payment systems in Medicare typically include a case-mix adjustment and may also use an outlier policy to account for differences in the cost of beneficiaries' care. In general, a case-mix adjustment varies payments based on factors associated with beneficiaries' expected costs of care.[35] As a result, a case-mix adjustment typically increases bundled payments for providers who treat high-cost beneficiaries. In addition, some bundled payment systems under Medicare use an outlier policy to partially offset providers' financial losses for treating beneficiaries whose costs of care substantially exceed what would be expected.[36] To reduce these financial losses, an outlier policy involves making provider payments in addition to the case-mix adjusted bundled rate for these high-cost beneficiaries.

The accuracy with which bundled payments are adjusted to account for differences in beneficiaries' expected costs of care may affect beneficiaries' access to and quality of care. In prior work, we and others have stated that if a bundled payment system's case-mix adjustment is not

[33]Medicare Programs; End-Stage Renal Disease Prospective Payment System, 74 Fed. Reg. at 49,922 (proposed Sept. 29, 2009); Pub. L. No. 110-275, § 153, 122 Stat. at 2553-59.

[34]CMS proposed to pay for additional treatments in a given week if they are medically necessary as it does under the current system.

[35]Medicare uses a case-mix adjustment to adjust bundled payments for services such as home health, skilled nursing, hospital inpatient care, and dialysis.

[36]Medicare uses an outlier policy under bundled payment systems for services such as hospital inpatient, home health, and inpatient rehabilitation care.

designed adequately, then payments may be too low for certain groups of beneficiaries.[37] Further, providers could respond to these inadequate payments by choosing not to treat or inappropriately limiting care for these groups, which could adversely affect these beneficiaries' access to and quality of care.[38,39] We and others have noted that underpaying for care, which could result from an inadequate case-mix adjustment, may result in care of poor quality.[40] In particular, poor quality of care could occur under bundled payment systems if, for example, providers furnish inadequate doses of drugs in an effort to minimize cost. Beneficiaries with above average costs of care may be particularly vulnerable because providers who treat these beneficiaries face the potential of financial losses on these patients if the bundled payments are not adjusted appropriately to take these above average costs into account.

The potential unintended effects of bundled payment systems on beneficiaries have led us and others to note that access to and quality

[37]For example, see GAO, *Medicare Home Health Care: Prospective Payment System Will Need Refinement as Data Become Available*, GAO/HEHS-00-9 (Washington, D.C.: Apr. 7, 2000); Chapin White, Steven D. Pizer, and Alan J. White, "Assessing the RUG-III Resident Classification System for Skilled Nursing Facilities," *Health Care Financing Review*, vol. 24, no. 2 (Winter 2002); 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).

[38]See GAO, *Skilled Nursing Facilities: Medicare Payment Changes Require Provider Adjustments But Maintain Access*, GAO/HEHS-00-23 (Washington, D.C.: Dec. 14, 1999), and Medicare Payment Advisory Commission, *Report to the Congress: Reforming the Delivery System* (Washington, D.C., June 2008).

[39]For the purposes of this report, we define access to care in terms of both potential (i.e., the availability of providers) and realized access (i.e., the use of health services). See Lu Ann Aday and Ronald M. Andersen, "Equity of Access to Medical Care: A Conceptual and Empirical Overview," *Medical Care*, vol. XIX, no. 12, supplement (1981). In addition, we define quality of care to include measures of health outcomes obtained, measures of the appropriateness of health care processes employed, and measures that assess patient perceptions of the care they received.

[40]See GAO/HEHS-00-9; Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C., March 1999); and Steven H. Sheingold, "Unintended Results of Medicare's National Prospective Payment Rates," *Health Affairs*, Winter (1986).

under various Medicare bundled payment systems should be monitored.[41] For example, in 1999, we noted that monitoring access to care would be necessary under Medicare's bundled payment system for skilled nursing care to ensure that Medicare beneficiaries continued to have access to medically necessary services.[42] Similarly, in its 2006 report, the HHS Office of Inspector General stressed the importance of monitoring quality under the bundled payment system for home health care.[43] Our work and work by others has also noted the importance of monitoring the effect of Medicare bundled payment systems on various groups of beneficiaries. Specifically, in 2000 we and the Medicare Payment Advisory Commission (MedPAC) reported on the bundled payment system for home health care and recommended that the delivery of these services be monitored across groups of beneficiaries, such as those whose care is more costly than average.[44] Furthermore, a study on the bundled payment system for inpatient rehabilitation services affirmed the importance of monitoring access to care for various groups of beneficiaries.[45]

[41]See GAO/HEHS-00-23; Melinda Beeuwkes Buntin et al., *Inpatient Rehabilitation Facility Care Use Before and After Implementation of the IRF Prospective Payment System* (Santa Monica, Calif.: RAND Health, 2006); Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C., March 2000); and Department of Health and Human Services Office of Inspector General, *Effect of the Home Health Prospective Payment System on the Quality of Home Health Care*, OEI-01-04-00160 (January 2006).

[42]GAO/HEHS-00-23.

[43]Department of Health and Human Services Office of Inspector General, *Effect of the Home Health Prospective Payment System on the Quality of Home Health Care.*

[44]See GAO/HEHS-00-9 and Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (2000).

[45]Buntin et al., 6.

Certain Groups of Beneficiaries, Including African Americans and Those with Medicaid Coverage, Had Above Average Expenditures for Injectable ESRD Drugs in 2007

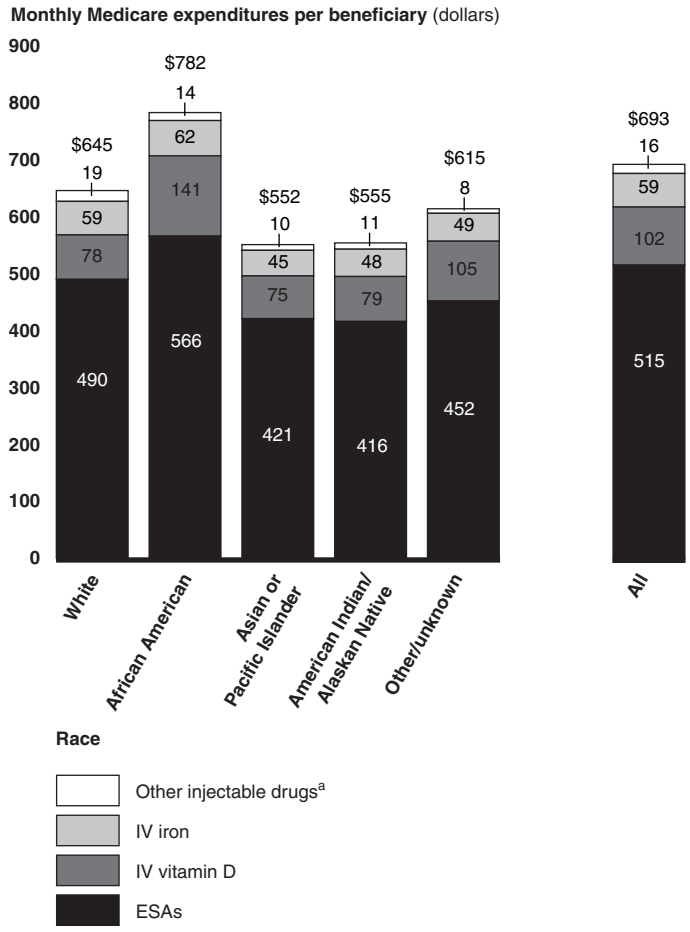
Monthly Medicare expenditures per beneficiary for injectable ESRD drugs in 2007 were above average for certain demographic groups, and African Americans and persons with Medicaid coverage were among the groups for which this difference was largest. In particular, Medicare expenditures on injectable ESRD drugs in 2007 were $782 per African American beneficiary per month—about 13 percent more than the $693 spent for all Medicare beneficiaries on dialysis (see fig. 1).[46,47] The above average spending per African American beneficiary was due primarily to higher spending on ESAs and IV vitamin D. Monthly Medicare spending per African American beneficiary on ESAs was about 10 percent higher than the average across all beneficiaries on dialysis, and spending on IV vitamin D was about 38 percent higher than average. Average monthly Medicare expenditures per beneficiary for other racial groups were below the average for all beneficiaries on dialysis in 2007. As a result, average monthly expenditures for African Americans were about 41 to 42 percent higher than spending for beneficiaries who classified themselves as American Indian/Alaskan Native or Asian or Pacific Islander and about 21 percent higher than for expenditures for White beneficiaries.[48]

[46]We do not address the extent to which these relationships between Medicare expenditures and beneficiaries' demographic characteristics are driven by clinical or other factors.

[47]The results we present were generally consistent for the period 2003-2007.

[48]Consistent with these descriptive results, recent studies have found that African Americans on dialysis receive higher average ESA doses than do Whites on dialysis. For example, see Ishani et al., "Possible Effects of the New Medicare Reimbursement Policy on African Americans with ESRD," 3, and Lacson et al., "The Association of Race with Erythropoietin Dose in Patients on Long-term Hemodialysis," *American Journal of Kidney Diseases*, vol. 52, no. 6 (2009). However, in one of these studies (Lacson et al.), differences in dose by race largely disappeared after controlling for factors such as age, PTH level, and hemoglobin level. This suggests that factors such as these may partially explain the observed racial differences in ESA dose.

Figure 1: Average Monthly Medicare Expenditures on Injectable ESRD Drugs by Race, 2007



Source: Data from the United States Renal Data System for 2007.

Note: Dollar amounts may not sum to totals because of rounding.

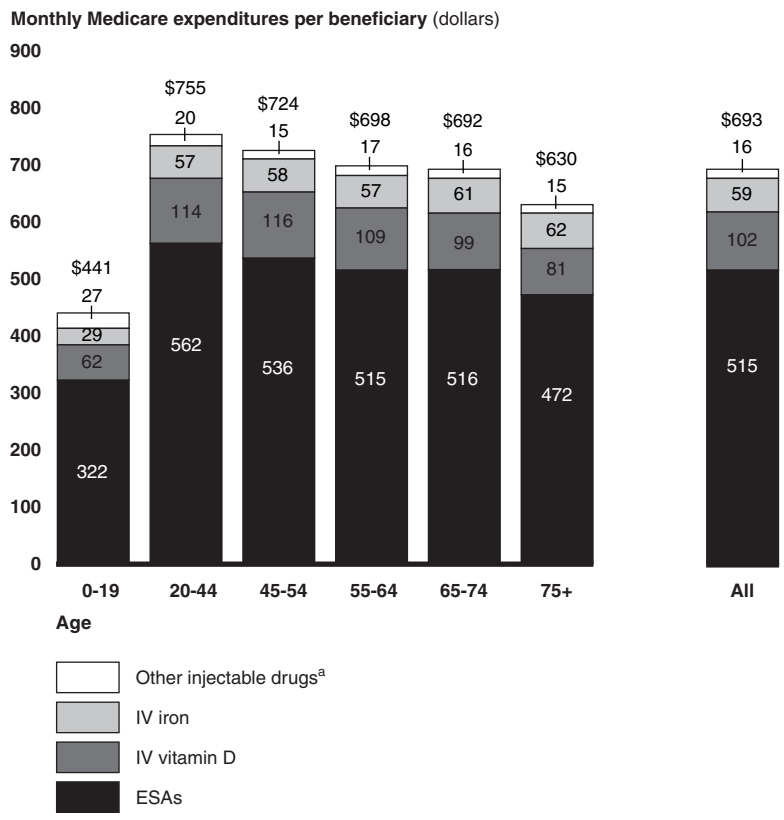
[a]Other injectable drugs include Levocarnitine (used to address a deficiency in carnitine, which helps the body produce energy), Alteplase (used to restore blood flow through a patient's vascular access), and Vancomycin (an antibiotic used for treatment of certain infections).

Average monthly expenditures per beneficiary for injectable ESRD drugs were also above average for beneficiaries enrolled in both Medicare and Medicaid. Specifically, average monthly expenditures per beneficiary enrolled in Medicare and Medicaid were $735 in 2007, which was about 6 percent higher than the $693 spent across all beneficiaries on dialysis and about 12 percent higher than the $659 for Medicare beneficiaries who were not in Medicaid. This difference was mainly due to above average

expenditures on ESAs and IV vitamin D for beneficiaries enrolled in both Medicare and Medicaid. For beneficiaries with both Medicare and Medicaid coverage, expenditures on ESAs were about 6 percent higher than the average for all beneficiaries in 2007, while expenditures on IV vitamin D were about 11 percent higher than average.

Monthly Medicare expenditures per beneficiary for adults age 20 to 64 were generally higher than the average for all Medicare beneficiaries on dialysis. Most notably, Medicare spending per beneficiary age 20 to 44 was about 9 percent more than the monthly average for all Medicare beneficiaries on dialysis (see fig. 2). Monthly Medicare expenditures per beneficiary age 20 to 44 were also higher when compared to those of other age groups, in particular beneficiaries age 19 and under or age 75 and older. The higher-than-average spending for beneficiaries age 20 to 44 was driven primarily by above average expenditures on ESAs and IV vitamin D. Specifically, Medicare spending on ESAs per beneficiary age 20 to 44 was about 9 percent higher than the average across all beneficiaries on dialysis in 2007. Similarly, Medicare spending on IV vitamin D per beneficiary age 20 to 44 was about 12 percent higher than the average for all beneficiaries.

Figure 2: Average Monthly Medicare Expenditures on Injectable ESRD Drugs by Age, 2007



Source: Data from the United States Renal Data System for 2007.

Note: Dollar amounts may not sum to totals because of rounding.

[a]Other injectable drugs include Levocarnitine (used to address a deficiency in carnitine, which helps the body produce energy), Alteplase (used to restore blood flow through a patient's vascular access), and Vancomycin (an antibiotic used for treatment of certain infections).

Monthly expenditures per beneficiary in 2007 for females, non-Hispanic beneficiaries, and urban residents also exceeded the average for all beneficiaries on dialysis, but to a lesser extent than for African Americans and beneficiaries in both Medicare and Medicaid. For example, female beneficiaries had average monthly expenditures of $715, which was about 3 percent higher than the monthly average across all Medicare beneficiaries on dialysis and about 6 percent higher than monthly expenditures per male beneficiary. Similarly, the $708 that Medicare spent per month on non-Hispanic beneficiaries was about 2 percent higher than

the average across all beneficiaries on dialysis and about 19 percent higher than the average for Hispanic beneficiaries.

For more detailed information on Medicare expenditures for injectable ESRD drugs, by demographic characteristics, see appendix III.

A Majority of Selected Clinicians and Researchers Identified Primarily Clinical Factors as Likely to Result in Above Average Doses of Injectable ESRD Drugs

While we report that certain demographic groups were associated with above average Medicare expenditures for injectable ESRD drugs in 2007, we did not identify the factors that led to these differences in expenditures across groups of beneficiaries. However, we collected information from nephrology clinicians and ESRD researchers on the factors they consider likely to result in above average doses of injectable drugs—ESAs, IV iron, and IV vitamin D.

A majority of the 73 clinicians and researchers who completed our Web-based data collection instrument identified clinical factors, rather than demographic characteristics, as likely to result in above average doses of injectable ESRD drugs. Specifically, at least 50 percent of these experts identified 14 such factors, including chronic blood loss, low iron stores, and recent hospitalization, as likely to result in above average doses of ESAs (see table 1).[49] Further, a majority of the clinicians and researchers who completed our data collection instrument indicated that demographic factors were not likely to result in above average doses of ESAs. Specifically, at least 50 percent of these experts identified 16 of the 17 demographic factors, such as age, race, and socioeconomic status, as not likely to result in above average doses of ESAs (see app. IV for detailed results). These results are consistent with information from our structured interviews with nephrology clinicians, who indicated that they consider clinical factors, rather than demographic characteristics, when making dosing decisions for ESAs and other injectable ESRD drugs.

[49]At least 75 percent of clinicians and researchers who completed the data collection instrument identified 12 of these same clinical factors as likely to result in above average doses of ESAs.

Table 1: Factors Identified by Selected Clinicians and Researchers as Likely or Not Likely to Result in Above Average Doses of ESAs

	Percentage who responded "likely"		Percentage who responded "not likely"	
Factors	**At least 50 percent**	**At least 75 percent**	**At least 50 percent**	**At least 75 percent**
Clinical factors				
Chronic blood loss	✓	✓		
Concurrent treatment with antihypertensive medication			✓	
Fewer than 4 months on dialysis	✓			
Hemoglobin production disorders	✓	✓		
Inadequate dialysis	✓	✓		
Infection or inflammatory conditions	✓	✓		
Large body size	✓	✓		
Low hemoglobin level	✓	✓		
Low iron stores	✓	✓		
Malnutrition	✓	✓		
Nonadherence to dialysis treatment	✓	✓		
Nonadherence to ESA treatment	✓	✓		
Nonadherence to iron treatment	✓	✓		
Recent hospitalization	✓	✓		
Refusal to receive immunizations			✓	
Use of a dialysis catheter	✓			
Demographic factors				
Age: 0-19				
Age: 20-44			✓	
Age: 45-54			✓	
Age: 55-64			✓	
Age: 65-74			✓	
Age: 75+			✓	
Ethnicity: Hispanic			✓	
Ethnicity: Non-Hispanic			✓	
Race: African American			✓	
Race: Other			✓	
Race: White			✓	
Residential location: Rural			✓	
Residential location: Urban			✓	

Factors	Percentage who responded "likely"		Percentage who responded "not likely"	
	At least 50 percent	At least 75 percent	At least 50 percent	At least 75 percent
Socioeconomic status: Low			✓	
Socioeconomic status: High			✓	✓
Sex: Female			✓	
Sex: Male			✓	✓

Source: GAO's August and September 2009 data collection instrument on the dose of dialysis-related drugs.

Notes: Results are based on information from 73 clinicians and researchers. The list of clinical factors above for ESAs is based on information obtained from 20 structured interviews with representatives of dialysis organizations and dialysis-related professional organizations, nephrology clinicians, and ESRD researchers. See apps. I and II for more information on our data collection instrument.

The literature we reviewed on the use of ESAs provides some explanation for how clinical factors impact the dose of this drug. For example, chronic blood loss is a common occurrence among hemodialysis patients. Blood loss can increase a person's ESA requirements by reducing the level of iron in the blood. Sources of blood loss include blood lost during the hemodialysis process, regular blood draws for laboratory testing, and gastrointestinal bleeding. As another example, the clinical literature describes how recent hospitalizations relate to ESA use. Studies demonstrate that hospitalized ESRD patients usually experience a decline in hemoglobin levels, which worsens anemia and increases posthospitalization ESA requirements.[50] The literature offers multiple explanations for this decline in hemoglobin levels. For example, hospitalized ESRD patients commonly experience infection, inflammation, and iron deficiency.[51] All of these conditions can contribute to increased

[50]Muhammad S. Yaqub, Jeffery Leiser, and Bruce A. Molitoris, "Erythropoietin Requirements Increase following Hospitalization in End-Stage Renal Disease Patients," *American Journal of Nephrology*, vol. 21, no 5 (2001); James P. Ebben et al., "Hemoglobin Level Variability: Associations with Comorbidity, Intercurrent Events, and Hospitalizations," *Clinical Journal of the American Society of Nephrology*, vol. 1 (2006); and Michael Heung, Bruce A. Mueller, and Jonathan H. Segal, "Optimizing Anemia Management in Hospitalized Patients with End-Stage Renal Disease," *The Annals of Pharmacotherapy*, vol. 43 (2009).

[51]For example, see Heung, Mueller, and Segal, "Optimizing Anemia Management in Hospitalized Patients with End-Stage Renal Disease," 276, and Kamyar Kalantar-Zadeh et al., "Malnutrition-Inflammation Complex Syndrome in Dialysis Patients: Causes and Consequences," *American Journal of Kidney Diseases*, vol. 42, no. 5 (2003).

ESA requirements.[52] Additionally, the literature explains the effect of dialysis catheters on the use of ESAs. According to published research, the use of dialysis catheters compared to other forms of vascular access makes ESRD patients more prone to infection and inflammation, which increase ESA requirements.[53]

As with ESAs, a majority of clinicians and researchers who completed our data collection instrument identified clinical factors, such as chronic blood loss and low iron stores, as likely to result in above average doses of IV iron (see table 2). These individuals identified six clinical factors as likely to result in above average doses of IV iron. Five of these six clinical factors overlap with the clinical factors identified for ESAs.[54] Moreover, at least 50 percent of clinicians and researchers who completed our data collection instrument identified demographic factors, such as age, race and residential location, as not likely to result in an above average dose of IV iron (see app. IV for detailed results).

[52]Iain Macdougall and Angela C. Cooper, "Erythropoietin Resistance: The Role of Inflammation and Pro-inflammatory Cytokines," *Nephrology Dialysis Transplantation*, vol. 17, suppl. 11 (2002), and Anne E. Dar Santos, Karen F. Shalansky, and Jacek P. Jastrzebski, "Management of Anemia in Erythropoietin-Resistant Hemodialysis Patients," *The Annals of Pharmacotherapy*, vol. 37 (2003).

[53]Tricia Roberts et al., "Relationship among Catheter Insertions, Vascular Access Infections, and Anemia Management in Hemodialysis Patients," *Kidney International*, vol. 66 (2004), and Adriana M. Hung and T. Alp Ikizlert, "Hemodialysis Central Venous Catheters as a Source of Inflammation and Its Implications," *Seminars in Dialysis*, vol. 21, no. 5 (2008).

[54]ESRD patients with anemia may receive ESAs in conjunction with IV iron.

Table 2: Factors Identified by Selected Clinicians and Researchers as Likely or Not Likely to Result in Above Average Doses of IV Iron

	Percentage who responded "likely"		Percentage who responded "not likely"	
Factors	**At least 50 percent**	**At least 75 percent**	**At least 50 percent**	**At least 75 percent**
Clinical factors				
Chronic blood loss	✓	✓		
Concurrent treatment with ESAs	✓			
Fewer than 4 months on dialysis	✓			
Inadequate dialysis				
Infection or inflammatory conditions				
Large body size			✓	
Low iron stores	✓	✓		
Malnutrition	✓			
Recent hospitalization	✓	✓		
Refusal to receive immunizations			✓	
Demographic factors				
Age: 0-19				
Age: 20-44			✓	
Age: 45-54			✓	
Age: 55-64			✓	
Age: 65-74			✓	
Age: 75+				
Ethnicity: Hispanic			✓	
Ethnicity: Non-Hispanic			✓	
Race: African American			✓	
Race: Other			✓	
Race: White			✓	
Residential location: Rural			✓	
Residential location: Urban			✓	
Socioeconomic status: Low				
Socioeconomic status: High			✓	✓
Sex: Female				
Sex: Male			✓	✓

Source: GAO's August and September 2009 data collection instrument on the dose of dialysis-related drugs.

Notes: Results are based on information from 73 clinicians and researchers. The list of clinical factors above for IV iron is based on information obtained from 20 structured interviews with representatives of dialysis organizations, dialysis-related professional organizations, nephrology clinicians, and ESRD researchers. See apps. I and II for more information on our data collection instrument.

Also similar to ESAs, the literature on the use of IV iron provides some context for the clinical factors that are likely to result in above average doses of IV iron. For example, chronic blood loss can result in iron deficiency and increase a person's IV iron requirement.[55] Sources of blood loss leading to increased IV iron requirements include blood retention in the dialyzer tubing, blood testing, and gastrointestinal bleeding.[56] Also, the literature explains that the state of having low iron stores is more common in patients on dialysis for less than 6 months than those on dialysis for longer amounts of time.[57]

As table 3 shows, a majority of the clinicians and researchers who completed our data collection instrument identified two clinical factors—hyperparathyroidism and a lack of predialysis care—and one demographic factor—low socioeconomic status—as likely to result in higher-than-average doses of IV vitamin D (see app. IV for detailed results). Hyperparathyroidism is present in almost all ESRD patients and develops early in the course of chronic kidney disease. In fact, research shows that PTH levels start to increase early in the course of chronic kidney disease and can lead to the development of hyperparathyroidism.[58] In addition, new ESRD patients who have not received predialysis care from a nephrologist may be at greater risk of health complications.[59] According to the clinical literature, new ESRD patients may begin dialysis treatment without receiving predialysis care from a nephrologist because they face

[55]Allen R. Nissenson and Jur Strobos, "Iron Deficiency in Patients with Renal Failure," *Kidney International*, vol. 55, supp. 69 (1999).

[56]Ajay Singh, "Hemoglobin Control, ESA Resistance, and Regular Low-Dose IV Iron Therapy: A Review of the Evidence," *Seminars in Dialysis*, vol. 22, no. 1 (2009).

[57]Michael V. Rocco et al., "Duration of Dialysis and Its Relationship to Dialysis Adequacy, Anemia Management, and Serum Albumin Level," *American Journal of Kidney Diseases*, vol. 38, no. 4 (2001).

[58]Csaba P. Kovesdy and Kamyar Kalantar-Zadeh, "Bone and Mineral Disorders in Pre-Dialysis CKD," *International Urology and Nephrology*, vol. 40 (2008), and Melanie S. Joy, Paul C. Karagiannis, and Fred W. Peyerl, "Outcomes of Secondary Hyperparathyroidism in Chronic Kidney Disease and the Direct Costs of Treatment," *Journal of Managed Care Pharmacy*, vol. 13, no. 5 (2007).

[59]Paul Jungers, "Late Referral: Loss of Chance for the Patient, Loss of Money for Society," *Nephrology Dialysis Transplantation*, vol. 17 (2002).

barriers to receiving care.[60,61] One such barrier is low socioeconomic status.[62] Specifically, the literature shows that low socioeconomic status may be associated with limited access to health care services.[63]

[60]Sally A. Hood and James H. Sondheimer, "Impact of Pre-ESRD Management on Dialysis Outcomes: A Review," *Seminars in Dialysis*, vol. 11, no. 3 (1998).

[61]In 2007, approximately 43 percent of new ESRD patients did not receive any predialysis care from a nephrologist. See U.S. Renal Data System, *USRDS 2009 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*.

[62]Chamberlain I. Obialo et al., "Ultralate Referral and Presentation for Renal Replacement Therapy: Socioeconomic Implications," *American Journal of Kidney Diseases*, vol. 46, no. 5 (2005).

[63]Hood and Sondheimer, "Impact of Pre-ESRD Management on Dialysis Outcomes: A Review," 179; Thomas V. Perneger, Paul K. Whelton, and Michael J. Klag, "Race and End-Stage Renal Disease: Socioeconomic Status and Access to Health Care as Mediating Factors," *Archives of Internal Medicine*, vol. 155 (1995); and Sharon Stein Merkin et al., "Individual and Neighborhood Socioeconomic Status and Progressive Chronic Kidney Disease in an Elderly Population: The Cardiovascular Health Study," *Social Science and Medicine*, vol. 65 (2007).

Table 3: Factors Identified by Selected Clinicians and Researchers as Likely or Not Likely to Result in Above Average Doses of IV Vitamin D

	Percentage who responded "likely"		Percentage who responded "not likely"	
Factors	**At least 50 percent**	**At least 75 percent**	**At least 50 percent**	**At least 75 percent**
Clinical factors				
Hyperparathyroidism	✓	✓		
Lack of predialysis care	✓	✓		
Malnutrition				
Demographic factors				
Age: 0-19				
Age: 20-44			✓	
Age: 45-54			✓	
Age: 55-64			✓	
Age: 65-74			✓	
Age: 75+			✓	
Ethnicity: Hispanic				
Ethnicity: Non-Hispanic			✓	
Race: African American				
Race: Other				
Race: White			✓	✓
Residential location: Rural			✓	
Residential location: Urban				
Socioeconomic status: Low	✓			
Socioeconomic status: High			✓	✓
Sex: Female			✓	
Sex: Male			✓	

Source: GAO's August and September 2009 data collection instrument on the dose of dialysis-related drugs.

Notes: Results are based on information from 73 clinicians and researchers. The list of clinical factors above for IV vitamin D is based on information obtained from 20 structured interviews with representatives of dialysis organizations and dialysis-related professional organizations, nephrology clinicians, and ESRD researchers. See apps. I and II for more information on our data collection instrument.

CMS Proposed Several Case-Mix Adjustment Factors and an Outlier Policy to Address Cost Differences among Beneficiaries

Issued in September 2009, CMS's proposed rule for the new bundled payment system for dialysis care identified several clinical and demographic factors that the agency proposed to use in the case-mix adjustment model required by MIPPA.[64] The case-mix adjustment factors that CMS proposed include age, sex, body surface area, body mass index, length of time on dialysis, and comorbid conditions.[65,66] CMS and UM-KECC studied the relationship between these proposed factors and the cost of dialysis care and used the results to determine how to adjust payments under the new bundled payment system. For example, based on CMS's proposed case-mix adjustment, the bundled payment for a beneficiary who has been on dialysis for fewer than 4 months would be 47 percent higher than the payment for the same beneficiary on dialysis for more than
4 months.

CMS used the criteria listed below to select potential case-mix adjustment factors.[67] Specifically, a factor

- had to have a statistically significant relationship with beneficiaries' costs of dialysis care that was large enough to result in an economically meaningful difference in payments to providers,
- could not introduce incentives for providers to furnish inappropriate or poor quality care,
- must be measured based on objective guidelines, and

[64]Medicare Programs; End-Stage Renal Disease Prospective Payment System, 74 Fed. Reg. at 49,922, 49,927 (proposed Sept. 29, 2009). In addition to beneficiary characteristics, CMS proposed adjusting bundled payments to account for differences in the cost of dialysis care furnished by low-volume facilities, those facilities furnishing fewer than 3,000 dialysis treatments in a given year.

[65]CMS included indicators of 11 comorbid conditions in its case-mix adjustment model. These conditions included, for example, alcohol or drug dependence, HIV/AIDS, certain types of infections, and hepatitis B.

[66]CMS proposed different case-mix adjustment factors for pediatric patients, who accounted for less than 1 percent of beneficiaries on dialysis in 2007. CMS's proposed case-mix adjusters for pediatric patients consisted of age, type of dialysis (i.e,. hemodialysis or peritoneal dialysis), and comorbid conditions.

[67]See Department of Health and Human Services, *Report to Congress: A Design for a Bundled End Stage Renal Disease Prospective Payment System* (Washington, D.C., 2008), and Medicare Programs; End-Stage Renal Disease Prospective Payment System, 74 Fed. Reg. at 49,966 (proposed Sept. 29, 2009).

- must be based on reliable data.

CMS considered some factors as potential case-mix adjusters but did not propose them because they did not meet CMS's criteria.[68] One example of a factor that CMS considered but did not propose as a potential case-mix adjuster is congestive heart failure. CMS officials stated that they did not propose this factor in part because of the lack of clear and objective guidelines for diagnosing this condition. As another example, a beneficiary's prior ESA use was not proposed as a case-mix adjuster because, according to CMS officials, this factor would introduce inappropriate incentives for providers. Specifically, they concluded that if the extent of prior ESA use were a case-mix adjustment factor, a provider would have the incentive to increase a beneficiary's ESA dose to obtain higher Medicare payments under the new bundled payment system.

CMS also considered including race and ethnicity in the proposed case-mix adjustment model, but chose not to include these factors. CMS invited public comment on this decision, noting that an adjustment based on race and ethnicity may be warranted.[69] One of the reasons CMS cited in its proposed rule for not including race and ethnicity in the proposed model was the lack of objective guidelines for classifying beneficiaries' race or ethnicity.[70] This absence of objective guidelines implies that there is likely to be an inconsistency across individuals in how they classify themselves into racial or ethnic categories. CMS also noted that its concerns with the quality of data on race and ethnicity made it difficult to propose these variables as case-mix adjusters.[71] One quality issue that CMS cited is the inconsistency over time in how Medicare data on race and ethnicity were collected for one of its two sources of this information—the Renal

[68]See Richard Hirth et al., *End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle* (Ann Arbor, Mich.: University of Michigan Kidney Epidemiology and Cost Center, February 2008), for a description of the range of factors considered for inclusion in the case-mix adjustment model.

[69]74 Fed. Reg. at 49,966.

[70]74 Fed. Reg. at 49,962.

[71]CMS noted, in its proposed rule for the new bundled payment system for dialysis care, that it plans to explore opportunities for improving Medicare program data on race and ethnicity, in accordance with MIPPA. 74 Fed. Reg. at 49,966.

Management Information System (REMIS) database.[72] Additionally, CMS cited studies indicating that information on race and ethnicity from Medicare's second source of these data—the Medicare Enrollment Database (EDB)—may be inaccurate. These studies found that the EDB may not accurately identify beneficiaries' race and ethnicity, particularly for beneficiaries in smaller minority groups, such as Asians and Hispanics.[73]

In addition to a case-mix adjustment model, CMS proposed using an outlier policy, as required by MIPPA, to increase payments to providers when they treat beneficiaries whose costs of dialysis care substantially exceed what would be expected. CMS proposed identifying these high-cost beneficiaries based on their cost of outlier services, which CMS defines as ESRD services that are separately billable under the current payment system for dialysis care, such as injectable ESRD drugs.[74] The agency has noted that it is primarily the variation in the cost of outlier services that poses a financial risk to providers and that could therefore adversely affect beneficiaries' access to and quality of dialysis care. Furthermore, according to CMS officials, the agency collects beneficiary-level data on the use of outlier services but not on those covered under the composite rate, such as the dialysis procedure.[75] Such data would be necessary to identify beneficiaries with higher-than-expected costs for dialysis care overall. Based on CMS's proposed outlier policy, providers could receive outlier payments when they treat beneficiaries whose costs for injectable ESRD drugs and other outlier services exceed a certain threshold.[76]

[72]The REMIS database contains demographic, diagnosis, and ESRD treatment history data for all beneficiaries with ESRD. The categories for race and ethnicity on the Medical Evidence Form—a standardized form used to collect the race and ethnicity data in the REMIS database—have changed over time. See app. I for more detail.

[73]See Marshall McBean, *Medicare Race and Ethnicity Data*, a report prepared for the National Academy of Social Insurance (December 2004). Also see Daniel R. Waldo, "Accuracy and Bias of Race/Ethnicity Codes in the Medicare Enrollment Database," *Health Care Financing Review*, vol. 26, no. 2 (Winter 2004-2005).

[74]74 Fed. Reg. at 49,988.

[75]CMS proposed to estimate the cost of outlier services based on the beneficiary-level data it collects on the use of these services and estimates of the cost of each service.

[76]74 Fed. Reg. at 50,024-25. This threshold is the sum of a fixed amount and a beneficiary's expected cost for outlier services.

The case-mix adjustment and outlier policy may need to be recalibrated periodically. The specific parameters of these payment mechanisms initially will be based on patterns of utilization, and therefore spending, that existed before the new bundled payment system was implemented. The bundling of payments changes financial incentives for providers and is intended to encourage the efficient provision of care. To the extent that providers change how they practice after the new payment system is implemented, in response to the financial incentives of the new bundled payment system to provide dialysis care more efficiently or other factors, the parameters of the case-mix adjustment and outlier policy could become less accurate over time. As a result, CMS officials stated that they may recalibrate these payment mechanisms using data collected after implementation of the new bundled payment system. However, CMS officials noted that they had not established a time frame for this recalibration.

CMS's Preliminary Monitoring Plans Build on Existing Initiatives, but Whether CMS Will Monitor Quality of and Access to Care for Groups of Beneficiaries Is Unclear

CMS officials told us that their preliminary plans for monitoring the effects of the new bundled payment system on beneficiaries include three current CMS initiatives that focus on monitoring the quality of dialysis care (see table 4). In comments on a draft of this report, CMS reported that it plans to have a comprehensive monitoring strategy in place when the new bundled payment system is implemented on January 1, 2011. One of the three key initiatives in CMS's preliminary monitoring plans is its network of 18 private organizations—called ESRD networks. Each network is charged with monitoring and promoting the quality of dialysis care in a geographic area, which generally covers one or more states. The networks' monitoring responsibilities include analyzing facility-level data on quality measures to identify facilities that need assistance with quality improvement.[77] The networks are also responsible for evaluating and addressing patient complaints. The second quality monitoring initiative that CMS plans to rely on is the Clinical Performance Measures (CPM) project. Under this project, CMS has monitored quality by collecting and analyzing data on dialysis quality measures for a nationally representative sample of beneficiaries on dialysis. CMS has used these data to report annually on comparisons of the quality of dialysis care across the country and across groups of beneficiaries. The third initiative involves monitoring

[77]The facility-level measures analyzed by the ESRD networks include a measure of the quality of anemia management—that is, whether a beneficiary's hemoglobin level is within a specified range.

the quality of individual dialysis facilities by ensuring that they comply with Medicare's conditions for coverage that a facility must fulfill in order to receive Medicare payment for dialysis care. One of these conditions requires that a dialysis facility develop and implement a program to monitor and improve the quality of services it provides.[78] CMS requires that this plan include the collection and monitoring of data on patient satisfaction with care and the adequacy of dialysis, among other measures.

Table 4: Current CMS Initiatives to Monitor the Quality of Dialysis Care

Quality initiative	Description
ESRD networks	Network responsibilities include • monitoring facility-level indicators of the quality of dialysis care, such as anemia management and dialysis adequacy; • evaluating and resolving patient complaints and grievances; • collecting data on and tracking beneficiaries who were discharged from dialysis facilities involuntarily; • providing technical assistance to dialysis facilities in developing and implementing quality improvement projects; and • identifying dialysis facilities not meeting network goals and assisting facilities in developing appropriate plans for correction.
Clinical Performance Measures (CPM) project	Under this project, CMS has collected, analyzed, and reported data on CPMs. The CPMs that CMS currently uses cover the following topics: (1) anemia management; (2) dialysis adequacy; (3) mineral metabolism; (4) vascular access; (5) influenza vaccination; (6) patient education, perception of care, and quality of life; and (7) mortality.
Survey and certification program	Facilities' compliance with Medicare's conditions for coverage is monitored through on-site inspections—called surveys, which are conducted by state survey agencies. Facilities must comply with these conditions in order for CMS to certify them to be paid for Medicare-covered dialysis services. The conditions for coverage address issues such as patient safety and care.

Source: GAO review of CMS documentation.

In addition to the monitoring initiatives described above, CMS has or is developing two other quality initiatives focused primarily on promoting the quality of dialysis care rather than monitoring. The first of these initiatives that CMS plans to continue under the new bundled payment system is Dialysis Facility Compare, which is a tool on the Medicare program's Web site that allows users to compare dialysis facilities based on measures of the quality of dialysis care. By making public each facility's quality information, Dialysis Facility Compare gives facilities the incentive to improve the quality of care they furnish. CMS is developing the second

[78]42 C.F.R. § 494.110.

of these initiatives—a quality incentive program (QIP)—which is required by MIPPA to be implemented beginning January 1, 2012. Under the QIP, Medicare is required to reduce payments to dialysis providers by up to 2 percent if the dialysis care they furnish does not meet a total performance score based on quality standards established by CMS.[79] CMS proposed using indicators of dialysis adequacy and anemia management to measure quality under the QIP.[80] By linking a portion of provider payments to measures of dialysis adequacy and anemia management, the QIP would give providers a financial incentive to improve these aspects of dialysis care. However, the QIP would not address other aspects of dialysis care, such as mineral metabolism, which is related to the use of IV vitamin D, unless CMS incorporated additional measures into the program.[81]

We and others have noted the importance of monitoring quality of and access to care under bundled payment systems to help ensure that beneficiaries receive appropriate care.[82] Although CMS intends to monitor quality under the new bundled payment system, the extent to which CMS will conduct such monitoring for various groups of beneficiaries is uncertain. CMS officials told us that it was too early in the process of developing a monitoring plan to address how they might monitor various groups of beneficiaries. CMS is developing the capacity to monitor the quality of dialysis care for groups of beneficiaries, such as those with above average costs of care. Specifically, CMS is implementing a new database called the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb), which is designed to collect CPM data as well as other clinical and demographic information for all beneficiaries with

[79]Pub. L. No. 110-275, § 153(c), 122 Stat. at 2556-59 (codified at 42 U.S.C. § 1395rr(h)).

[80]CMS outlined a conceptual model for ESRD QIP components that CMS is considering proposing in a future proposed rule. CMS proposed to implement other components of the QIP in future rule making.

[81]MIPPA gives CMS the authority to use additional measures, such as those on iron management and mineral metabolism. 42 U.S.C. § 1395rr(h)(2). CMS noted in its proposed rule that it may incorporate such measures into the QIP in the future. 74 Fed. Reg. at 50,012.

[82]For example, see GAO/HEHS-00-9, 24, and Buntin et al., *Inpatient Rehabilitation Facility Care Use Before and After Implementation of the IRF Prospective Payment System*, 6.

ESRD.[83] However, because CMS is still developing its monitoring plans, it is uncertain to what extent CMS will use these data to monitor the quality of dialysis care for various groups of beneficiaries under the new bundled payment system.

While CMS has initiatives it plans to use to monitor the quality of dialysis care beneficiaries receive under the new bundled payment system, these initiatives involve systematic monitoring of only one measure of beneficiaries' access to such care. Specifically, CMS systematically monitors the extent to which beneficiaries are discharged involuntarily from facilities by requiring the networks to track these beneficiaries.[84] To improve the networks' ability to track these beneficiaries, CMS is developing a database designed to allow the networks to track the number of involuntary discharges based on beneficiary characteristics, such as age, race, and ethnicity. However, according to CMS officials, the agency does not systematically monitor other measures of access to dialysis care, such as the use of dialysis services.[85]

Although CMS's monitoring initiatives do not generally focus on beneficiaries' access to dialysis care, CMS has the data sources necessary to conduct more comprehensive monitoring of access for various groups of beneficiaries, including those with above average costs of care. In

[83]According to CMS officials, CMS is implementing CROWNWeb in three phases. Phase I occurred from February through July 2009 and involved implementing CROWNWeb with selected dialysis facilities in four ESRD networks. Phase II, which began in August 2009, involves implementing CROWNWeb in all 18 networks with a total of up to 180 dialysis facilities. In phase III, CMS plans to implement CROWNWeb in all dialysis facilities. CMS officials noted that they plan to begin phase III in late spring of 2010.

[84]CMS permits dialysis facilities to discharge patients involuntarily if, for example, facility personnel have determined that a patient's behavior is disruptive and abusive to the extent that the delivery of care to the patient or the ability of the facility to operate effectively is seriously impaired. In the event of an involuntary discharge for such behavior, facility requirements include (1) providing the patient with a 30-day notice of the planned discharge and (2) attempting to place the patient at another facility. 42 C.F.R. § 494.180(f).

[85]According to CMS officials, the agency monitors access to dialysis care in some ways that are not systematic. For example, the ESRD networks are required to monitor complaints from patients, which could relate to access. However, the data system used by the networks to track complaints does not indicate which complaints relate to access to dialysis care. In addition, CMS requires, under the conditions of coverage for dialysis facilities, that facilities monitor patient satisfaction—another measure of access to care. However, according to CMS officials, facilities are not required to collect this information in the same way, so it would be difficult for CMS to use these data to conduct systematic monitoring across dialysis facilities.

particular, one data source that CMS has available to monitor access to dialysis care is the information it generates on the characteristics of beneficiaries receiving care in dialysis facilities. This facility-level information—the Dialysis Facility Report—is compiled by UM-KECC in part from Medicare claims and the REMIS database. CMS could use these data, in addition to information it has on which facilities open or close during a given year, to compare the characteristics of beneficiaries in these facilities.[86] This information could indicate whether facility openings and closures affect the availability of dialysis facilities for certain groups of beneficiaries more than others.

CMS also has the data necessary to monitor other measures of access to care, such as changes in the use of dialysis services and shifts in the site of dialysis care. CMS collects data on the use of Medicare-covered services, such as ESRD drugs, through the process of paying claims for these services.[87] In addition, the CROWNWeb database will contain beneficiary-level data on demographic and clinical characteristics. CMS could use these data sources to identify groups of beneficiaries whose service use is higher than average and who therefore may have above average costs of dialysis care. CMS could then use these data to monitor the use of dialysis services for groups of beneficiaries with above average costs of care. Changes in the use of dialysis services could indicate how the new bundled payment system may have affected beneficiaries' access to these services. For example, if the use of a given dialysis-related drug declined over time for certain groups of beneficiaries but not for others, then this could prompt an assessment of whether this reduction was appropriate and whether the payment system may have caused this difference. CMS could also monitor the extent to which beneficiaries receive emergency dialysis in hospitals rather than outpatient dialysis facilities as an indicator of access to dialysis care. An increase in hospital admissions for emergency dialysis services for certain groups of beneficiaries could indicate that these groups are having difficulty gaining admission to outpatient dialysis facilities.

[86]MedPAC has conducted similar analyses for its annual assessments of the adequacy of Medicare payments for dialysis services. For example, see Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C., March 2009).

[87]CMS officials stated that they plan to continue collecting these data under the new bundled payment system for dialysis care.

Conclusions

The new bundled payment system for dialysis care—required to be implemented for services furnished on or after January 1, 2011—has the potential to improve the efficiency of care delivery, in part by reducing the financial incentive to use more injectable ESRD drugs than are necessary. However, if this new payment system causes providers to consistently experience financial losses when treating beneficiaries with above average costs, then some beneficiaries could face problems accessing dialysis care or with the quality of that care. Groups of beneficiaries with above average costs of dialysis care, whether related to clinical or demographic factors, may be more vulnerable to these types of problems. Therefore it will be important for CMS to monitor the effect of the new bundled payment system on the access to and quality of dialysis care for these beneficiaries—which is consistent with previous work on the need for such monitoring under other bundled payment systems in Medicare. Furthermore, early identification of any adverse effects of the payment system on beneficiaries will be crucial because their need for life-sustaining dialysis makes them particularly sensitive to disruptions in dialysis care.

CMS recognizes the importance of monitoring the effect of its new bundled payment system on beneficiaries and is developing plans for these efforts. In commenting on a draft of this report, CMS stated that it plans to have a comprehensive monitoring strategy in place when the new bundled payment system is implemented on January 1, 2011. However, because CMS's monitoring plans are preliminary, the extent to which CMS intends to monitor quality for various groups of beneficiaries, such as those with above average costs of care, is unclear. Furthermore, while CMS's preliminary plans for monitoring under the new bundled payment system contain initiatives designed to monitor the quality of dialysis care, these plans involve very limited monitoring of access to these services. CMS has or is developing the tools it could use to monitor access to and quality of dialysis care for various groups of beneficiaries, including those with above average costs of dialysis care. Specifically, CMS currently collects data on the use of injectable ESRD drugs and other Medicare services that could be used to monitor access to these services. CMS is also developing a data system that will contain quality measures for each beneficiary with ESRD. CMS could draw on this capacity as it plans and conducts its monitoring efforts. Moreover, CMS could use information from these efforts to help refine the payment system over time.

Recommendation for Executive Action

To help ensure that changes in Medicare payment methods for dialysis care do not adversely affect beneficiaries, we recommend that the Administrator of CMS monitor the access to and quality of dialysis care for groups of beneficiaries, particularly those with above average costs of dialysis care, under the new bundled payment system. Such monitoring should begin as soon as possible once the new bundled payment system is implemented and be used to inform potential refinements to the payment system.

Agency and Industry Comments and Our Evaluation

We received written comments on a draft version of this report from CMS and oral comments on the draft report from representatives from dialysis facility organizations and from a nephrologist specialty association.

Comments from CMS

In written comments on a draft of this report, CMS agreed with our recommendation and noted that it is planning to actively monitor the effects of the new bundled payment system on all ESRD beneficiaries, including those with above average costs. CMS noted that it plans to have a comprehensive monitoring strategy in place when the payment system is implemented on January 1, 2011. In particular, CMS plans to use its existing data sources to examine overall trends in care delivery and quality to help the agency ensure that beneficiaries continue to receive quality care under the new payment system. CMS stated that it would use its existing infrastructure, including the ESRD networks, for quality oversight in the ESRD facilities. Furthermore, CMS indicated that it plans to use information from these monitoring activities for potential refinements to the new bundled payment system and the QIP.

CMS noted that our statement that the agency's preliminary plans involve limited monitoring of access to dialysis care did not reflect the agency's current planning efforts because our assessment was based on interviews conducted prior to the publication of the ESRD proposed rule, which occurred on September 29, 2009. However, we spoke with CMS officials in December 2009 to review our evidence and findings regarding the agency's preliminary monitoring plans, and at that time, agency officials told us that our information was accurate.

CMS commented that our report suggests that clinical factors, rather than demographic characteristics, are more likely to relate to higher doses of injectable ESRD drugs, resulting in above average expenditures for certain groups of beneficiaries. CMS also noted that the case-mix adjustment model is designed to predict dialysis facility costs and be used in making

payments to such facilities based on information they are able to provide on claims. CMS further noted that demographic and other factors had been determined to be statistically significant in predicting facility costs. The results of our study indicate that while Medicare expenditures on injectable ESRD drugs were related to beneficiaries' demographic characteristics, a majority of clinicians and researchers from whom we obtained input noted that these characteristics by themselves generally were not likely to result in higher doses of injectable ESRD drugs. However, we do not draw any conclusions regarding the relative importance of demographic or clinical characteristics in predicting dialysis facility costs for the purposes of a case-mix adjustment model and payment system. Evaluating the appropriateness of CMS's proposed case-mix adjustment factors was beyond the scope of this study. CMS provided technical comments, which we incorporated as appropriate. We have reprinted CMS's letter in appendix V.

Comments from Industry Representatives

We invited representatives of both large and small dialysis facility organizations and a nephrologist specialty association to review and provide oral comments on the draft report. The groups represented were the Kidney Care Council (KCC), the National Renal Administrators Association (NRAA), and the Renal Physicians Association (RPA). The three groups generally agreed with our message and recommendation to CMS. Their comments focused on three areas: the data and populations analyzed in the report, our findings related to beneficiaries' demographic characteristics and clinical conditions, and the nature and timeliness of CMS's monitoring plans. Industry representatives also provided technical comments, which we incorporated as appropriate.

First, representatives from each of the organizations commented on the scope of the report by raising potential issues with the data and populations we analyzed. RPA representatives noted that our data on Medicare expenditures for injectable ESRD drugs, which were based on USRDS data for 2007, may not represent current trends in utilization and expenditures. They asserted that prescribing patterns for injectable ESRD drugs may have changed since 2007 and that this may have been due in part to safety concerns associated with ESA use. In addition, representatives from both KCC and NRAA stated that the report did not sufficiently examine the socioeconomic status of ESRD beneficiaries, including how beneficiaries with both Medicare and Medicaid coverage would fare under the new bundled payment system. An NRAA representative also noted that our report did not examine data on the poorest ESRD beneficiaries who have Medicaid coverage but do not

qualify for Medicare coverage. In addition, KCC representatives noted that the report did not provide enough information on Part D drugs, which CMS proposed to cover under the new bundled payment system. Moreover, RPA representatives noted that there is a great deal of anxiety in the provider community about whether the bundled payment will be sufficient to cover the cost of these drugs.

In our report, we analyzed USRDS data on Medicare expenditures for injectable ESRD drugs and demographic characteristics such as age, sex, race, and Medicaid status for 2007 because these were the most recent data available. Moreover, our analysis of data from 2003 through 2006 indicated that the results based on 2007 data were consistent with data from the previous 4 years. We acknowledge, however, that the safety concerns about ESAs could have influenced prescribing practices and that such changes could affect the relationship between expenditures on injectable ESRD drugs and demographic characteristics and have added some detail to the report on these issues. We examined beneficiaries covered by both Medicare and Medicaid because detailed information on beneficiaries' socioeconomic status is not available. We did not examine data on beneficiaries without Medicare coverage because they are not included in the data CMS used to develop the new bundled payment system. We agree that Part D drugs will be important under the new bundled payment system. However, data on the use of these drugs, which according to CMS constituted about 14 percent of Medicare expenditures on all ESRD drugs in 2007,[88] were not available.

Second, industry representatives commented on our findings related to beneficiaries' demographic characteristics and clinical conditions. Representatives from KCC pointed out that our findings on the relationship between Medicare expenditures on injectable ESRD drugs and beneficiaries' demographic characteristics were consistent with published research on this topic and noted that these relationships are driven by underlying clinical factors. However, RPA representatives noted that the report did not address the reason for these observed relationships. In addition, representatives from KCC and RPA agreed with our finding that clinicians do not take beneficiaries' demographic characteristics into account when making dosing decisions. However, KCC representatives noted that there was an apparent disconnect between the results of our first and second findings. In order to facilitate interpretation of these

[88]74 Fed. Reg. at 49,940.

results, KCC representatives suggested that we include in the report a copy of the instrument used to collect information from clinicians and researchers on the factors that are likely or not likely to result in above average doses of injectable ESRD drugs.

We did not address the extent to which the relationships between Medicare expenditures on injectable ESRD drugs and beneficiaries' demographic characteristics were driven by underlying clinical factors because doing so was beyond the scope of our study. We did, however, obtain input from clinicians and ESRD researchers to gain insight into the factors that may affect the dose of these drugs for dialysis patients. We agree with KCC's suggestion and have included the structured data collection instrument in appendix II.

Finally, representatives from all three organizations agreed that it will be important to monitor the effects of the new bundled payment system on beneficiaries but expressed concern about how CMS would conduct such monitoring. Representatives from NRAA stressed the need to identify vulnerable populations, such as those with high costs of dialysis care, as part of the monitoring process. However, NRAA and RPA representatives questioned how CMS would identify these populations through its monitoring activities. In addition, KCC representatives expressed concern about the timeliness of CMS's monitoring activities, noting that data from CMS on the provision of dialysis care can have a long lag time, which makes the information less relevant. Representatives from all three organizations expressed concerns related to CROWNWeb implementation. Specifically, both NRAA and RPA representatives noted that they view CROWNWeb as a potentially useful tool for CMS monitoring activities, but are concerned about when it would be fully implemented. NRAA representatives noted that challenges remain to making the database operational. Furthermore, representatives from KCC cautioned that if data in CROWNWeb are not collected in a consistent way across dialysis facilities, the information from this database could be unreliable.

Our report recommends that CMS monitor the effect of the new payment system on beneficiaries, such as those who are vulnerable to adverse effects of the payment system because of their above average costs of dialysis care. We also point out in the report that it will be important for CMS to draw on data sources it has or is developing to identify and monitor access to and quality of dialysis care for such groups of beneficiaries. We agree with KCC representatives that CMS's monitoring activities should be timely so that any problems resulting from the new payment system can be addressed as soon as possible after

implementation. Our recommendation to CMS emphasizes the need for timely monitoring, particularly given the sensitivity of the dialysis population to potential disruptions in access to and quality of care. We also reported that CROWNWeb is a key element in CMS's preliminary plans for its monitoring approach, and agree that it is important for CMS to develop reliable data and ensure that such data are available to use as soon as possible after the bundled payment system is implemented.

As agreed with your offices, 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. The report will also be available at no charge on the GAO Web site 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. GAO staff who made major contributions to this report are listed in appendix VI.

James C. Cosgrove
Director, Health Care

Appendix I: Objectives, Scope, and Methodology

Our objectives were to (1) provide information on Medicare expenditures for injectable end-stage renal disease (ESRD) drugs, by beneficiaries' demographic characteristics; (2) identify the factors that clinicians and researchers indicate are likely to result in a higher-than-average dose of injectable drugs for a dialysis patient; (3) describe the Centers for Medicare & Medicaid Services' (CMS) approach for addressing differences among beneficiaries in the cost of dialysis care under the new bundled payment system for these services; and (4) examine CMS's plans for monitoring the effects of the new bundled payment system on beneficiaries.

To provide information on Medicare expenditures for injectable ESRD drugs, by beneficiaries' demographic characteristics, we analyzed the most recent available data from a national data system containing information on beneficiaries with ESRD. Specifically, we obtained data from the United States Renal Data System (USRDS) on monthly Medicare expenditures per beneficiary on dialysis in 2007 for injectable ESRD drugs.[1,2] We focused our analysis on erythropoiesis stimulating agents (ESA), intravenous (IV) iron, and IV vitamin D because these three types of drugs accounted for about 98 percent of the approximately $2.2 billion in Medicare expenditures on injectable ESRD drugs in 2007.[3] We analyzed data for 326,899 Medicare beneficiaries on dialysis in 2007. The data we analyzed did not contain all of the 413,540 beneficiaries on dialysis in 2007 because we excluded beneficiaries (1) who were in Medicare managed care plans, (2) for whom Medicare was not the primary payer, or (3) for whom no claims for Medicare services provided in 2007 were submitted.

We analyzed monthly Medicare expenditures per beneficiary in 2007 on ESAs, IV iron, and IV vitamin D across the following demographic characteristics available through the USRDS database: age, sex, race, ethnicity, urban/rural residential location, and whether a beneficiary was

[1]USRDS 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 of the National Institutes of Health in conjunction with CMS.

[2]We analyzed monthly expenditures to correspond to Medicare's monthly billing cycle for ESRD services.

[3]Of the approximately $2.2 billion in Medicare expenditures on injectable ESRD drugs in 2007, about 75 percent was for ESAs, 15 percent for IV vitamin D, 9 percent for IV iron, and 2 percent for other injectable ESRD drugs. These percentages do not sum to 100 because of rounding.

enrolled in Medicaid.[4] Additionally, we analyzed USRDS data for 2003 through 2006 to determine whether the results for 2007 were consistent in prior years. We did not address in our expenditure analysis the extent to which the relationships we presented between demographic characteristics and Medicare expenditures reflected underlying clinical or other factors. Data on monthly Medicare expenditures per beneficiary were based on Medicare claims. The expenditure amounts that we presented did not include beneficiary cost sharing. Monthly Medicare expenditures per beneficiary were calculated by dividing Medicare expenditures for a given drug by the number of months beneficiaries were on dialysis in 2007.

USRDS data on demographic characteristics—with the exception of Medicaid enrollment status—were drawn primarily from CMS's Renal Management Information System (REMIS) database.[5] Dialysis providers collected these data using a standardized form called the Medical Evidence Form.[6] We used these data to present results on monthly Medicare expenditures on injectable ESRD drugs across the following age categories: 0-19, 20-44, 45-54, 55-64, 65-74, and 75 and older. We selected these age categories to capture the pediatric population (i.e., age 19 and under) and to make the number of beneficiaries within each of the remaining categories similar. The USRDS data we analyzed on race and ethnicity are based on subjective determinations of beneficiaries' racial and ethnic identity. In addition, these data were collected using different racial and ethnic categories depending on which version of the Medical Evidence Form was used. Figure 3 demonstrates how the racial and ethnic categories on the different versions of the Medical Evidence Form link to the categories we used in this report. A beneficiary's residence was classified as urban if it was in an area with at least 500 people per square

[4]These expenditure amounts are only for the drugs themselves and do not cover the cost of administering the drugs, which is covered under the composite rate.

[5]The REMIS database contains demographic, diagnosis, and ESRD treatment history data for all beneficiaries with ESRD.

[6]This form, which is also called Form CMS-2728, serves to establish Medicare eligibility for individuals who previously were not Medicare beneficiaries, reclassify previously eligible Medicare beneficiaries as ESRD patients, and provide demographic and diagnostic information on all new ESRD patients. CMS requires that this form be completed and submitted to the ESRD networks. CMS requires the ESRD networks to review these forms for accuracy and completeness. The networks periodically update data in the REMIS database on age, sex, race, ethnicity, and residential location.

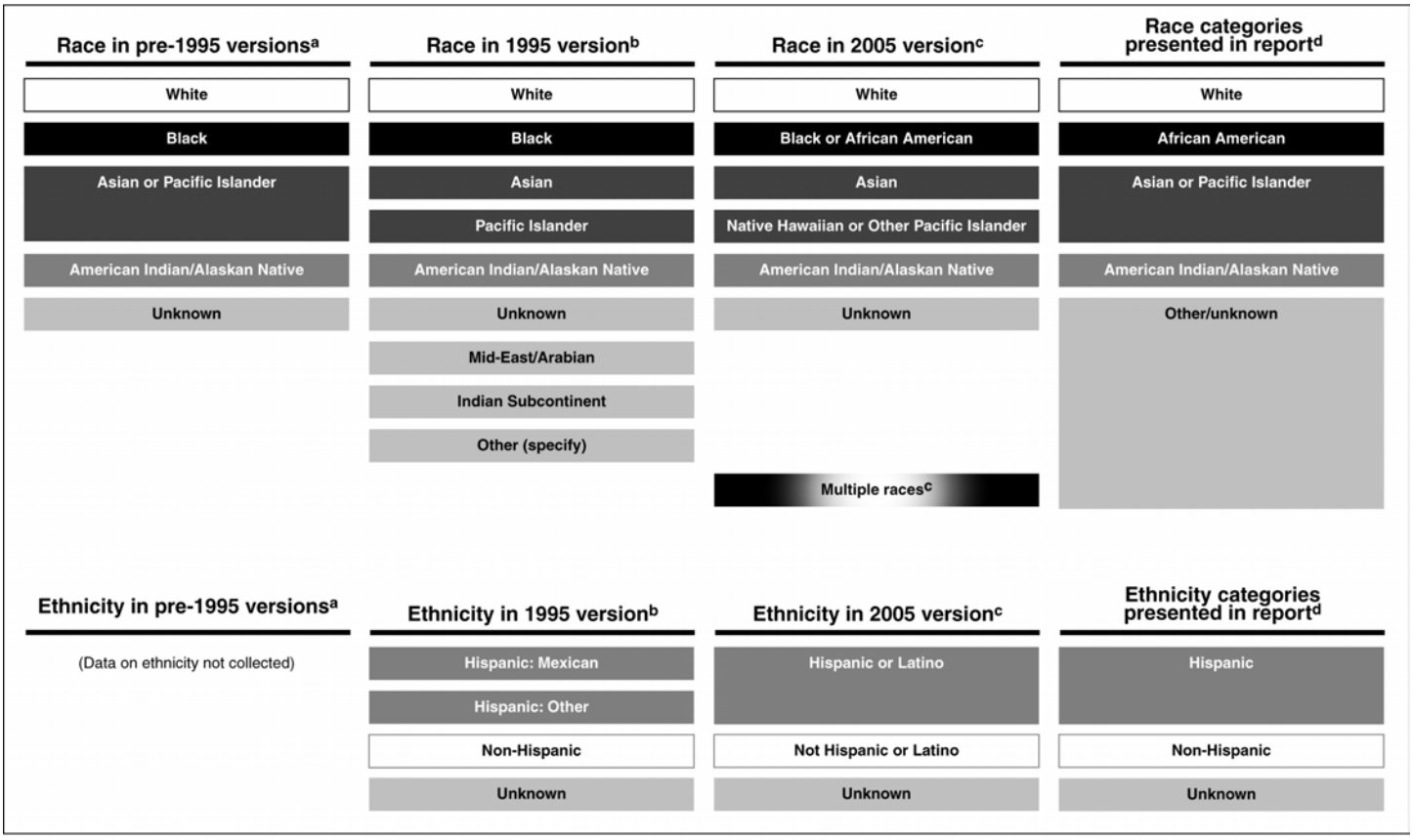
mile, and all other areas were considered rural.[7] Finally, USRDS data on Medicaid enrollment status were drawn from the Medicare Enrollment Database.[8] We used beneficiaries' Medicaid enrollment status as an indicator of their socioeconomic status because beneficiaries' income and asset levels determine their eligibility for Medicaid, which provides financial assistance with the cost of medical care.[9]

[7]This classification was based on the U.S. Census Bureau's definition of urban and rural areas.

[8]This database primarily contains information on Medicare enrollment for all beneficiaries and is updated daily.

[9]To be eligible for Medicaid in 2007, an unmarried Medicare beneficiary who was not disabled generally was required to have income of less than 135 percent of the federal poverty level and assets of at most $4,000. The federal poverty level for a single beneficiary in the 48 states and the District of Columbia was $10,210 in 2007.

Figure 3: Crosswalk between Race and Ethnicity Categories on CMS Medical Evidence Forms and the Categories Used in This Report



Sources: CMS Medical Evidence Forms for pre-1995, 1995, and 2005.

Notes: About 4.0 percent of the 413,540 Medicare beneficiaries on dialysis at some point in 2007 had race and ethnicity data in the USRDS based on a pre-1995 version of the Medical Evidence Form, 45.5 percent had these data based on the 1995 version, 50.0 percent had data based on the 2005 version, and 0.5 percent did not have data from any version of the Medical Evidence Form.

[a]The pre-1995 versions of the form did not indicate that beneficiaries could select multiple races and also did not collect data on ethnicity.

[b]CMS required that dialysis providers use the 1995 version of the Medical Evidence Form beginning on April 1, 1995. This version of the form instructed beneficiaries to select a single race category. However, the form did not specify whether beneficiaries should check one or more ethnicity categories. In addition, the form did not have an option for unknown ethnicity, so this category in the table above refers to missing information for this characteristic.

[c]CMS required that dialysis providers use the 2005 version of the Medical Evidence Form beginning on June 1, 2005. This version of the form indicated that beneficiaries could select multiple race categories. CMS noted in its 2009 proposed rule for the new bundled payment system that while the form does not provide instructions for whether to select multiple ethnicity categories, it is assumed that the beneficiary would select one of the two categories. Medicare Programs; End-Stage Renal Disease Prospective Payment System, 74 Fed. Reg. at 49,222, 49,963 (proposed Sept. 29, 2009). In addition, the form did not have options for unknown race or ethnicity, so these categories in the table above refer to missing information for these characteristics.

[d]See app. III for detailed results by race and ethnicity on monthly Medicare expenditures per beneficiary on injectable ESRD drugs.

We assessed the reliability of data from the USRDS by interviewing officials responsible for producing these data, reviewing relevant documentation, comparing the results to published sources, and examining the data for obvious errors. Although we report that CMS has concerns about using data on race and ethnicity for the purposes of adjusting bundled payments, we determined that data on these characteristics as well as other USRDS data that we used were sufficiently reliable for the descriptive analytical purposes of our study.

To identify the factors that clinicians and researchers indicate are likely to result in a higher-than-average dose of injectable ESRD drugs (specifically, ESAs, IV iron, and IV vitamin D) for a dialysis patient, we developed a structured data collection approach that included interviews with relevant industry groups, clinicians, and researchers with expertise in ESRD as well as the administration of a Web-based data collection instrument to selected nephrology clinicians and ESRD researchers (see app. II for the data collection instrument). To develop this instrument and provide context for our findings, we conducted 20 structured interviews with representatives of large and small dialysis organizations and dialysis-related professional organizations, nephrology clinicians, and researchers with expertise in ESRD and also reviewed the clinical literature related to the use of the three types of drugs.[10,11] We asked each interviewee about the beneficiary characteristics associated with high or low use of these drugs. We summarized the information obtained from these interviews and used it to develop the lists of clinical factors used for our data collection instrument. The demographic factors listed on the data collection

[10]The term "large dialysis organizations" refers to the three dialysis organizations that accounted for about 64 percent of dialysis facilities in 2008—DaVita and Fresenius accounted for about 60 percent of all facilities, and Dialysis Clinic Inc. accounted for 4 percent. Alternatively, "small dialysis organizations" are dialysis providers that are not a part of these three large chains.

[11]We interviewed representatives of the following dialysis organizations: Centers for Dialysis Care, DaVita, Fresenius, Northwest Kidney Centers, and Satellite Healthcare. We interviewed representatives of the following professional organizations: American Society of Nephrology, American Society of Pediatric Nephrology, National Kidney Foundation, National Renal Administrators Association, and Renal Physicians Association. We also interviewed clinicians and researchers from Geisinger Health System, Kaiser Permanente, Massachusetts General Hospital, Saint Louis University, USRDS, University Hospitals Case Medical Center, VA Boston Healthcare System, and Washington University in Saint Louis School of Medicine.

instrument were those we examined in our analysis of Medicare expenditures on injectable ESRD drugs. We pretested the data collection instrument with nephrologists and revised it based on comments we received.

Through the data collection instrument, clinicians and researchers were asked to identify the clinical and demographic factors that are likely to result in a higher-than-average dose of ESAs, IV iron, or IV vitamin D for a dialysis patient. In addition, individuals who completed the data collection instrument had the option of writing in factors not already listed in the instrument. We analyzed results by calculating the percentage of the 73 clinicians and researchers who completed our data collection instrument who identified a given factor as being likely or not likely to result in a higher-than-average dose of each of the three types of ESRD drugs we examined. These results represent the views of the 73 clinicians and researchers and are not generalizable to a broader population.

We administered the Web-based data collection instrument to a select number of clinicians and researchers with expertise related to the factors that could impact the dose of injectable ESRD drugs. We selected these individuals in two ways. First, we obtained referrals from national, U.S.-based professional organizations that represent nephrology clinicians (i.e., nephrologists, nephrology nurses, nephrology physician assistants, and advanced practitioners specializing in nephrology) who evaluate and treat dialysis patients.[12] We compiled an initial list of nephrology-related professional societies and associations based on our background research on ESRD.[13] To identify additional organizations, we visited the Web site of each of these organizations and obtained a list of related organizations, if available. We selected eight organizations from these lists that met the above criteria. We asked each organization that we identified for referrals to up to 20 nephrology clinicians who have expertise related to factors that could impact the dose of ESAs, IV iron, or IV vitamin D for dialysis patients. We specified in our request that these individuals must (1) be nephrologists, nephrology nurses, physician assistants or advanced

[12]We selected national societies and associations based in the United States to help ensure that (1) the organizations we chose drew their membership from the country overall rather than a potentially small local area and (2) the clinicians selected resided in the United States to facilitate our contacting them.

[13]These organizations were the American Society of Nephrology, American Nephrology Nurses' Association, American Society of Pediatric Nephrology, American Academy of Nephrology Physicians Assistants, and Renal Physicians Association.

practitioners specializing in nephrology, or nephrology technicians/technologists; (2) evaluate and treat dialysis patients; and (3) reside in the United States. We also asked for referrals to major national societies or associations, other than the ones we already planned to contact, that are based in the United States and represent nephrology clinicians. If referrals to additional organizations were provided, we contacted these groups as described above and asked them for referrals to clinicians. We received referrals from the following seven organizations[14]:

- American Academy of Nephrology Physicians Assistants
- American Nephrology Nurses' Association
- American Society of Nephrology
- American Society of Pediatric Nephrology
- Council of Advanced Practitioners[15]
- Renal Physicians Association
- Women in Nephrology

The second way we identified clinicians and researchers was through the ESRD literature. Using multiple databases, including BIOSIS Previews®, Elsevier BIOBASE, MEDLINE, SciSearch®, EMBASE®, EMCare, and EMBASE AlertTM, we conducted a review of the literature published from 2004 through 2009 related to the use of ESAs, IV iron, and IV vitamin D to treat ESRD patients.[16] We searched these databases for articles related to the dose of these drugs.[17]

We administered the Web-based data collection instrument in August and September 2009. We sent the instrument to 131 clinicians and researchers—the 100 referrals we received from professional

[14]We also requested, but did not receive, referrals from the National Association of Nephrology Technicians/Technologists.

[15]The Council of Advanced Practitioners is a professional membership council within the National Kidney Foundation.

[16]We conducted a separate literature search for each of the three types of drugs.

[17]We excluded articles not written in English and articles with no available abstracts.

organizations and an additional 31 primary authors that we identified through the literature. We received 73 completed instruments.

To describe CMS's approach for addressing differences among beneficiaries in the cost of dialysis care under the new bundled payment system for these services, we reviewed CMS's proposed rule on the design of the new payment system.[18] We also reviewed the Department of Health and Human Services' report to Congress on the design of the new payment system as well as reports on this topic by the University of Michigan, Kidney Epidemiology and Cost Center (UM-KECC), which has assisted CMS with the payment system's design.[19] In addition, we interviewed CMS officials and representatives from UM-KECC. We also interviewed representatives of three non-Medicare payers of dialysis care—the Department of Veterans Affairs (VA) and two large health plans—to obtain contextual information about other bundled payment systems.[20,21] Finally, to examine CMS's plans for monitoring the effects of the new bundled payment system on beneficiaries' access to and quality of dialysis care, we interviewed CMS officials and reviewed prior reports as well as CMS's proposed rule on the design of the new bundled payment system.

[18]Medicare Programs; End-Stage Renal Disease Prospective Payment System, 74 Fed. Reg. at 49,922 (proposed Sept. 29, 2009).

[19]See Department of Health and Human Services, *Report to Congress: A Design for a Bundled End Stage Renal Disease Prospective Payment System* (Washington, D.C., 2008), and Hirth et al., *End Stage Renal Disease Payment System: Results of Research on Case-Mix Adjustment for an Expanded Bundle.*

[20]The two plans whose representatives we interviewed were among the largest in the country with regard to overall plan enrollment.

[21]According to VA officials, VA uses Medicare's current payment system for dialysis care when this care is provided to veterans in non-VA dialysis facilities. The two plans whose representatives we interviewed use bundled payment systems to pay for dialysis care but do not adjust these payments based on demographic or clinical factors.

Appendix II: GAO Data Collection Instrument on Dose of Dialysis-Related Drugs

GAO Questionnaire on the Dose of Dialysis-Related Drugs

U.S. Government Accountability Office

Purpose of the Questionnaire

The U.S. Government Accountability Office (GAO), the research arm of Congress, has been asked by the Chairman of U.S. House of Representatives, Committee on Ways and Means, Subcommittee on Health to study the treatment of Medicare beneficiaries with end-stage renal disease (ESRD). As part of this work we are collecting expert opinion on the factors that are likely to result in a higher than average dose of dialysis-related drugs used for a dialysis patient.

Below is a brief questionnaire that we are using to systematically collect information from experts on the factors that are likely to result in a higher than average dose of injectable vitamin D, injectable iron, and erythropoietin stimulating agents (ESAs) used for a dialysis patient. Your response to this questionnaire is particularly important given that we are sending it to a select group of experts. We developed the list of potential factors in the tables below based on interviews with individuals who have expertise in this area. We realize that there are many demands on your time and greatly appreciate your response to this questionnaire, which should take about 15 minutes.

Completion Date

Please complete the questionnaire within **2 weeks**.

How to Get Help

See how to get help if you have questions or are experiencing difficulties responding to the questionnaire.

Navigation Instructions

We have provided navigation instructions to help you complete the questionnaire, answer questions and edit answers, exit and re-enter the questionnaire, and print your responses.

Factors that Are Likely to Result in a Higher than Average Dose of Injectable Vitamin D, Injectable Iron, and ESAs

Injectable Vitamin D

For each factor listed below, please indicate whether it is likely or unlikely to result in a higher than average dose of injectable vitamin D for a dialysis patient.

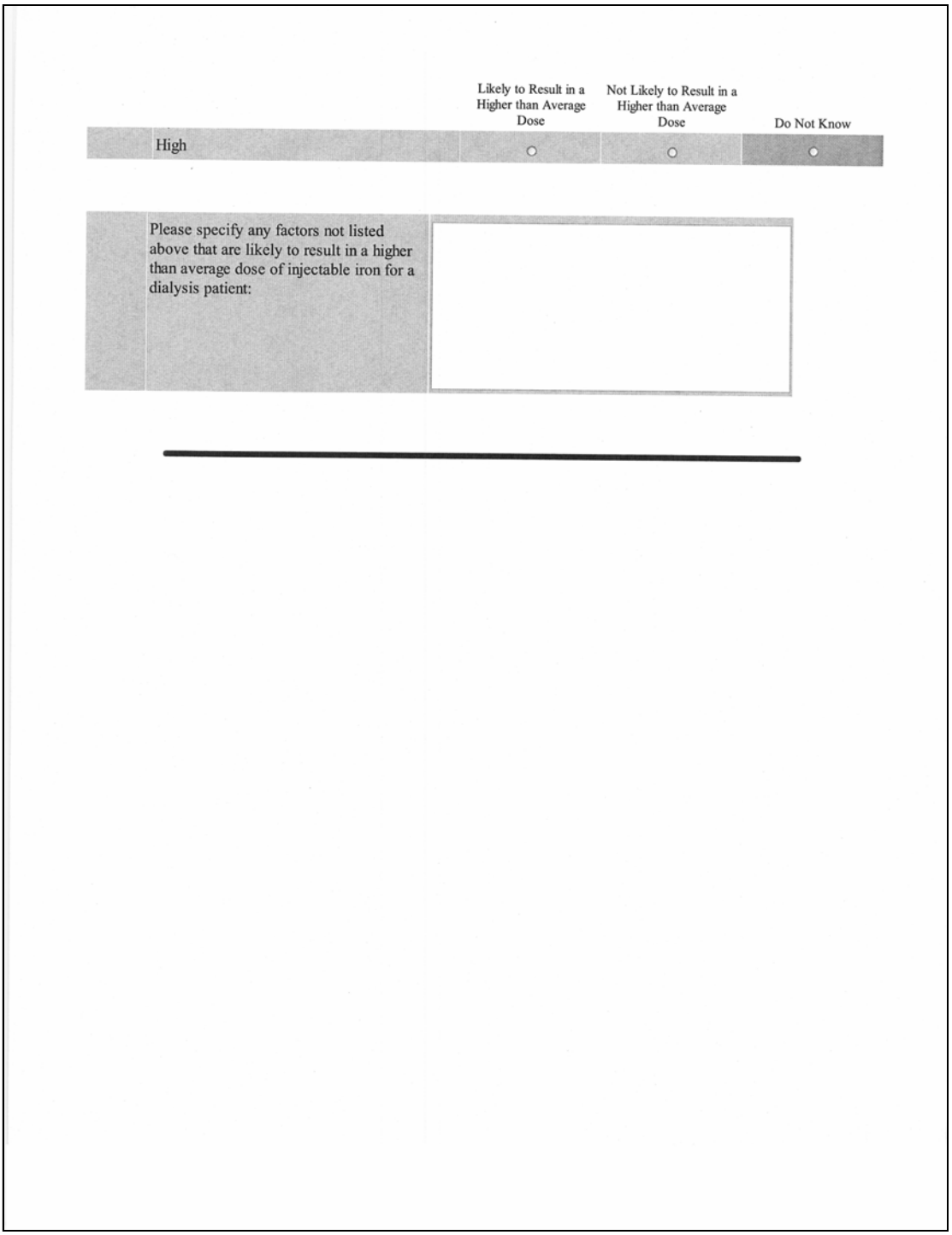
	Likely to Result in a Higher than Average Dose	Not Likely to Result in a Higher than Average Dose	Do Not Know
Hyperparathyroidism	○	○	○
Malnutrition	○	○	○
Lack of Pre-dialysis care	○	○	○
Age: 0-19	○	○	○
20-44	○	○	○
45-54	○	○	○
55-64	○	○	○
65-74	○	○	○
75+	○	○	○
Sex: Female	○	○	○
Male	○	○	○
Race: African American	○	○	○
White	○	○	○
Other	○	○	○
Ethnicity: Hispanic	○	○	○
Non-Hispanic	○	○	○
Residential Location: Urban	○	○	○
Rural	○	○	○
Socioeconomic Status: Low	○	○	○
High	○	○	○

Please specify any factors not listed above that are likely to result in a higher than average dose of injectable vitamin D for a dialysis patient:	

Injectable Iron

For each factor listed below, please indicate whether it is likely or unlikely to result in a higher than average dose of injectable iron for a dialysis patient.

	Likely to Result in a Higher than Average Dose	Not Likely to Result in a Higher than Average Dose	Do Not Know
Large Body Size	○	○	○
Low iron stores (e.g. transferrin saturation <= 20%)	○	○	○
Inadequate dialysis (e.g. URR < 65%)	○	○	○
Recent hospitalization (e.g. within the last 90 days)	○	○	○
Fewer than 4 months on dialysis	○	○	○
Chronic blood loss	○	○	○
Malnutrition	○	○	○
Concurrent treatment with ESAs	○	○	○
Infection or inflammatory conditions (e.g. lupus, multiple myeloma, pneumonia, etc.)	○	○	○
Refusal to receive immunizations	○	○	○
Age: 0-19	○	○	○
20-44	○	○	○
45-54	○	○	○
55-64	○	○	○
65-74	○	○	○
75+	○	○	○
Sex: Female	○	○	○
Male	○	○	○
Race: African American	○	○	○
White	○	○	○
Other	○	○	○
Ethnicity: Hispanic	○	○	○
Non-Hispanic	○	○	○
Residential Location: Urban	○	○	○
Rural	○	○	○
Socioeconomic Status: Low	○	○	○



	Likely to Result in a Higher than Average Dose	Not Likely to Result in a Higher than Average Dose	Do Not Know
High	○	○	○

Please specify any factors not listed above that are likely to result in a higher than average dose of injectable iron for a dialysis patient:	

ESAs

For each factor listed below, please indicate whether it is likely or unlikely to result in a higher than average dose of ESAs for a dialysis patient.

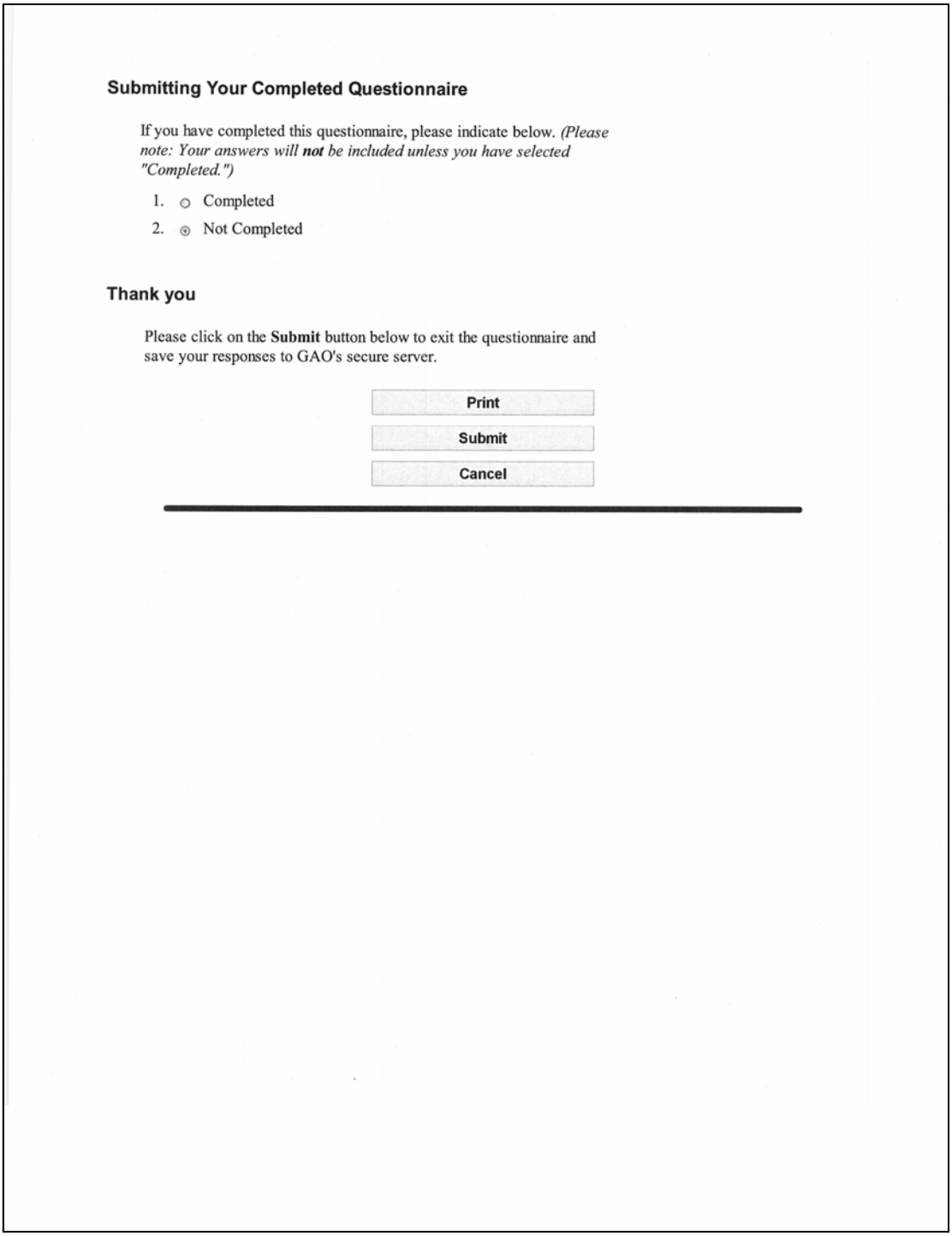
	Likely to Result in a Higher than Average Dose	Not Likely to Result in a Higher than Average Dose	Do Not Know
Large Body Size	○	○	○
Low iron stores (e.g. transferrin saturation <= 20%)	○	○	○
Inadequate dialysis (e.g. URR < 65%)	○	○	○
Low hemoglobin level (e.g. <10 g/dl)	○	○	○
Recent hospitalization (e.g. within the last 90 days)	○	○	○
Use of a dialysis catheter	○	○	○
Fewer than 4 months on dialysis	○	○	○
Malnutrition	○	○	○
Chronic bleeding	○	○	○
Infection or inflammatory conditions (e.g. lupus, multiple myeloma, pneumonia, etc.)	○	○	○
Hemoglobin production disorders (e.g. thalassemia, sickle cell anemia)	○	○	○
Concurrent treatment with antihypertensive medication (e.g. Angiotensin-Converting Enzyme inhibitors, Angiotensin II Receptor Blockers)	○	○	○
Non-adherence to dialysis treatment (not due to recent hospitalization)	○	○	○
Non-adherence to ESA treatment (not due to recent hospitalization)	○	○	○
Non-adherence to iron treatment (not due to recent hospitalization)	○	○	○
Refusal to receive immunizations	○	○	○
Age: 0-19	○	○	○
20-44	○	○	○
45-54	○	○	○
55-64	○	○	○
65-74	○	○	○
75+	○	○	○

	Likely to Result in a Higher than Average Dose	Not Likely to Result in a Higher than Average Dose	Do Not Know
Sex: Female	○	○	○
Male	○	○	○
Race: African American	○	○	○
White	○	○	○
Other	○	○	○
Ethnicity: Hispanic	○	○	○
Non-Hispanic	○	○	○
Residential Location: Urban	○	○	○
Rural	○	○	○
Socioeconomic Status: Low	○	○	○
High	○	○	○

Please specify any factors not listed above that are likely to result in a higher than average dose of ESAs for a dialysis patient:	

Please indicate which of the following apply to you:
(Check all that apply.)

1. ☐ I evaluate and treat dialysis patients
2. ☐ I am a nephrologist
3. ☐ I am a pediatric nephrologist
4. ☐ I am a Medical Director of a dialysis facility
5. ☐ I am a nephrology nurse
6. ☐ I am a physician assistant or advanced practitioner who specializes in nephrology
7. ☐ I am a nephrology technologist or technician
8. ☐ My professional work focuses on research related to dialysis or the dose of dialysis-related drugs



Submitting Your Completed Questionnaire

If you have completed this questionnaire, please indicate below. *(Please note: Your answers will* ***not*** *be included unless you have selected "Completed.")*

1. ○ Completed
2. ◉ Not Completed

Thank you

Please click on the **Submit** button below to exit the questionnaire and save your responses to GAO's secure server.

Print

Submit

Cancel

Appendix III: Medicare Expenditures for Injectable ESRD Drugs by Demographic Characteristics

Table 5 presents detailed information on average monthly Medicare expenditures per beneficiary for injectable ESRD drugs in 2007, by beneficiaries' demographic characteristics. These results are based on data for 326,899 Medicare beneficiaries on dialysis in 2007 from USRDS. See appendix I for additional detail on the methodology used to generate these results.

Table 5: Average Monthly Medicare Expenditures per Beneficiary for Injectable ESRD Drugs by Demographic Characteristics, 2007

Demographic characteristic	Percentage of beneficiaries	Average monthly Medicare expenditures per beneficiary				
		Total	ESA	IV iron	IV vitamin D	Other injectable drugs[a]
Age						
0-19	0.5	**$441**	$322	$29	$62	$27
20-44	13.1	**755**	562	57	114	20
45-54	15.6	**724**	536	58	116	15
55-64	21.7	**698**	515	57	109	17
65-74	24.8	**692**	516	61	99	16
75+	24.3	**630**	472	62	81	15
Sex						
Male	54.4	**673**	496	59	103	15
Female	45.6	**715**	537	59	101	19
Race						
White	57.5	**645**	490	59	78	19
African American	36.5	**782**	566	62	141	14
Asian or Pacific Islander	3.9	**552**	421	45	75	10
American Indian/ Alaskan Native	1.5	**555**	416	48	79	11
Other/unknown	0.7	**615**	452	49	105	8
Ethnicity						
Non-Hispanic	85.7	**708**	527	60	104	17
Hispanic	13.4	**596**	441	54	91	10
Unknown	0.9	**686**	504	51	106	26
Residence[b]						
Urban	71.2	**699**	517	60	106	16
Rural	26.0	**688**	517	59	93	18
Unknown	2.8	**584**	442	51	80	11
Medicaid enrollment						
Medicare only	57.9	**659**	492	58	93	16
Medicare and Medicaid	42.1	**735**	545	61	113	16
All	100.0	**693**	515	59	102	16

Source: Data from the United States Renal Data System for 2007.

Notes: Results are for 326,899 Medicare patients who were on dialysis at some point in 2007. Dollar amounts do not include beneficiary coinsurance and deductible amounts and were calculated by dividing Medicare expenditures for a given injectable ESRD drug category by the total number of months beneficiaries were on dialysis in 2007. Results do not include beneficiaries who were in Medicare managed care plans, for whom Medicare was a secondary payer or for whom no claims for Medicare services in 2007 were submitted. Percentages may not sum to 100.0 and dollar amounts may not sum to totals because of rounding.

[a]Other injectable drugs include Levocarnitine (used to address a deficiency in carnitine, which helps the body produce energy), Alteplase (used to restore blood flow through a patient's vascular access), Vancomycin (used for treatment of serious infections), and certain vaccines.

[b]Urban areas are defined as those having at least 500 people per square mile, and all other areas are defined as rural.

Appendix IV: Detailed Results from Data Collection Instrument on Dose of Dialysis-Related Drugs

This appendix contains additional information on the results of the data collection instrument we used to systematically collect information on the factors likely to result in a higher-than-average dose of three types of injectable dialysis-related drugs—ESAs, IV iron, and IV vitamin D (see app. II for the data collection instrument). Table 6 presents data on the factors identified by the 73 clinicians and researchers that are either likely or unlikely to result in higher-than-average doses of ESAs. Tables 7 and 8 present data on IV iron and IV vitamin D, respectively. Following these tables is a brief summary of the open-ended responses to the data collection instrument.

Table 6: Percentage of Selected Clinicians and Researchers Indicating Whether a Factor Is Likely or Not Likely to Result in a Higher-Than-Average Dose of ESAs

	Likely to result in a higher-than-average dose	Not likely to result in a higher-than-average dose	Do not know/ no response
Clinical factors			
Chronic blood loss	98.6	0.0	1.4
Concurrent treatment with antihypertensive medication	26.0	63.0	11.0
Fewer than 4 months on dialysis	67.1	27.4	5.5
Hemoglobin production disorders	79.5	11.0	9.6
Inadequate dialysis	76.7	16.4	6.8
Infection or inflammatory conditions	91.8	6.8	1.4
Large body size	80.8	11.0	8.2
Low hemoglobin level	98.6	1.4	0.0
Low iron stores	86.3	13.7	0.0
Malnutrition	86.3	12.3	1.4
Nonadherence to dialysis treatment	91.8	6.8	1.4
Nonadherence to ESA treatment	84.9	9.6	5.5
Nonadherence to iron treatment	84.9	11.0	4.1
Recent hospitalization	95.9	2.7	1.4
Refusal to receive immunizations	2.7	56.2	41.1
Use of a dialysis catheter	63.0	27.4	9.6

	Likely to result in a higher-than-average dose	Not likely to result in a higher-than-average dose	Do not know/ no response
Demographic factors			
Age			
0-19	13.7	32.9	53.4
20-44	12.3	58.9	28.8
45-54	8.2	63.0	28.8
55-64	9.6	61.6	28.8
65-74	15.1	53.4	31.5
75+	20.5	52.1	27.4
Ethnicity			
Hispanic	6.8	63.0	30.1
Non-Hispanic	2.7	64.4	32.9
Race			
African American	24.7	57.5	17.8
Other	2.7	58.9	38.4
White	6.8	74.0	19.2
Residential location			
Rural	5.5	67.1	27.4
Urban	11.0	64.4	24.7
Sex			
Female	32.9	52.1	15.1
Male	6.8	80.8	12.3
Socioeconomic status			
Low	30.1	50.7	19.2
High	2.7	78.1	19.2
Other factors	**23.3**	**N/A**	**N/A**

Source: GAO's August and September 2009 data collection instrument on the dose of dialysis-related drugs.

Legend: N/A = not applicable.

Notes: All percentages are calculated based on a total of 73 clinicians and researchers. The list of clinical factors above for ESAs is based on information obtained from 20 structured interviews with representatives of dialysis organizations and dialysis-related professional organizations, nephrology clinicians, and ESRD researchers. Percentages may not sum to 100.0 because of rounding.

Table 7: Percentage of Selected Clinicians and Researchers Indicating Whether a Factor Is Likely or Not Likely to Result in a Higher-Than-Average Dose of IV Iron

	Likely to result in a higher-than-average dose	Not likely to result in a higher-than-average dose	Do not know/ no response
Clinical factors			
Chronic blood loss	95.9	2.7	1.4
Concurrent treatment with ESAs	57.5	38.4	4.1
Fewer than 4 months on dialysis	65.8	27.4	6.8
Inadequate dialysis	47.9	46.6	5.5
Infection or inflammatory conditions	49.3	45.2	5.5
Large body size	34.2	50.7	15.1
Low iron stores	90.4	8.2	1.4
Malnutrition	64.4	27.4	8.2
Recent hospitalization	78.1	16.4	5.5
Refusal to receive immunizations	0.0	53.4	46.6
Demographic factors			
Age			
0-19	9.6	42.5	47.9
20-44	12.3	61.6	26.0
45-54	6.8	67.1	26.0
55-64	5.5	67.1	27.4
65-74	17.8	56.2	26.0
75+	23.3	47.9	28.8
Ethnicity			
Hispanic	9.6	56.2	34.2
Non-Hispanic	1.4	65.8	32.9
Race			
African American	15.1	64.4	20.5
Other	1.4	56.2	42.5
White	5.5	74.0	20.5
Residential location			
Rural	4.1	67.1	28.8
Urban	11.0	63.0	26.0
Sex			
Female	42.5	38.4	19.2
Male	2.7	82.2	15.1

	Likely to result in a higher-than-average dose	Not likely to result in a higher-than-average dose	Do not know/ no response
Socioeconomic status			
Low	41.1	42.5	16.4
High	1.4	78.1	20.5
Other factors	19.2	N/A	N/A

Source: GAO's August and September 2009 data collection instrument on the dose of dialysis-related drugs.

Legend: N/A = not applicable.

Notes: All percentages are calculated based on a total of 73 clinicians and researchers. The list of clinical factors above for IV iron is based on information obtained from 20 structured interviews with representatives of dialysis organizations and dialysis-related professional organizations, nephrology clinicians, and ESRD researchers. Percentages may not sum to 100.0 because of rounding.

Table 8: Percentage of Selected Clinicians and Researchers Indicating Whether a Factor Is Likely or Not Likely to Result in a Higher-Than-Average Dose of IV Vitamin D

	Likely to result in a higher-than-average dose	Not likely to result in a higher-than-average dose	Do not know/ no response
Clinical factors			
Hyperparathyroidism	87.7	11.0	1.4
Lack of predialysis care	84.9	8.2	6.8
Malnutrition	38.4	49.3	12.3
Demographic factors			
Age			
0-19	15.1	32.9	52.1
20-44	19.2	53.4	27.4
45-54	19.2	52.1	28.8
55-64	16.4	57.5	26.0
65-74	16.4	56.2	27.4
75+	20.5	52.1	27.4
Ethnicity			
Hispanic	17.8	47.9	34.2
Non-Hispanic	2.7	61.6	35.6
Race			
African American	46.6	38.4	15.1
Other	0.0	49.3	50.7
White	6.8	76.7	16.4
Residential location			
Rural	5.5	65.8	28.8
Urban	31.5	43.8	24.7
Sex			
Female	15.1	64.4	20.5
Male	9.6	68.5	21.9
Socioeconomic status			
Low	61.6	23.3	15.1
High	4.1	75.3	20.5
Other factors	34.2	N/A	N/A

Source: GAO's August and September 2009 data collection instrument on the dose of dialysis-related drugs.

Legend: N/A = not applicable.

Notes: All percentages are calculated based on a total of 73 clinicians and researchers. The list of clinical factors above for IV vitamin D is based on information obtained from 20 structured interviews with representatives of dialysis organizations and dialysis-related professional organizations, nephrology clinicians, and ESRD researchers. Percentages may not sum to 100.0 because of rounding.

Summary of Open-Ended Responses

In addition to selecting from among the list of factors in the data collection instrument, individuals completing the instrument had the option of writing in factors not already listed that they considered as likely to result in above average doses of ESAs, IV iron, or IV vitamin D. Of the 73 clinicians and researchers who completed the data collection instrument, about 23 percent wrote in additional factors for ESAs, 19 percent wrote in such information for IV iron, and about 37 percent did so for IV vitamin D. Examples of additional factors provided by clinicians and researchers for ESAs and IV iron include nonadherence to diet, hyperparathyroidism, lack of predialysis care, and smoking. Examples of factors supplied for IV vitamin D include nonadherence to phosphate binders, nonadherence to diet, and recent hospitalization.[1]

[1]Phosphate binders are a group of oral medications designed to reduce the absorption of phosphorus from food and drink.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

MAR 9 2010

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

Dear Mr. Cosgrove:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "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).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Andrea Palm
Acting Assistant Secretary for Legislation

Enclosure

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "END-STAGE RENAL DISEASE: CMS SHOULD MONITOR ACCESS TO QUALITY OF DIALYSIS CARE PROMPTLY AFTER IMPLEMENTATION OF NEW BUNDLED PAYMENT SYSTEM" (GAO-10-295)

Thank you for the opportunity to review and comment on the Government Accountability Office's (GAO) draft report entitled, "END-STAGE RENAL DISEASE: CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System." We appreciate the GAO's interest in ensuring that the proposed bundled payment system for end-stage renal disease (ESRD) will not have an adverse effect on certain beneficiary groups, specifically those that have above average Medicare expenditures for injectable ESRD drugs.

GAO Recommendations:

GAO recommends that the Centers for Medicare & Medicaid Services (CMS) begin monitoring access to and quality of dialysis care for certain beneficiary groups, particularly those with above average costs of dialysis care, as soon as possible after implementation of the new bundled payment system.

CMS Response:

The CMS concurs with the GAO's recommendation and is planning to actively monitor the effect of the expanded bundled payment on all ESRD beneficiaries, including categories of beneficiaries such as those ESRD beneficiaries who may use an above average amount of ESRD related items and services. CMS notes that the GAO based its findings on interviews conducted before publication of the ESRD prospective payment system (PPS) proposed rule. Therefore, the statement made by the GAO indicating that "CMS's preliminary plans for monitoring access to dialysis care are limited" does not reflect planning efforts currently underway. CMS plans to have a comprehensive monitoring strategy in place when the payment system is implemented on January 1, 2011.

The CMS currently collects detailed claims data on patients' hemoglobin levels and adequacy of dialysis, and also has information on treatments provided, drugs, hospitalizations, deaths, etc. CMS also collects beneficiary enrollment data which provides important demographic and other information. This will provide a basis for early examination of overall trends in care delivery and quality. In addition, CMS will utilize its existing infrastructure for quality oversight in the ESRD facilities, including the ESRD networks, as the new system is implemented. As part of its monitoring strategy, CMS plans to use existing data sources such as the Standard Information Management System (SIMS), Renal Management Information System (REMIS), Online Survey Certification and Reporting System (OSCAR) to analyze beneficiary and provider level data to determine whether patterns emerge indicating particular effects of the new system, e.g., whether there are increases/decreases in utilization of injectable ESRD drugs and use of home modalities for certain groups of ESRD beneficiaries. Data from this monitoring plan will assist CMS in ensuring that beneficiaries continue to receive quality dialysis services under the new system, and ultimately inform potential refinements to the payment system and quality incentive program (QIP) moving forward.

1

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "END-STAGE RENAL DISEASE: CMS SHOULD MONITOR ACCESS TO QUALITY OF DIALYSIS CARE PROMPTLY AFTER IMPLEMENTATION OF NEW BUNDLED PAYMENT SYSTEM" (GAO-10-295)

In addition, CMS expects to issue a proposed rule on the new QIP program in the near future that is part of this larger monitoring effort.

Finally, in developing this report, GAO analyzed certain data, surveyed physicians and others with relevant knowledge, and determined that groups of beneficiaries, whether it is related to clinical or demographic factors, may be vulnerable to problems with accessing dialysis care or with the quality of that care. The report suggests that clinical factors, rather than demographic characteristics, are more likely to relate to higher doses of injectable ESRD drugs, therefore resulting in above average Medicare expenditures for certain groups of beneficiaries. CMS understands that physicians examine relevant clinical information for the purpose of determining dosage of drugs. We note, however, that the payment model included in the proposed ESRD PPS rule is designed to predict ESRD facility costs, and be used in making payments to such facilities based on the information they are able to provide on claims. We further note that the demographic and other items in the proposed payment model have been determined to be statistically significant, and the payment model itself is effective in predicting facility costs.

Again, we appreciate the GAO's efforts to ensure that ESRD beneficiaries receive quality care.

2

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

James C. Cosgrove, (202) 512-7114 or cosgrovej@gao.gov

Acknowledgments

In addition to the contact named above, Jessica Farb, Assistant Director; Amyre Barker; William Black; Manuel Buentello; Krister Friday; Rich Lipinski; and Jennifer Whitworth made key contributions to this report.

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