

May 2009

END-STAGE RENAL DISEASE

CMS Should Monitor Effect of Bundled Payment on Home Dialysis Utilization Rates



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Highlights of [GAO-09-537](#), a report to congressional committees

Why GAO Did This Study

Medicare covers dialysis—a process that removes excess fluids and toxins from the bloodstream—for most individuals with end-stage renal disease (ESRD), a condition of permanent kidney failure. Most patients with ESRD receive dialysis in a facility, while some patients with ESRD are trained to self-perform dialysis in their homes. The Centers for Medicare & Medicaid Services (CMS)—the agency that administers the Medicare program—has taken steps to encourage home dialysis and is in the process of changing the way it pays for dialysis services. Effective 2011, CMS will pay for dialysis services using an expanded bundled payment.

The Tax Relief and Health Care Act of 2006 required GAO to report on the costs of home dialysis treatments and training. GAO examined (1) the extent to which the costs of home dialysis differ from the costs of dialysis received in a facility, and (2) CMS's plans to account for home dialysis costs in the expanded bundled payment. GAO obtained information from CMS, the U.S. Renal Data System, ESRD experts, and self-reported cost information from six dialysis providers.

What GAO Recommends

GAO recommends that CMS establish and implement a formal plan to monitor the expanded bundled payment system's effect on home dialysis utilization rates. CMS agreed with GAO's recommendation.

[View GAO-09-537](#) or [key components](#). For more information, contact Linda T. Kohn at (202) 512-7114 or kohnl@gao.gov.

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What GAO Found

The self-reported cost information GAO obtained from dialysis providers—including a large chain provider, small nonprofit providers, and a hospital-based provider—indicated variation in the costs to provide home dialysis when compared with costs to provide dialysis in their facility. The six dialysis providers reported lower costs per treatment to provide home dialysis than to provide dialysis at a facility, though the amount by which home dialysis costs were lower varied widely among the providers. Because patients who dialyze at home typically receive dialysis treatments more than three times per week, some providers' costs to provide home dialysis on a weekly basis can be higher than their costs to provide dialysis at a facility. However, other dialysis providers reported lower costs per week to provide home dialysis compared with dialysis provided in a facility. Additionally, several dialysis providers indicated that, for home dialysis patients, the costs of a dialysis treatment with a training session were significantly higher than the costs of a dialysis treatment without a training session.

At the time of GAO's review CMS officials said they are considering factoring the costs of home dialysis treatments and training into the expanded bundled payment, but the details for the expanded bundled payment are still under development and subject to change. CMS officials told GAO that the expanded bundled payment would create incentives for providers to offer home dialysis instead of dialysis at a facility, because although some costs associated with home dialysis may be higher for providers, other efficiencies will offset those costs. For example, although supply costs may be higher for home dialysis, other costs of providing home dialysis—such as drugs, staff, and overhead—will be lower, and thus, in CMS's view, will encourage providers to offer home dialysis. However, concerns have been raised that the way that CMS is considering accounting for the costs of home dialysis in the expanded bundled payment might not encourage providers to offer home dialysis, as CMS expects. For example, some dialysis providers raised concerns that because home dialysis generally consists of more than three dialysis treatments per week—which may result in higher weekly costs to provide home dialysis compared with dialysis received in a facility—providers may not be encouraged to offer home dialysis. CMS officials indicated that CMS intends to assess the effect of the expanded bundled payment on home dialysis utilization rates, but CMS has not established formal plans to monitor this effect.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
ESRD	end-stage renal disease
HHS	Department of Health and Human Services
HMO	Health Maintenance Organization
MedPAC	Medicare Payment Advisory Commission
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
NIH	National Institutes of Health
UM-KECC	University of Michigan Kidney Epidemiology and Cost Center
USRDS	United States Renal Data System

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United States Government Accountability Office
Washington, DC 20548

May 22, 2009

Congressional Committees

End-stage renal disease (ESRD) is a chronic illness characterized by permanent kidney failure. Regardless of age, most individuals with ESRD are eligible for Medicare coverage.¹ Individuals with ESRD can receive a kidney transplant or undergo dialysis—a process that removes wastes and fluid from the body to replace kidney functioning. In 2006, about 70 percent of patients with ESRD underwent dialysis and Medicare was the primary payer for approximately 84 percent of dialysis patients nationwide.^{2,3} In 2005, Medicare spending on dialysis and dialysis-related drugs totaled about \$7.9 billion.⁴

Individuals with ESRD may receive dialysis treatments in a dialysis facility or be trained to perform dialysis treatments at home.⁵ Patients who receive dialysis at a facility receive hemodialysis, a process where blood is allowed to flow, a few ounces at a time, through a special filter that removes wastes and extra fluids and then returns the blood to the body.⁶ Patients who conduct dialysis at home perform either home hemodialysis or peritoneal dialysis—which uses the individual’s own peritoneal membrane, located within the abdomen, as the filter for screening toxins from the body. Figure 1 describes the two types of dialysis.

¹For individuals who have employer group coverage, Medicare is the secondary payer for 30 months, after which Medicare becomes the primary payer. 42 U.S.C. § 1395y(b)(1)(C).

²According to the United States Renal Data System (USRDS), about 53 percent of dialysis patients live for 3 years after being diagnosed with end-stage renal disease (ESRD), and the 10-year survival rate is less than 12 percent.

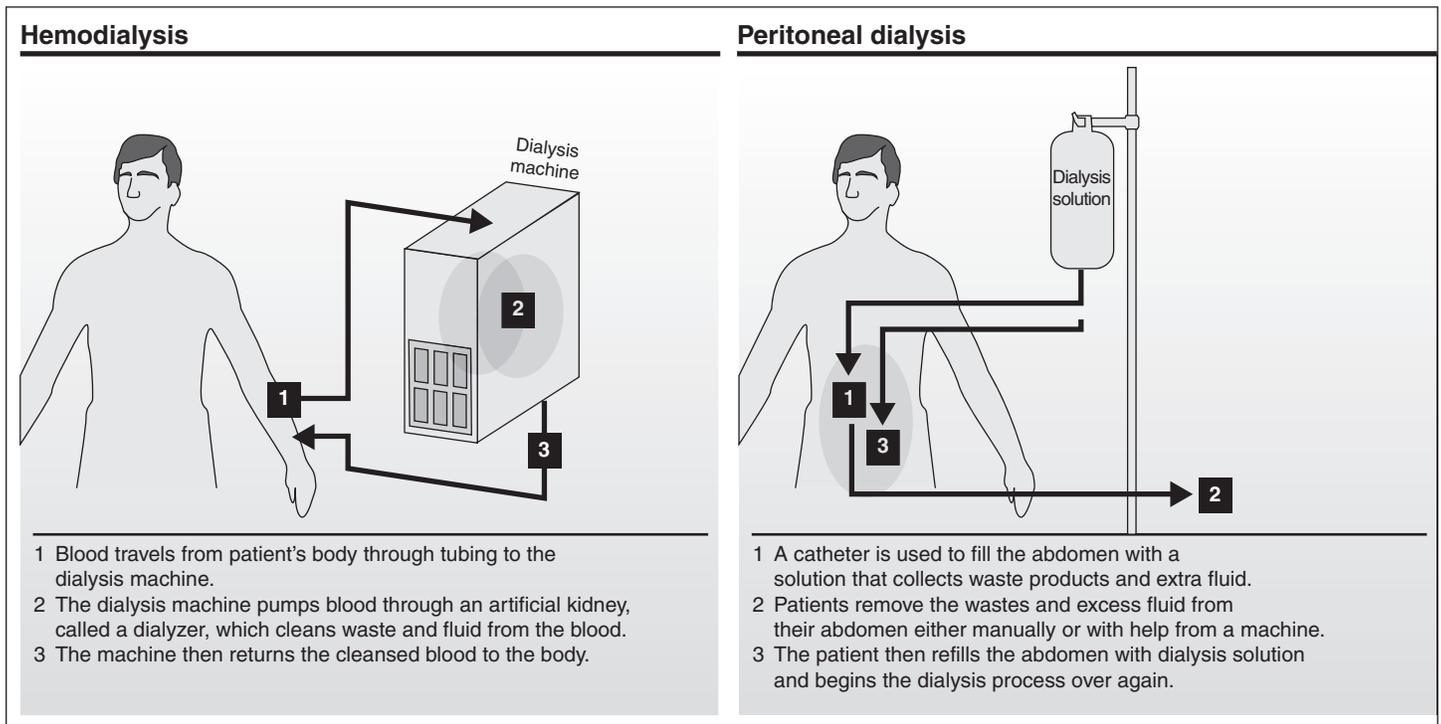
³GAO analysis of 2006 USRDS data. Data from 2006 were the most recent data available from USRDS.

⁴GAO, *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).

⁵Dialysis facilities can be freestanding dialysis facilities, which are not associated with hospitals, or can be hospital-based facilities.

⁶Some dialysis facilities allow patients to self-perform hemodialysis in a dialysis facility. We do not address this type of dialysis in this report.

Figure 1: Process for Hemodialysis and Peritoneal Dialysis



Source: GAO.

According to the United States Renal Data System (USRDS)—a national data system that collects, analyzes, and distributes information about ESRD in the United States—use of peritoneal dialysis peaked in the mid-1990s—reaching about 14.4 percent of the dialysis population—but has since declined. Utilization of home hemodialysis declined steadily from 1985 to 2002, when the home hemodialysis population began to increase. In 2006, of the 355,000 individuals with ESRD nationwide who received dialysis treatments—including both patients who were covered by Medicare and patients who had other insurance coverage—approximately 92 percent received dialysis in a facility, while about 7.4 percent

performed peritoneal dialysis at home, and 0.7 percent performed home hemodialysis.^{7,8}

The Centers for Medicare & Medicaid Services (CMS)—the agency that administers the Medicare program—has made an effort to promote home dialysis,⁹ whenever clinically appropriate. In April 2008, CMS issued a final rule establishing new conditions of coverage for Medicare dialysis facilities.¹⁰ It requires such facilities to inform patients about the options of home and facility dialysis treatments, and the patients’ care team—which includes the patients, their physician, and nurses—to identify a plan for each patient’s home dialysis treatments or explain why the patient is not a candidate for home dialysis. According to CMS, one of the goals of the rule is to foster patient independence by encouraging ESRD patients to receive dialysis at home. Some medical experts and dialysis providers have estimated that anywhere from less than 10 percent to up to 50 percent of all patients who receive dialysis nationwide could be good candidates for home dialysis.¹¹

As CMS takes steps to promote home dialysis, the agency also is required by law to change the way Medicare pays for dialysis and other ESRD services. Currently, Medicare pays dialysis providers a prospective payment—known as a composite rate—for three dialysis treatments per week, whether the treatment is provided at home or in a facility.^{12,13} The composite rate covers a partial bundle of dialysis services, including items associated with dialysis treatments, such as certain tests, drugs, and

⁷Roughly 355,000 patients with ESRD were receiving dialysis services on December 31, 2006.

⁸GAO analysis of USRDS data from 2006.

⁹We use the term home dialysis when referring to both home hemodialysis and peritoneal dialysis.

¹⁰Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule, 73 *Fed. Reg.* 20370, 20475 (Apr. 15, 2008) (to be codified at 42 C.F.R. pt. 494). Among other things, the conditions for coverage require that all dialysis facilities providing services to Medicare patients meet specified patient safety and care standards.

¹¹Many of the experts and providers we interviewed provided estimates that from 15 to 35 percent of all dialysis patients would be good candidates for home dialysis.

¹²A dialysis provider can operate multiple dialysis facilities.

¹³Some dialysis patients may receive more than three dialysis treatments per week, but Medicare typically does not reimburse for more than three treatments per week.

supplies that are frequently used during dialysis. In addition to the composite rate, providers can also receive additional Medicare reimbursements for separately billable ESRD services, which include other injectable drugs (such as Epogen, vitamin D, and iron), laboratory tests, supplies, and blood products that are often used during the course of dialysis. Providers can also receive additional Medicare reimbursements for training patients to dialyze at home.¹⁴

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires CMS to implement a new, expanded bundled payment for dialysis services by January 1, 2011.^{15,16} MIPPA requires that the expanded bundled payment for ESRD services include a payment for providing both composite rate services and separately billable services. This would include the costs of providing home dialysis.¹⁷

As we have previously reported, an expanded bundled payment for ESRD services should promote efficient care delivery, as providers retain the difference if Medicare's payment exceeds the costs they incur to provide dialysis services. We also reported that an expanded bundled payment would afford clinicians more flexibility in decision making because incentives to provide a particular drug or treatment would be reduced.¹⁸ According to the Secretary of the Department of Health and Human Services' (HHS) 2008 Report to Congress that outlined CMS's proposed design for the expanded bundled payment for ESRD services, the new payment is intended to eliminate incentives for providers to overutilize certain services that are separately billable, to target higher payments to

¹⁴Currently, dialysis facilities can bill separately and receive payments for training patients how to dialyze at home. Facilities can receive \$12 per training session to train a patient how to manually conduct peritoneal dialysis, for up to 15 training sessions. Facilities can receive \$20 per training session to train a patient how to use a machine to conduct peritoneal dialysis, for up to 15 training sessions. Facilities can receive \$20 per training session to train a patient how to conduct hemodialysis, for three sessions per week for up to 3 months.

¹⁵Pub. L. No. 110-275, § 153, 122 Stat. 2494, 2553.

¹⁶In 2006, we reported that Congress should consider establishing a fully bundled payment system for dialysis services that would eliminate separate payments for ESRD services that are now separately billable. See [GAO-07-77](#).

¹⁷The Medicare Payment Advisory Commission (MedPAC)—an agency that advises Congress on issues affecting the Medicare program—noted in its 2009 Report to Congress that CMS could consider setting different payment rates for different methods of dialysis.

¹⁸See [GAO-07-77](#).

providers that treat more costly patients, and to create incentives for efficiencies.

The Tax Relief and Health Care Act of 2006 required us to review and report on the costs associated with providing home hemodialysis and patient training for home hemodialysis and peritoneal dialysis. Several congressional committees¹⁹ also asked us to review the implications of the expanded bundled payment for home dialysis. For our review, we examined (1) the extent to which the costs of home dialysis differ from the costs of dialysis provided in a facility, and (2) CMS's plans to account for home dialysis costs in the expanded bundled payment for ESRD services.

To examine the extent to which the costs of home dialysis differ from the costs to provide dialysis in a facility, we conducted interviews with officials from 12 dialysis providers, including large chain providers, small nonprofit providers, and a hospital-based provider. Additionally, we obtained self-reported cost information from 6 of the 12 dialysis providers we interviewed that offered both home and facility dialysis.²⁰ The 6 providers shared with us annual cost information (which ranged from August 2006 to June 2008), including their average cost per treatment and total annual costs for specific cost categories associated with providing dialysis services (such as supplies, overhead, equipment, drugs, laboratory, staff, and administrative costs). In total, we obtained cost information from the providers on the costs for dialysis services provided in nearly 1,600 facilities to approximately 130,000 dialysis patients, including almost 11,000 peritoneal dialysis patients and over 850 home hemodialysis patients.²¹ We reviewed the cost information each provider sent to us if the provider had 20 or more patients on either home

¹⁹U.S. Senate Committee on Finance, U.S. Senate Committee on Health, Education, Labor, & Pensions, U.S. House of Representatives Committee on Energy and Commerce, U.S. House of Representatives Committee on Ways and Means.

²⁰Some home dialysis patients choose not to be associated with a facility and make independent arrangements with a supplier to receive equipment and supplies. Payment to these suppliers is known as Method II. For these patients, the supplier is required to maintain a written agreement with a dialysis facility to provide back-up and support services. We do not discuss this type of payment in the report because dialysis providers only offer back-up and support services to these patients.

²¹Some of the dialysis providers that we contacted operated multiple dialysis facilities.

hemodialysis or peritoneal dialysis²² and calculated the percentage difference in average self-reported costs between home dialysis and dialysis provided in a facility (or chain of facilities).²³ We also used the cost information reported to us to calculate the providers' weekly costs for providing home dialysis and dialysis in a facility. We regard the cost information reported to us as testimonial and we did not independently assess the accuracy of that information. We identify the cost information as self-reported throughout this report, and we did not aggregate or average the self-reported costs across different providers. We also conducted interviews with representatives from the Medicare Payment Advisory Commission (MedPAC) and professional organizations, and we conducted site visits to two dialysis facilities that offered both home dialysis and dialysis in a facility. In addition, to obtain information on the costs of home dialysis, we examined over 30 articles about the costs of home dialysis published between 2002 and 2008, obtained through a MEDLINE literature search or recommended by representatives we interviewed.

To examine CMS's plans to account for the costs of home dialysis in the expanded bundled payment, we reviewed the Secretary of HHS's 2008 Report to Congress on the Proposed Design for a Bundled ESRD Prospective Payment System and conducted interviews with CMS officials. We also conducted interviews with CMS's contractor, the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC), dialysis facilities, dialysis equipment suppliers, and medical experts on home dialysis. We also interviewed dialysis providers to learn their views on home dialysis issues that CMS should consider when developing the expanded bundled payment for ESRD services. Appendix I provides more detailed information on our methodology. We conducted our work from October 2008 through May 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit

²²Of the six dialysis providers that reported cost information to us, five providers had 20 or more patients on peritoneal dialysis, and thus, were included in our review. Separately, five of the six providers had 20 or more patients on home hemodialysis, and thus, were included in our review.

²³The average costs per treatment for home hemodialysis and peritoneal dialysis did not include the costs of training patients to receive dialysis at home. The dialysis providers reported cost information about training patients separately.

objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Individuals diagnosed with ESRD may be influenced by a variety of factors when choosing the type of dialysis to receive. One factor that may influence the individual's choice of dialysis is the individual's awareness about the different types of dialysis available. For example, some individuals may not be aware that peritoneal dialysis is an option to replace kidney functioning and, as a result, would not choose to undergo peritoneal dialysis. The individual's choice of which dialysis to perform can also be influenced by the type of dialysis that the individual's physician recommends and if the individual has a partner to assist with dialysis treatments. Additionally, some individuals may have physical conditions that prevent them from self-performing dialysis—such as vision problems or dexterity issues. The individual's choice may also be influenced by how quickly the dialysis treatments need to begin—as individuals who need to urgently start dialysis may not have time to be trained in conducting dialysis at home.

Hemodialysis conducted in a facility typically consists of three dialysis treatments per week. Peritoneal dialysis is conducted daily. Recent technological changes in hemodialysis equipment have occurred, making it easier for hemodialysis to be done more frequently. For example, a new hemodialysis machine—designed for use at home—requires patients to dialyze five to seven times per week and is reported by some dialysis providers to be more user-friendly than traditional dialysis machines. As a result, most home hemodialysis patients dialyze five to seven times per week.

Data from USRDS show that, compared to patients who dialyzed in a facility, in 2006, home dialysis patients were more likely to be younger, white, located in rural areas, employed, and have employer or group health insurance coverage, and were less likely to be Hispanic. USRDS data for 2006 also indicate that patients who received home dialysis may be healthier than patients who dialyzed in a facility. Home dialysis patients were more likely to be on the wait-list for a kidney transplant (which requires a certain level of health status) and had lower rates of diabetes

and hypertension as the primary disease that caused their ESRD compared with patients who received dialysis in a facility.²⁴

Limited evidence suggests and several dialysis provider officials and medical experts we interviewed believe that home dialysis results in better clinical outcomes for individuals with ESRD. These better clinical outcomes include better control over fluid levels, less need for dialysis drugs, fewer hospitalizations, and better quality of life. Improved clinical outcomes may be due to the features of home dialysis that its supporters believe more closely mimic natural kidney functioning—home dialysis can be done more frequently with less time between treatments, for longer periods of time than dialysis received in a facility, three times a week. Perhaps as a result of this more frequent dialysis, USRDS reported that the overall Medicare costs for peritoneal dialysis patients—including hospitalization costs as well as costs for dialysis services—were about 26 percent less than the total Medicare costs for hemodialysis patients in 2006. Similarly, a Medicare health maintenance organization (HMO) reported to us that moving some of its patients from facility hemodialysis to home hemodialysis has substantially reduced hospitalizations, and overall health costs, for those patients. That HMO has also published a study documenting relatively low hospitalization rates for its home hemodialysis patients.²⁵

However, in general, it is challenging to determine the causes of differences in clinical outcomes between patients who receive dialysis at home versus in a facility because—as we previously noted—the characteristics of patients who dialyze at home are different than those who dialyze in a facility. The National Institutes of Health (NIH) is conducting randomized clinical trials that are intended to provide information on the clinical outcomes associated with more frequent dialysis received in a facility compared to dialysis received three times a week in a facility, and with home nocturnal hemodialysis compared to

²⁴With one exception, USRDS data from 2006 describe patients with ESRD on December 31, 2006. USRDS data on ESRD patients' employment describes patients who were diagnosed with ESRD sometime during 2006.

²⁵V.A. Kumar, M.L. Ledezma, M.L. Idroos, R.J. Burchette, and S.A. Rasgon, "Hospitalization Rates in Daily Home Hemodialysis Versus Peritoneal Dialysis Patients in the United States," *American Journal of Kidney Diseases*, vol. 52, no. 4 (October 2008), pp. 737-744.

three times weekly home hemodialysis.²⁶ Results from the NIH trials are expected to be available in 2010.

Selected Dialysis Providers Reported Wide Variation in the Costs of Providing Dialysis at Home Compared to Facility Dialysis

The self-reported cost information we obtained from the six dialysis providers indicated variation in the cost to provide home dialysis when compared with dialysis provided in a facility. The six dialysis providers reported lower costs per treatment to provide home dialysis than to provide dialysis at a facility, though the amount by which home dialysis costs were lower varied widely among the providers. Because patients who dialyze at home typically receive dialysis treatments more than three times per week, some providers' costs to provide home dialysis on a weekly basis can be higher than their costs to provide dialysis at a facility. However, other dialysis providers reported lower costs per week to provide home dialysis compared with dialysis provided in a facility. Additionally, several dialysis providers indicated that, for home dialysis patients, the costs of a dialysis treatment with a training session were significantly higher than the costs of a dialysis treatment without a training session.

Six Dialysis Providers Reported a Range of Lower Costs per Treatment for Home Dialysis When Compared with the Costs per Treatment for Dialysis Provided in a Facility

The self-reported cost information that we obtained from six dialysis providers indicated that the average costs per treatment for home dialysis were lower than the average costs per treatment for dialysis provided in a facility.²⁷ However, there was a wide range among the dialysis providers in terms of how much lower the average costs per treatment for home dialysis were than dialysis provided in a facility. For home hemodialysis, dialysis providers reported to us that their average costs per treatment were 17 to 50 percent lower than the average costs per treatment for dialysis provided in a facility. For peritoneal dialysis, dialysis providers reported to us that their average costs per treatment were 48 to 68 percent

²⁶A.S. Klinger, for the Frequent Hemodialysis Network Study Group, "High-frequency Hemodialysis: Rationale for Randomized Clinical Trials," *Clinical Journal of the American Society of Nephrology*, vol. 2 (March 2007), pp. 390-392.

²⁷The average costs per treatment that the dialysis providers self-reported to us did not include the costs to train patients to conduct home dialysis. The dialysis providers reported cost information about training patients separately.

lower than the average costs per treatment for hemodialysis provided in a facility.²⁸

The average costs per treatment that the dialysis providers reported to us include costs for certain items associated with providing dialysis services, including supplies, equipment, drugs, overhead, and staff. Officials from dialysis providers indicated to us that supply costs are higher for home dialysis compared with dialysis provided in a facility. One reason that supply costs for home dialysis patients are higher is because certain supplies that can be reused for patients who receive dialysis in a facility often cannot be reused by home patients. For example, patients who receive dialysis in a facility can reuse their own dialyzer—the artificial kidney used to filter the blood during hemodialysis—because the facility is able to sterilize the dialyzer between dialysis treatments. Patients who dialyze at home need to use dialyzers that are intended for one-time use, which results in higher supply costs. In contrast, other cost items (such as drugs and staff) were reported to be lower for home dialysis than for dialysis provided in a facility. For example, after home dialysis patients have been trained to conduct dialysis, there are lower staffing costs associated with home dialysis because patients require less staffing resources—as the patients (or their caregiver) are performing the dialysis treatments at home that are performed by staff for dialysis provided in a facility.²⁹ Table 1 provides one dialysis provider’s self-reported average costs per treatment in 2008 for hemodialysis provided in a facility compared to hemodialysis provided at home, which indicates that the supply costs are higher for home hemodialysis while the other items are lower for home hemodialysis compared with hemodialysis provided in a facility.

²⁸Peritoneal dialysis is performed continually throughout the day, as patients repeatedly fill their abdomen with dialysis solution, allow the dialysis solution to remain in their abdomen for several hours, and then drain the dialysis solution. As a result, we report that the average cost per treatment for peritoneal dialysis equals 1 day of peritoneal dialysis.

²⁹Staffing costs for home dialysis include the costs of nurses, dieticians, and social workers who meet with home dialysis patients.

Table 1: Self-Reported Average Costs per Treatment for Hemodialysis in a Facility and Home Hemodialysis from One Dialysis Provider, 2008

	Hemodialysis in a facility	Hemodialysis at home
Supplies	\$27	\$41
Equipment	\$7	\$5
Drugs	\$63	\$19
Laboratory	\$7	\$5
Staff	\$66	\$20
Other (including overhead)	\$72	\$41
Total average cost per treatment	\$243	\$133

Sources: Self-reported cost information provided by one dialysis provider.

Note: Entries may not sum to the total because of rounding. The average costs per treatment that the dialysis providers self-reported to us did not include the costs to train patients to conduct home dialysis.

Table 2 provides another dialysis provider’s self-reported average costs per treatment in 2006 for hemodialysis provided in a facility compared to peritoneal dialysis provided at home. The provider reported that its supply costs were higher for peritoneal dialysis provided at home, while the other items were lower for peritoneal dialysis compared with hemodialysis provided in a facility.

Table 2: Self-Reported Average Costs per Treatment for Hemodialysis in a Facility and Peritoneal Dialysis from One Dialysis Provider, 2006

	Hemodialysis in a facility	Peritoneal Dialysis at home
Supplies	\$22	\$45
Equipment	\$11	\$0
Drugs	\$80	\$18
Laboratory	\$1	\$0
Staff	\$70	\$16
Other (including overhead)	\$68	\$15
Total average cost per treatment	\$251	\$94

Sources: GAO analysis of self-reported cost information provided by one dialysis provider.

Note: Entries may not sum to the total because of rounding. The average costs per treatment that the dialysis providers self-reported to us did not include the costs to train patients to conduct home dialysis.

Some Dialysis Providers Reported Higher Costs per Week for Home Dialysis Compared to Dialysis Provided in a Facility, While Other Dialysis Providers Reported Lower Costs per Week for Home Dialysis

All six dialysis providers in our review reported lower average costs per treatment for home dialysis when compared to dialysis provided in a facility; however, some dialysis providers reported higher costs per week for home dialysis compared with dialysis provided in a facility, while others reported lower costs per week for home dialysis. For home hemodialysis, three of the five dialysis providers included in our review reported higher costs per week for providing home hemodialysis compared with the costs per week of providing dialysis in a facility.³⁰ Officials from these three dialysis providers indicated that the costs per week for patients who dialyze at home were higher because these patients typically dialyze more frequently than three times per week. Home hemodialysis is often performed five to seven times per week. For example, using one provider's self-reported average costs per treatment from table 1, the average costs per treatment for home hemodialysis were lower (\$133 per treatment) compared with dialysis provided in a facility (\$243 per treatment); however, for patients who received six dialysis treatments per week, the provider's weekly costs for home hemodialysis were higher (\$798 for six treatments during the week) compared with dialysis provided in a facility (\$729 for three treatments per week). The other two providers reported lower costs per week for home hemodialysis compared with dialysis provided in a facility. However, one of these providers indicated that their home hemodialysis patients only dialyze three times per week, which is not more frequent than patients who dialyze in a facility.

Providers also reported varying costs per week for peritoneal dialysis compared to dialysis provided in a facility. Of the five dialysis providers in our review,³¹ two providers indicated that their costs per week for providing peritoneal dialysis were higher than the weekly costs of providing dialysis in a facility. In contrast, three of the five dialysis providers in our review indicated that the costs per week of providing peritoneal dialysis were lower than the weekly costs of providing dialysis in a facility. Using one provider's self-reported average costs per treatment from table 2, the average costs per treatment for peritoneal dialysis were

³⁰Six dialysis providers self-reported costs to us; however, only five dialysis providers had 20 or more patients on home hemodialysis and were included in our review for home hemodialysis.

³¹Six dialysis providers self-reported costs to us; however, only five dialysis providers had 20 or more patients on peritoneal dialysis and were included in our review for peritoneal dialysis.

lower (\$94 per treatment) compared with dialysis provided in a facility (\$251 per treatment) and the weekly costs of peritoneal dialysis were also lower (\$658 for 7 days of peritoneal dialysis during the week) compared with dialysis provided in a facility (\$753 for three treatments per week). Based on self-reported cost information from dialysis providers, the costs per week of providing peritoneal dialysis were lower than the costs of providing hemodialysis in a facility, in part, because costs for drugs, staff, and overhead were lower for peritoneal dialysis patients.

As indicated by the dialysis providers' self-reported cost information, the higher weekly costs of home dialysis for some providers may be due—in part—to the increased frequency of dialysis. For hemodialysis, this is consistent with a 2001 MedPAC report, which estimated that the weekly costs to provide hemodialysis more than three times a week were 15 to 20 percent higher than the weekly costs to provide hemodialysis three times per week.

Several Dialysis Providers Reported That Training Costs for Home Dialysis Patients Are Significant

According to dialysis providers, the costs of training patients to dialyze at home can be significant. These costs are exclusively for home dialysis patients as patients who receive dialysis in a facility do not need to be trained. Dialysis providers reported to us that the costs of training patients to dialyze at home are significant because it typically takes 3 to 6 weeks, with up to 5 training sessions a week, to train a patient to perform home hemodialysis (approximately 15 to 30 sessions) and 1 to 2 weeks (approximately 5 to 10 sessions) to train a patient to perform peritoneal dialysis. In addition, training sessions are costly because they require the dedicated attention of one nurse for each training session. Table 3 shows an example of one dialysis provider's self-reported average costs for a home hemodialysis training session (which includes a dialysis treatment) compared with the average costs of a home hemodialysis treatment session during 2008.

Table 3: Self-Reported Average Cost for One Home Hemodialysis Training and Treatment Session, and One Home Hemodialysis Session from One Dialysis Provider, 2008

	Home hemodialysis training session + treatment	Home hemodialysis treatment
Supplies	\$41	\$41
Equipment	\$5	\$5
Drugs	\$19	\$19
Laboratory	\$5	\$5
Staff	\$150	\$20
Other (including overhead)	\$41	\$41
Total average cost per treatment	\$263	\$133

Sources: GAO analysis of self-reported cost information provided by one dialysis provider.

Note: Entries may not sum to the total because of rounding.

CMS Is Considering Factoring Current Home Dialysis Costs into the Expanded Bundled Payment, but Concerns Have Been Raised That Home Dialysis May Not Be Encouraged as CMS Expects

At the time of our review CMS officials indicated that they are considering factoring the costs of home dialysis treatments and training into the expanded bundled payment, but the details for the expanded bundled payment are still under development. CMS officials told us that the expanded bundled payment could create incentives for providers to offer home dialysis instead of dialysis in a facility, because although some costs associated with home dialysis may be higher for providers, other efficiencies will offset those costs. However, concerns have been raised that the way in which the expanded bundled payment may account for home dialysis costs might not encourage providers to offer home dialysis, as CMS expects. CMS officials indicated that it intends to assess the effect of the expanded bundled payment on home dialysis utilization rates, but CMS has not established formal plans to monitor this utilization.

CMS Is Considering Factoring Home Dialysis Costs into Calculation of Expanded Bundled Payment

In order to fulfill the requirements of MIPPA, CMS is developing an expanded bundled payment for ESRD services. Beginning in 2011, Medicare will pay for dialysis services using an expanded bundled payment, which will include both services currently paid under the composite rate and services that are separately billable. Although the details of the expanded bundled payment are still under development and subject to change, at the time of our review CMS officials said they were considering giving providers the same payment regardless of whether the dialysis treatments are provided in the patient's home or at a facility. They noted that a base payment for dialysis services—based on several factors—could be calculated by totaling providers' costs, including costs for home hemodialysis, peritoneal dialysis, and dialysis in a facility.³²

CMS officials and an official from UM-KECC, the contractor assisting CMS with developing the expanded bundled payment, told us that they will obtain cost information from cost reports that dialysis providers are required to submit to CMS and from Medicare claims for separately billable ESRD-related services.³³ Since dialysis providers submit cost reports to CMS, which include the costs of home dialysis, CMS officials told us that the costs associated with home dialysis could be factored into the development of the expanded bundled payment.

CMS officials told us that when implemented, the expanded bundled payment could create incentives for providers to offer home dialysis. CMS officials explained that while some costs associated with home dialysis may be higher for providers (such as supplies), these costs will be offset by efficiencies created by lower cost categories for such items as drugs, staff, and overhead expenses. However, CMS officials said they have not conducted an analysis to determine whether these cost assumptions are accurate.

³²MIPPA requires CMS to adjust its bundled payment to dialysis facilities based on several factors, including adjustments for the characteristics of patients that dialyze at that facility (such as patient's age, weight, and comorbidities); for higher costs in dialyzing certain patients due to unusual variations in medically necessary care; for low-volume facilities; and for other items as determined appropriate by the HHS Secretary.

³³In developing the expanded bundled payment, CMS is required to use data from the year in which per dialysis patient utilization was the lowest among 2007, 2008, or 2009.

Concerns Have Been Raised That the Way CMS Is Considering Accounting for Home Dialysis Costs in the Expanded Bundled Payment May Not Encourage Home Dialysis as CMS Expects

Some home dialysis providers and officials we interviewed have raised concerns that the way that CMS is considering accounting for the costs of home dialysis may not encourage use of home dialysis. In particular, concerns have been raised that the cost information CMS and its contractor are using to develop the expanded bundled payment may not account for all of the costs associated with providing home dialysis. For example, one analysis of CMS cost reports found that some providers only report cost information to CMS for the three treatments per week for which Medicare reimburses, even though some home dialysis patients receive more frequent treatments.³⁴ Also, USRDS officials reported to us that the claims information CMS is using to develop its expanded bundled payment does not always reliably distinguish between the costs for separately billable items and services for home hemodialysis and facility hemodialysis.

Concerns have also been raised that the expanded bundled payment might not encourage providers to offer home dialysis depending on how home dialysis training costs are accounted for in the bundled payment. At the time of our review, CMS officials noted that they are considering factoring providers' costs associated with training patients to dialyze at home into the expanded bundled payment rather than providing a separate, additional payment for training patients to dialyze at home. As we noted previously, some providers reported significant up-front costs to start a patient on home dialysis, in part because training for home dialysis requires one nurse to train one patient.³⁵

Moreover, some home dialysis providers are also concerned that providers will not have an incentive to provide home dialysis if the expanded bundled payment restricts reimbursement to three dialysis treatments per week. Indeed, under the current partially bundled payment system, we found that some home dialysis providers now have been granted medical necessity exceptions to receive Medicare reimbursements for additional

³⁴This analysis was commissioned by a dialysis equipment manufacturer.

³⁵Some dialysis facilities have received payments in addition to the training reimbursement (called exceptions) for training patients to dialyze at home if the costs of training their patients exceed the typical Medicare reimbursement for home dialysis training. CMS officials told us that they are unlikely to grant these exceptions under the expanded bundled payment.

dialysis treatments beyond three per week.³⁶ CMS officials told us that they are unlikely to allow these additional reimbursements under the expanded bundled payment system.

CMS officials indicated that, after the expanded bundled payment system has been implemented, they plan to assess its effect on home dialysis utilization rates and, if necessary, adjust the expanded bundled payment accordingly. However, CMS officials said that no formal plan to assess the bundled payment system's effect on home dialysis utilization rates has been established.

Conclusions

Some dialysis experts and officials from dialysis providers have estimated that anywhere from less than 10 percent to up to 50 percent of patients could be good candidates to perform dialysis at home—higher than the current home dialysis utilization rate of about 8 percent. In its April 2008 final rule, CMS took steps to encourage home dialysis for appropriate patients, including requiring that patients be informed of all types of dialysis treatments (including home dialysis). CMS officials told us that they believe that home dialysis could be encouraged under the forthcoming expanded bundled payment if providers receive the same reimbursement under the expanded bundled payment for dialysis provided in a facility or at home, because the reduced costs of home dialysis for drugs and staff would make home dialysis less costly to provide than dialysis in a facility. However, CMS has not independently verified if these assumptions are correct. Additionally, some home dialysis providers and officials we interviewed raised concerns about whether a bundled payment would encourage home dialysis, including concerns that the sources of cost information used to calculate the expanded bundled payment rate may not include all of the costs of providing home dialysis, such as the up-front costs associated with training patients to conduct home dialysis, and its increased frequency. Furthermore, although CMS has said it plans to monitor the effect of the expanded bundled payment system on utilization of home dialysis, it has not specified how this will be done. For these reasons, we believe that the effect of the expanded bundled payment system on home dialysis utilization rates is uncertain

³⁶Dialysis facilities receive Medicare reimbursements for providing dialysis services from CMS contractors. These contractors have some flexibility about what services they will reimburse. We found that at least two of these contractors have policies that grant reimbursements for additional dialysis treatments—beyond three treatments per week—for home dialysis patients based on medical necessity.

and that it is important to monitor its effect on the utilization of home dialysis.

Recommendation for Executive Action

To determine the effect of the expanded bundled payment system on home dialysis utilization rates, CMS should establish and implement a formal plan to monitor the expanded bundled payment system's effect on home dialysis utilization rates to determine whether home dialysis utilization rates have increased as CMS expects.

Agency Comments and Our Evaluation

In written comments on a draft of this report, CMS concurred with our recommendation to establish and implement a formal plan to monitor the expanded bundled payment system's effect on home dialysis utilization rates. CMS agreed with the need to establish a monitoring plan under the expanded bundled payment system and expects to establish a formal plan after it has promulgated the final rule associated with the ESRD bundled payment system. CMS also commented that our draft report implied that final decisions have been reached by CMS and the Secretary of HHS regarding the details of the expanded bundled payment system. We revised our draft report to clarify that the details of the expanded bundled payment are tentative and still subject to change.

CMS also provided a few additional comments. First, CMS noted that one dialysis provider that operates multiple dialysis facilities has recently trained patients to conduct and self-perform hemodialysis in a dialysis facility. We added a reference to this option for dialysis treatment in the report. CMS requested that we clarify information in reference to a MedPAC report on the costs of frequent home dialysis. We made changes as appropriate. Additionally, CMS stated that Medicare claims submitted by dialysis facilities do distinguish home hemodialysis from facility hemodialysis. However, we confirmed with USRDS officials that the claims information does not always reliably make this distinction for separately billable items and services and we clarified this in the report. Finally, CMS noted that when dialysis providers have presented information to CMS regarding the percentage of patients who would be good candidates for home dialysis, these percentages are usually closer to 10 to 15 percent of all dialysis patients. However, medical experts and dialysis providers we interviewed indicated a range of less than 10 percent to up to 50 percent of all dialysis patients could be good candidates for home dialysis, although many of the experts and providers we interviewed estimated that from 15 to 35 percent of all dialysis patients would be good

candidates for home dialysis. We have clarified this in the report. CMS's written comments are reprinted in appendix II.

We are sending copies of this report to the Administrator of CMS. In addition, the report is 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 kohnl@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 that made major contributions to this report are listed in appendix III.



Linda T. Kohn
Director, Health Care

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

Appendix I: Scope and Methodology

This report examines (1) the extent to which the costs of home dialysis differ from the costs of dialysis provided in a facility, and (2) the Centers for Medicare & Medicaid Services' (CMS) plans to account for home dialysis costs in the expanded bundled payment for end-stage renal disease (ESRD) services.

To meet our objectives, we conducted interviews with representatives from 12 dialysis providers—including large chain providers, small nonprofit providers, and a hospital-based provider. Based on the officials' self-reported estimates, these dialysis providers offered dialysis services to approximately 68 percent of all dialysis patients—including an estimated 77 percent of peritoneal dialysis patients and roughly all home hemodialysis patients.¹

To examine the extent to which the costs of home dialysis differ from the costs of dialysis provided in a facility, we obtained cost information from six dialysis providers that we interviewed—including average costs per treatment reported in CMS's renal facility cost reports for home dialysis and dialysis provided in a facility. Additionally, we requested that the dialysis providers include annual cost information for specific categories of costs associated with providing dialysis. The cost categories that we requested were supplies, overhead, equipment and maintenance, drugs, laboratory tests, staff, and administrative costs. We included descriptions of what services should be included in each cost category, basing the descriptions on CMS definitions from the renal facility cost reports. The average costs per treatment reported to us by the dialysis providers did not include the costs of training patients to dialyze at home. At our request, the dialysis providers gave us separate information on the costs of training patients to conduct home dialysis.

Six of the 12 dialysis providers we interviewed shared with us cost information for a 12-month period, which ranged from August 2006 through June 2008. In total, we obtained cost information from these 6 providers on the costs for dialysis services provided in nearly 1,600 facilities to approximately 130,000 dialysis patients, including almost 11,000 peritoneal dialysis patients and over 850 home hemodialysis patients. We analyzed the cost information each provider sent to us if the

¹We compared 2006 data on the number of dialysis patients to 2008 estimates from dialysis providers on the number of patients that they provided dialysis services to in order to estimate the percentages of patients who received dialysis services from the providers we interviewed.

provider had 20 or more patients on either home hemodialysis² or peritoneal dialysis.³ Using this self-reported cost information from the providers, we calculated the percentage difference in average costs per treatment between dialysis provided at home and dialysis provided in a facility (or chain of facilities). We also used the cost information reported to us to calculate the providers' weekly costs for providing home dialysis and dialysis in a facility. To calculate the weekly costs of home dialysis and dialysis provided in a facility, we multiplied the average cost per treatment by the frequency of the specific type of dialysis.⁴

We regard the cost information reported to us as testimonial and we did not independently assess the accuracy of that information. We identify the cost information as self-reported throughout the report, and we did not aggregate or average the self-reported costs across providers.

We also conducted interviews with representatives from the Medicare Payment Advisory Commission and professional organizations, including the National Kidney Foundation, the Renal Physicians Association, the National Renal Administrators Association, and the American Association of Kidney Patients. We also conducted site visits to two dialysis facilities that offered both home dialysis and dialysis in a facility to obtain additional information on how patients are trained to conduct home dialysis as well as obtain patients' perspectives on factors associated with performing home dialysis.

Additionally, to obtain information on the extent to which the costs of home dialysis are different than the costs of dialysis provided in a facility, we examined over 30 articles about the costs of home dialysis published between 2002 and 2008, obtained through a MEDLINE literature search or

²Five of the six providers had 20 or more patients on home hemodialysis, and thus, were included in our review.

³Five of the six providers had 20 or more patients on peritoneal dialysis, and thus, were included in our review.

⁴We determined the frequency of each type of dialysis based on interviews with officials from the dialysis providers, in which they indicated how often their patients typically dialyzed per week. The providers indicated that most of their patients who received dialysis in a facility did so three times per week. As a result, we calculated the weekly costs of providing dialysis in a facility by multiplying the average costs per treatment by 3. For home hemodialysis and peritoneal dialysis, we multiplied the average costs per treatment by the frequency of dialysis, based on information from the providers about how frequently their home dialysis patients received dialysis treatments during the week.

recommended by representatives we interviewed. We also examined over 27 articles about the clinical outcomes associated with home dialysis published between 2002 and 2008, obtained through a MEDLINE literature search.

To examine CMS's plans to account for the costs of home dialysis in the expanded bundled payment, we reviewed CMS's proposed design for the expanded bundled end-stage renal disease (ESRD) payment, outlined in the Secretary of the Department of Health and Human Services' 2008 Report to Congress on the Proposed Design for a Bundled ESRD Prospective Payment System. Additionally, to obtain information on how the costs of home dialysis would be included in the expanded bundled payment, we conducted interviews with CMS and CMS's contractor—the University of Michigan Kidney Epidemiology and Cost Center. We also conducted interviews with dialysis facilities' officials, dialysis equipment suppliers, and medical experts on home dialysis to obtain their perspective on the expanded bundled payment.

We conducted our work from October 2008 through May 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

MAY 8 2009

Assistant Secretary for Legislation
Washington, DC 20201

Linda T. Kohn
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Kohn:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "END-STAGE RENAL DISEASE: Although Costs of Home Dialysis Will Be Included in Bundled Payment, CMS Should Monitor Effect on Home Dialysis Utilization Rates (GAO-09-537).

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Barbara Pisaro Clark".

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Attachment

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

DATE: MAY - 8 2009

TO: Barbara Pisaro Clark
Acting Assistant Secretary for Legislation
Office of the Secretary

FROM: Charlene Frizzera *Charlene Frizzera*
Acting Administrator

SUBJECT: Government Accountability Office (GAO) Draft Report: "End-Stage Renal Disease: Although Costs of Home Dialysis Will Be Included in Bundled Payment, CMS Should Monitor Effect on Home Dialysis Utilization Rates" (GAO-09-537)

Thank you for the opportunity to review and comment on the GAO draft report entitled, "End-Stage Renal Disease: Although Costs of Home Dialysis Will Be Included in Bundled Payment, CMS Should Monitor Effect on Home Dialysis Utilization Rates." We appreciate GAO's interest in ensuring the bundled payment system for End-Stage Renal Disease (ESRD) currently under development provides incentives to encourage more home dialysis for ESRD patients. The GAO analyzed self-reported cost information from dialysis providers and determined that dialysis providers reported lower costs per treatment for home dialysis. However, several dialysis providers indicated that home dialysis patients who dialyze more than 3 times per week may be more costly than in-center patients, and that dialysis sessions with training were more costly than dialysis sessions without training.

While the Centers for Medicare & Medicaid Services (CMS) appreciates GAO's efforts in reviewing this topic, we are very concerned that the draft report implies, in many places, that final decisions have been reached by CMS and the Secretary regarding the ESRD prospective payment system (PPS). For example, the discussion that begins on page 17, describes specific details about the system design which the report attributes to CMS officials.

It is important for CMS to note that no final decisions have been made by CMS or the Department of Health and Human Services' officials regarding the details of this new system, and that CMS has not even published a proposed rule, as of this date. Further, we do not believe this report should offer speculation to the public regarding details of the new system prior to issuance of the ESRD PPS proposed rule based on GAO's interviews with CMS staff.

Page 2- Barbara Pisaro Clark

GAO Recommendation

GAO recommends that CMS establish and implement a formal plan to monitor the expanded bundled payment system's effect on home dialysis utilization rates.

CMS Response

The CMS concurs with the GAO's recommendation and intends to assess the effect of the expanded bundled payment on home dialysis utilization rates. We agree with GAO on the need to establish a monitoring plan under the new ESRD bundled payment system that includes an examination of home dialysis utilization. We expect to establish such a plan once we have received and analyzed public comments on a proposed rule, and developed and promulgated the final ESRD bundled payment system.

We have a few specific comments for your consideration.

Additional Comments

1. We note that one dialysis chain has recently developed an option for in-center self-hemodialysis. Although the report does not include costs of in-center hemodialysis, we believe the introductory remarks should acknowledge that it exists.
2. On page 15 in the discussion of the 1991 Medicare Payment Advisory Commission (MedPAC) report, reference is made to providing more frequent home dialysis when the MedPAC report was addressing home hemodialysis. Please review other references to verify that references to home dialysis are appropriate.
3. On page 18, there is information attributed to United States Renal Data System officials indicating that ESRD facility claims data do not distinguish between home hemodialysis and in-facility hemodialysis. In fact, ESRD facilities report revenue codes that identify the modality and the setting of hemodialysis and the separately billable services on that claim are related to the treatments.
4. In the discussion on page 4 and the conclusion section beginning on page 19, you indicate that medical experts and dialysis providers have estimated that anywhere from less than 10 percent to up to 50 percent of all patients who receive dialysis could be good candidates for home dialysis. We note that dialysis providers and medical experts who have discussed this issue with CMS have never indicated that up to 50 percent of patients could perform home dialysis. The percentage presented to us has generally been much lower, closer to 10-15 percent.

Thank you again for the opportunity to review this report.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Linda T. Kohn, (202) 512-7114 or kohnl@gao.gov

Acknowledgments

In addition to the contact named above, Martin T. Gahart, Assistant Director; George Bogart; Christie Enders; Krister Friday; and Hillary Loeffler made key contributions to this report.

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