



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

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October 2015

# END-STAGE RENAL DISEASE

## Medicare Payment Refinements Could Promote Increased Use of Home Dialysis

Accessible Text

# GAO Highlights

Highlights of [GAO-16-125](#), a report to the Subcommittee on Health, Committee on Ways and Means, House of Representatives

## Why GAO Did This Study

In 2013, Medicare spent about \$11.7 billion on dialysis care for about 376,000 Medicare patients with end-stage renal disease, a condition of permanent kidney failure. Some of these patients performed dialysis at home, and such patients may have increased autonomy and health-related quality of life.

GAO was asked to study Medicare patients' use of home dialysis and key factors affecting its use. This report examines (1) trends in home dialysis use and estimates of the potential for wider use, (2) incentives for home dialysis associated with Medicare payments to dialysis facilities, and (3) incentives for home dialysis associated with Medicare payments to physicians. GAO reviewed CMS policies and relevant laws and regulations, and GAO analyzed data from CMS (2010-2015), the United States Renal Data System (1988-2012), and Medicare cost reports (2012), the most recent years with complete data available. GAO also interviewed CMS officials, selected dialysis facility chains, physician and patient associations, and experts on home dialysis.

## What GAO Recommends

GAO recommends that CMS (1) take steps to improve the reliability of the cost report data, (2) examine and, if necessary, revise policies for paying physicians to manage the care of dialysis patients, and (3) examine and, if appropriate, seek legislation to revise the KDE benefit. HHS concurred with the first two recommendations but did not concur with the third. GAO continues to believe this recommendation is valid as discussed further in this report.

View [GAO-16-125](#). For more information, contact James Cosgrove at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov).

October 2015

## END-STAGE RENAL DISEASE

### Medicare Payment Refinements Could Promote Increased Use of Home Dialysis

## What GAO Found

The percentage of dialysis patients who received home dialysis generally declined between 1988 and 2008 and then slightly increased thereafter through 2012, and stakeholder estimates suggest that future increases in the use of home dialysis are possible. Dialysis patients can receive treatments at home or in a facility. In 1988, 16 percent of 104,200 dialysis patients received home dialysis. Home dialysis use generally decreased over the next 20 years, reaching 9 percent in 2008, and then slightly increased to 11 percent of 450,600 dialysis patients in 2012—the most recent year of data for Medicare and non-Medicare patients. Physicians and other stakeholders estimated that 15 to 25 percent of patients could realistically be on home dialysis, suggesting that future increases in use are possible. In the short term, however, an ongoing shortage of supplies required for peritoneal dialysis—the most common type of home dialysis—reduced home dialysis use among Medicare patients from August 2014 to March 2015. Some stakeholders were also concerned the shortage could have a long-term impact.

Medicare's payment policy likely gives facilities financial incentives to provide home dialysis, but these incentives may have a limited impact in the short term. According to the Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS), setting the facility payment for dialysis treatment at the same rate regardless of the type of dialysis gives facilities a powerful financial incentive to encourage the use of peritoneal dialysis when appropriate because it is generally less costly than other dialysis types. However, GAO found that facilities also have financial incentives in the short term to increase provision of hemodialysis in facilities, rather than increasing home dialysis. This is consistent with information from CMS and stakeholders GAO interviewed. For example, facilities may be able to add an in-center patient without paying for an additional dialysis machine, because each machine can be used by six to eight in-center patients. In contrast, for each new home patient, facilities may need to pay for an additional machine. The adequacy of Medicare payments for home dialysis training also affects facilities' financial incentives for home dialysis. Although CMS recently increased its payment for home dialysis training, it lacks reliable cost report data needed for effective fiscal management, which involves assessing payment adequacy. In particular, if training payments are inadequate, facilities may be less willing to provide home dialysis.

Medicare payment policies may constrain physicians' prescribing of home dialysis. Specifically, Medicare's monthly payments to physicians for managing the care of home patients are often lower than for managing in-center patients even though physician stakeholders generally said that the time required may be similar. Medicare also pays for predialysis education—the Kidney Disease Education (KDE) benefit—which could help patients learn about home dialysis. However, less than 2 percent of eligible Medicare patients received the benefit in 2010 and 2011, and use has declined since then. According to stakeholders, the low usage was due to statutory limitations in the categories of providers and patients eligible for the benefit. CMS has established a goal of encouraging home dialysis use among patients for whom it is appropriate, but the differing monthly payments and low usage of the KDE benefit could undermine this goal.

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### Abbreviations

CMS	Centers for Medicare & Medicaid Services
ESRD	end-stage renal disease
HDU	Home Dialyzors United
HHS	Department of Health and Human Services
KDE	Kidney Disease Education
NRAA	National Renal Administrators Association
RPA	Renal Physicians Association
USRDS	United States Renal Data System

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October 15, 2015

The Honorable Kevin Brady  
Chairman  
The Honorable Jim McDermott  
Ranking Member  
Subcommittee on Health  
Committee on Ways and Means  
House of Representatives

In 2013, Medicare spent about \$11.7 billion on dialysis care for about 376,000 Medicare patients. Dialysis, a process that removes excess fluids and toxins from the bloodstream, is the most common treatment for individuals with end-stage renal disease (ESRD), a condition of permanent kidney failure.<sup>1</sup> These patients may receive dialysis treatments in a dialysis facility or may perform dialysis treatments at home, for which they receive training and support from a facility. Most individuals with ESRD are eligible for Medicare regardless of their age.<sup>2</sup> Medicare pays dialysis facilities for treatments—conducted either in a facility or at home—and for training patients to perform home dialysis. Medicare also

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<sup>1</sup>ESRD is the last stage of chronic kidney disease, which is measured in five stages corresponding to the extent of a patient's decline in kidney function. In Stages III and IV, kidney function is moderately or severely decreased, and patients may begin to see a nephrologist. In Stage V or ESRD, patients experience kidney failure and generally start dialysis or require a kidney transplant.

<sup>2</sup>For individuals eligible for Medicare solely due to ESRD, Medicare coverage generally begins in the 4th month after patients start dialysis. 42 U.S.C. § 426-1(b). For individuals who have employer group coverage, Medicare is the secondary payer for the first 30 months of Medicare entitlement, after which Medicare becomes the primary payer. 42 U.S.C. § 1395y(b)(1)(C). Most individuals diagnosed with ESRD are eligible to receive Medicare benefits under Medicare Part A, Part B, and Part D. 42 U.S.C. §§ 426-1(a), 1395w-101(a)(3)(A). Medicare Part A covers inpatient hospital, skilled nursing facility, and hospice care, as well as some home health care, and generally does not require a monthly premium. Individuals diagnosed with ESRD who choose to enroll in Medicare Part B and/or Medicare Part D are subject to monthly premiums. Medicare Part B covers outpatient dialysis treatment, injectable ESRD drugs, certain oral ESRD drugs, physician services, hospital outpatient services, and certain other services, such as physical therapy. Medicare Part D covers outpatient prescription drugs.

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pays physicians to manage patients' dialysis care and training and to provide education to certain patients with chronic kidney disease.<sup>3</sup>

The Centers for Medicare & Medicaid Services (CMS) has established a goal of fostering patient independence through greater use of home dialysis among patients for whom it is appropriate.<sup>4</sup> In addition, studies have shown that patients who perform dialysis at home may have increased autonomy and health-related quality of life.<sup>5</sup> Policymakers and researchers have raised questions about whether home dialysis, despite these potential benefits, is underused.

You asked us to study Medicare patients' use of home dialysis and key factors that affect home dialysis use. In this report, we examine (1) trends in the use of home dialysis and estimates of the potential for wider use of home dialysis, (2) incentives for providing home dialysis associated with Medicare payments to dialysis facilities, and (3) incentives for prescribing home dialysis associated with Medicare payments to physicians and the role of nephrology training in prescribing home dialysis.

To examine trends in the use of home dialysis, we analyzed data for dialysis patients—including both Medicare and non-Medicare patients—for 1988 to 2012 from the United States Renal Data System (USRDS).<sup>6</sup>

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<sup>3</sup>Of the \$11.7 billion that Medicare spent on dialysis care in 2013, \$11 billion was for facilities' provision of dialysis treatments conducted in a facility and at home and related items and services, and \$704 million was for physician management of patients' care and training. In 2013, Medicare also spent \$400,000 to educate certain patients with chronic kidney disease about their choices for therapy, such as dialysis.

<sup>4</sup>CMS is the agency within the Department of Health and Human Services (HHS) that administers the Medicare program. For examples of CMS statements concerning its goal to encourage use of home dialysis, see ESRD Prospective Payment System, CMS final rule for CY 2011, 75 Fed. Reg. 49030, 49059, 49115 (Aug. 12, 2010) (preamble II.A.7.a.ii, II.F.3.h.); Conditions for Coverage for End-Stage Renal Dialysis Facilities, CMS final rule, 73 Fed. Reg. 20370, 20471 (Apr. 15, 2008) (preamble, VII.B.); and Revisions to Payment Policies Under the Physician Fee Schedule for CY 2004, CMS final rule with comment period, 68 Fed. Reg. 63196, 63219 (Nov. 7, 2003) (preamble, II.C.5.).

<sup>5</sup>Many of these studies are on the more frequent use of dialysis, which is more common with dialysis performed at home. For example, see Bruce F. Culleton et al., "Effect of Frequent Nocturnal Hemodialysis vs Conventional Hemodialysis on Left Ventricular Mass and Quality of Life: A Randomized Controlled Trial," *The Journal of the American Medical Association*, vol. 298, no. 11 (2007), 1291-1299.

<sup>6</sup>USRDS was established in 1988, and 2012 was the most recent year of data available at the time of our analysis.

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We also reviewed CMS's analysis of Medicare claims data from 2010 to 2015 for information on more recent trends among Medicare patients.<sup>7</sup> To gain insight into the factors that contributed to these trends and to identify estimates of the potential for wider use of home dialysis, we conducted a literature review and interviewed stakeholders, including two large dialysis facility chains, an association representing small dialysis facility chains and independent facilities, patient and physician associations, and experts on home dialysis identified through a review of published literature.<sup>8</sup> Information from these interviews cannot be generalized to all stakeholders.

To examine incentives associated with Medicare payments to dialysis facilities, we reviewed Medicare policies and relevant federal laws, regulations, and guidance, and we analyzed facilities' profit margins associated with their Medicare-covered dialysis treatments. Specifically, using Medicare cost reports for freestanding dialysis facilities in the 50 states and the District of Columbia in 2012, we calculated each facility's Medicare margin as payments minus costs divided by payments for Medicare-covered dialysis treatments.<sup>9</sup> We examined each facility's total costs, total Medicare payments, and the number of dialysis treatments provided, and we excluded facilities with (1) internal inconsistencies among these variables; (2) unusually high or low average costs or average Medicare payments per treatment, which may be indicative of data entry errors; or (3) inconsistencies between the numbers of Medicare-covered treatments reported on the cost reports and the number reported in Medicare claims. Beyond these exclusions, we did not independently verify the accuracy or completeness of the cost report data

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<sup>7</sup>According to USRDS, about 89 percent of all dialysis patients had Medicare coverage with Medicare as either a primary or secondary payer in 2012.

<sup>8</sup>Our literature review comprised peer-reviewed journal articles, government publications, trade and industry news, dissertations, and association and nonprofit publications published from January 2004 to March 2014.

<sup>9</sup>Dialysis facilities can be affiliated with a hospital (9 percent of facilities in 2012) or freestanding (91 percent of facilities). We did not analyze margins for hospital-based facilities because these facilities' costs may be driven in part by hospitals' methods for allocating overhead costs within hospitals rather than by the costs of the dialysis facility itself. Cost report data for 2012 were the most recent available when we began our analysis. Although data for 2013 subsequently became available, we continued using the 2012 data because they were more likely to have undergone CMS's initial review. Specifically, 77 percent of the 2012 cost reports in our analysis had undergone CMS's initial review compared to 32 percent of the 2013 cost reports as of June 2015.

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that dialysis facilities submitted to CMS. We then used regression analysis to measure the incentive that facilities may have to provide home dialysis in the short term. Specifically, the regression estimated the extent to which expanding the provision of home dialysis or dialysis conducted in facilities was associated with an increase or decrease in facilities' Medicare margins. (See app. I for additional details about our methodology for analyzing facilities' Medicare margins.) We also interviewed officials from CMS and dialysis facility chains about the costs for providing dialysis both in a facility and at home and the methods and requirements for completing the cost reports.

To examine incentives associated with Medicare payments to physicians and the role of nephrology training, we reviewed Medicare policies and relevant federal laws, regulations, and guidance. In addition, we analyzed data from CMS's Part B National Summary Data File on (1) total Medicare payments to physicians for the management of patients' dialysis care and training in 2013 and (2) the provision of kidney disease education from 2011—the first full year in which this benefit was implemented—through 2013. We also conducted interviews on physician payment policies and training with CMS officials, physician associations, and experts on home dialysis identified through a review of published literature.

We assessed the reliability of the CMS and USRDS data we used by interviewing officials responsible for overseeing these data sources, reviewing relevant documentation, examining the data for obvious errors, and—for cost report data—excluding certain facilities as described above. We determined that the data were sufficiently reliable for the purposes of this report.

We conducted this performance audit from June 2014 to October 2015 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.

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## Background

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### Types of Dialysis

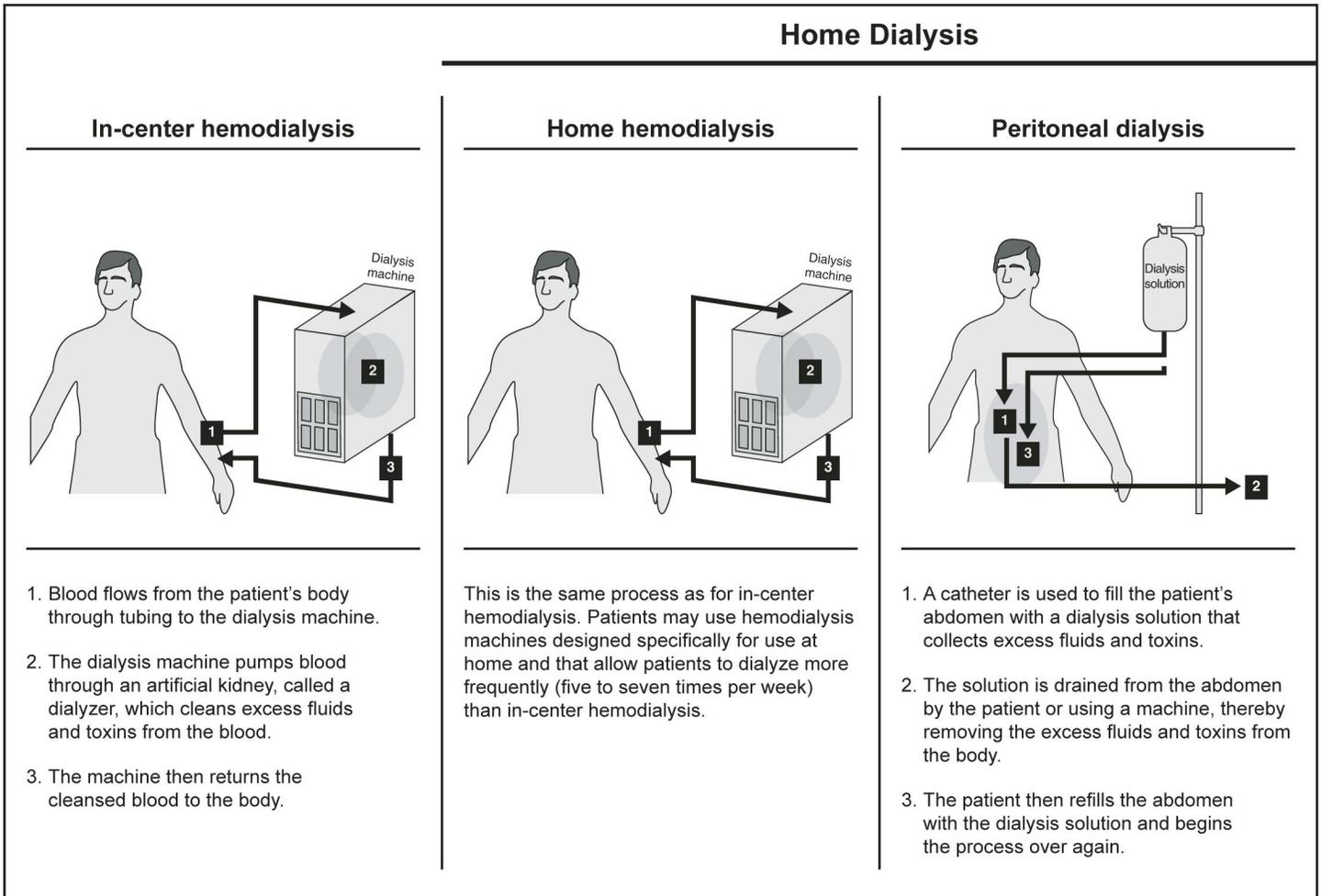
There are three types of dialysis, which is a process that removes excess fluids and toxins from the bloodstream: (1) hemodialysis performed in a facility (referred to as in-center hemodialysis in this report); (2) hemodialysis performed at home; and (3) peritoneal dialysis, which is generally performed at home. In-center hemodialysis is the most common type of dialysis and was used by about 89 percent of dialysis patients in 2012; the remaining patients received either peritoneal dialysis (9 percent) or home hemodialysis (2 percent). Similarly, almost all—approximately 96 percent of—dialysis facilities had in-center hemodialysis patients in 2012; just over two-fifths of facilities had peritoneal dialysis patients and nearly one-fifth had home hemodialysis patients.

The processes for hemodialysis—performed either in a facility or at home—and peritoneal dialysis differ. (See fig. 1.) For in-center hemodialysis treatments, blood flows from the patient's body through a surgically created vein or a catheter, known as a vascular access site, and through tubing to the dialysis machine. The machine pumps the blood through an artificial kidney, called a dialyzer, to cleanse the excess fluids and toxins from the bloodstream and then returns the cleansed blood to the body. Patients typically receive in-center hemodialysis for 3 to 4 hours three times per week. For home hemodialysis treatments, the process is the same, but the patient performs the treatments and may perform treatments more frequently and at night.<sup>10</sup> For peritoneal dialysis treatments, a catheter is used to fill the patient's abdomen with a dialysis solution that collects excess fluids and toxins over several hours; those excess fluids and toxins are removed from the body when the patient drains the dialysis solution from the abdomen. To conduct the exchanges—draining and then refilling the abdomen with the dialysis solution—most peritoneal dialysis patients use a machine that performs several exchanges during the night while they are asleep, and other patients do manual exchanges during the day.

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<sup>10</sup>Hemodialysis machines designed specifically for use at home allow patients to dialyze five to seven times per week. In December 2014, the Food and Drug Administration approved a machine for use with nocturnal home hemodialysis.

**Figure 1: Process for In-center Hemodialysis and Home Dialysis**



Source: GAO. | GAO-16-125

The three types of dialysis are also associated with various clinical advantages and disadvantages. For example, some studies have suggested that more frequent use of home hemodialysis can achieve better health outcomes for certain patients such as those with

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hypertension.<sup>11</sup> In another example, some studies have suggested that peritoneal dialysis may have a lower risk for death in the first few years of dialysis therapy, and peritoneal dialysis can also help patients retain residual kidney function. However, the causes of some differences in clinical outcomes between the types of dialysis can be challenging to determine because of differences in patient characteristics; younger patients, for example, were more likely to receive peritoneal dialysis than other types, according to USRDS data. In addition, there may also be clinical disadvantages. For example, home hemodialysis patients' more frequent use of the vascular access site may result in a higher risk for complications such as damage to the site that requires repair. Additionally, peritoneal dialysis patients may develop peritonitis, an infection of the peritoneal membrane, and the peritoneal membrane may become less effective over time, meaning a patient may eventually have to switch to either home or in-center hemodialysis.

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## Factors Affecting Type of Dialysis

Patients' preferences may influence whether patients receive home dialysis (either peritoneal dialysis or home hemodialysis) or in-center hemodialysis. For example, some patients may prefer home dialysis because they do not need to travel to the facility three times per week, giving them greater flexibility to work during the day and undergo dialysis at night in their home. Some patients also may prefer home dialysis because there may be fewer diet and fluid restrictions and less recovery time following each dialysis treatment. On the other hand, successfully performing home dialysis requires patients to undergo training and assume other responsibilities that they would not otherwise have if they dialyzed in a facility.<sup>12</sup> As a result, patients who feel unprepared to accept such responsibilities or who lack a spouse or caregiver to help them may be less likely to choose home dialysis. For similar reasons, some experts and stakeholders have indicated that switching from in-center to home dialysis can be challenging once patients become accustomed to in-

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<sup>11</sup>For example, see Michael V. Rocco et al., "The effects of frequent nocturnal home hemodialysis: The Frequent Hemodialysis Network Nocturnal Trial," *Kidney International*, vol. 80, no. 10 (2011), 1080-1091; and Culleton et al., "Effect of Frequent Nocturnal Hemodialysis vs Conventional Hemodialysis."

<sup>12</sup>Patients who choose home dialysis need space to store supplies and also a home hemodialysis or peritoneal dialysis machine, if applicable. Examples of other responsibilities are setting up the machine and operating it for each treatment, tracking information on each treatment, and maintaining a sanitary environment.

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center hemodialysis. Furthermore, the greater complexity of home hemodialysis training—including learning to place needles in the vascular access site and how to respond to alarms from the dialysis machine—relative to peritoneal dialysis training could lead some patients to prefer one type of home dialysis over the other.

In addition to patients' preferences, clinical factors may affect whether patients receive home dialysis or in-center hemodialysis. One factor is whether a patient has received care from a nephrologist prior to beginning dialysis. Patients who did not receive such care and who have an urgent need to start dialysis often do so with in-center hemodialysis because training is not required and because a venous catheter can be placed and used immediately.<sup>13</sup> More lead time can be required for peritoneal dialysis to allow the site where the peritoneal dialysis catheter was placed to heal.<sup>14</sup> As another example, a patient with poor vision or dexterity may have difficulty performing the tasks associated with home dialysis. In addition, a patient who has received multiple abdominal surgeries may not be an appropriate candidate for peritoneal dialysis. Finally, patients with multiple comorbidities (i.e., multiple chronic diseases or disorders) may choose in-center hemodialysis because it can allow the nephrologist to more closely manage those other conditions.

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## Medicare Payment for Dialysis Care

Medicare uses different methods to pay (1) dialysis facilities for providing dialysis treatments to patients and for training them to perform home dialysis and (2) physicians for managing patients' dialysis care and educating them about their condition.<sup>15</sup>

### Payments to Facilities

For dialysis treatments—including any training that occurs in the first 4 months of treatment—Medicare has paid facilities a single bundled

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<sup>13</sup>Although a venous catheter can be used immediately for hemodialysis, an arteriovenous fistula, which is a surgically-created vein, is the preferred kind of vascular access site. However, an arteriovenous fistula can take 2 to 3 months after surgery to develop, and clinical guidance from the National Kidney Foundation recommends that, when possible, the surgery be performed at least 6 months before dialysis is needed.

<sup>14</sup>There are options where a patient can start peritoneal dialysis at a lower volume and in a facility, allowing the peritoneal dialysis catheter to be used immediately, but these options have been less frequently used.

<sup>15</sup>Although dialysis facilities and physicians are the main providers for dialysis care, dialysis patients may also receive care from a variety of other providers such as hospitals.

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payment per treatment since 2011. The bundled payment is designed to cover the average costs incurred by an efficient facility to provide the dialysis, injectable drugs, laboratory tests, and other ESRD-related items and services.<sup>16</sup> In 2015, Medicare paid a base rate of \$239.43 per treatment for up to three hemodialysis treatments per week, and Medicare sets the daily rate for peritoneal dialysis such that payments for 7 days of peritoneal dialysis would equal the sum of payments for three hemodialysis treatments. Medicare adjusts the base rate to account for certain factors that affect the cost of a treatment, including costs to stabilize patients and to provide training during the first 4 months of dialysis treatments, as well as certain other patient and facility factors.<sup>17</sup> CMS implemented its Quality Incentive Program beginning in 2012, which can reduce Medicare payments for dialysis treatments to facilities by up to 2 percent based on the quality of care they provided.<sup>18</sup>

When training occurs after the first 4 months of the patient's dialysis treatments, Medicare pays dialysis facilities the bundled payment plus an additional fixed amount (often referred to as the training add-on). The training add-on is for the facilities' additional staff time to train the patient. This training, which can happen in an individual or group setting, is required to be furnished by a registered nurse.<sup>19</sup> The number of treatments that include home dialysis training—called training treatments—varies by type of dialysis and by patient. Medicare currently pays facilities a training add-on amount of \$50.16 per treatment for up to 25 home hemodialysis training treatments or a daily equivalent rate for up to 15 days of peritoneal dialysis training; CMS increased the training add-on payment from \$33.44 to \$50.16 in 2014.

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<sup>16</sup>For home patients, the bundled payment also covers the equipment provided to patients at home, including home hemodialysis and peritoneal dialysis machines.

<sup>17</sup>Patient-level factors are comorbidities, age, body surface area, body mass index, and onset period (first 4 months of dialysis treatment); facility-level factors are geographic location and whether the facility has a low volume of dialysis treatments, as defined by CMS. In addition to the bundled payment for a dialysis treatment, Medicare pays an additional amount—called an outlier payment—when the cost of a treatment exceeds a threshold specified by CMS.

<sup>18</sup>See 42 U.S.C. § 1395rr(h).

<sup>19</sup>42 C.F.R. §494.100(a)(2) (2014).

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## Payments to Physicians

Medicare pays physicians (typically nephrologists) a monthly amount per patient to manage patients' dialysis care. This monthly amount covers dialysis-related management services such as establishing the frequency of and reviewing dialysis sessions, interpretation of tests, and visits with patients. To receive the payment, Medicare requires the physician to provide at least one face-to-face visit per month to each patient for examining the patient's vascular access site. The monthly amount paid to the physician for managing in-center patients varies on the basis of the patient's age and the number of visits provided to the patient, but the amount for managing the care of a home patient varies only on the basis of the patient's age and not the number of visits.<sup>20</sup> Besides the monthly payment for patients' dialysis care, Medicare provides a one-time payment to physicians of up to \$500 for each patient who completes home dialysis training under the physician's supervision; this payment is separate from Medicare's payments to facilities for training patients.

Medicare also pays physicians to provide kidney disease education to patients who have not yet started dialysis. Congress established the Kidney Disease Education (KDE) benefit as part of the Medicare Improvements for Patients and Providers Act of 2008 to provide predialysis education to Medicare patients with Stage IV chronic kidney disease.<sup>21</sup> Topics to be covered include the choice of therapy (such as in-center hemodialysis, home dialysis, or kidney transplant) and the management of comorbidities, which can help delay the need for dialysis.

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<sup>20</sup>There are three age categories for payments for managing pediatric patients (age less than 2, ages 2 through 11, and ages 12 through 19) and one age category for payments for managing adult patients (ages 20 and older).

<sup>21</sup>Pub. L. No. 110-275, § 152(b), 122 Stat. 2494, 2551 (codified at 42 U.S.C. § 1395x(gg(1))).

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## Percentage of Patients on Home Dialysis Generally Declined between 1988 and 2008 and then Slightly Increased; Stakeholder Estimates Suggest Potential for Future Growth

Historical trends in the overall percentage of all dialysis patients on home dialysis—including both Medicare and non-Medicare patients—show a general decrease between 1988 and 2008 and a more recent increase thereafter through 2012. According to USRDS data, 16 percent of 104,200 dialysis patients received home dialysis in 1988. Home dialysis use generally decreased over the next 20 years, reaching 9 percent in 2008, and then slightly increased to 11 percent of 450,600 dialysis patients in 2012—the most recent year of data available from USRDS. (See fig. 2.) More generally, the percentage of all patients on home dialysis declined from 1988 through 2012 because the number of these patients increased at a slower rate than the total number of all patients on dialysis.<sup>22</sup> During the time period from 1988 through 2012, most home dialysis patients received peritoneal dialysis as opposed to home hemodialysis.<sup>23</sup> The more recent increase in use of home dialysis is also reflected in CMS data for adult Medicare dialysis patients, showing an increase from 8 percent using home dialysis in January 2010 to about 10 percent as of March 2015.<sup>24</sup>

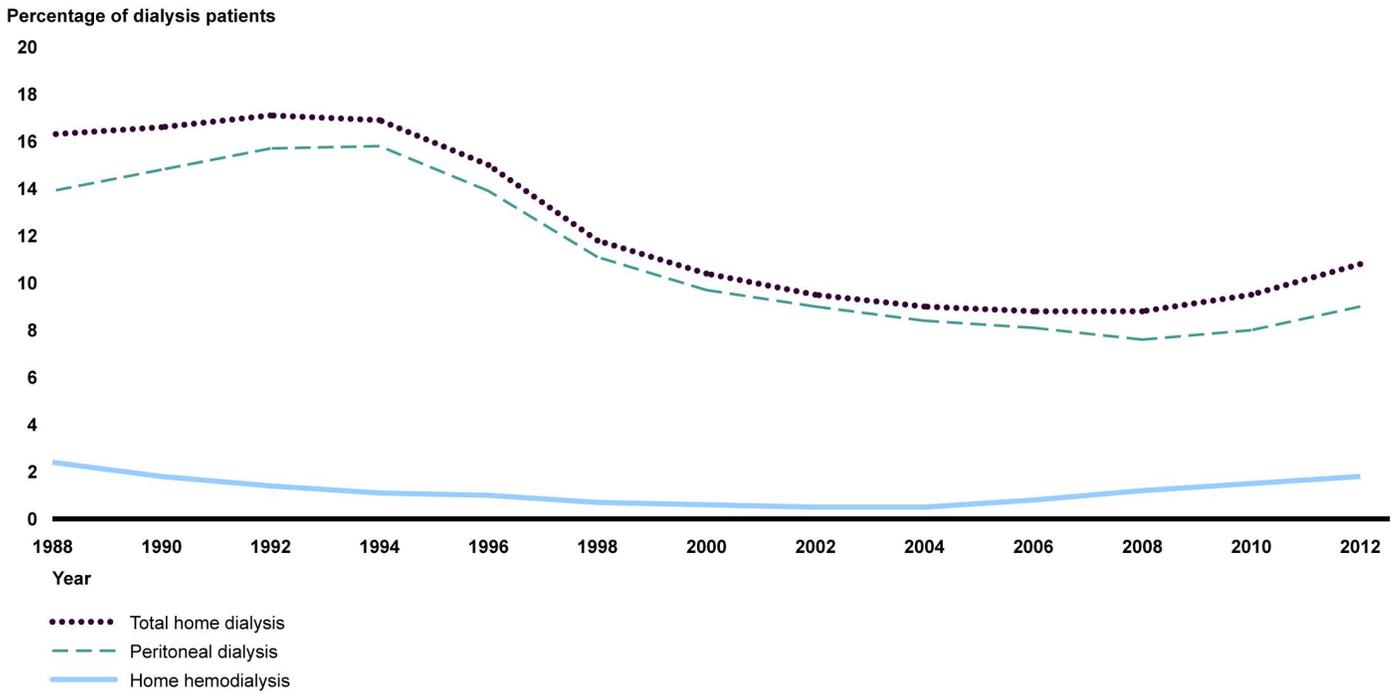
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<sup>22</sup>The number of home dialysis patients increased from approximately 17,000 in 1988 to 48,600 in 2012—an average annual growth rate of 4.5 percent. The total number of dialysis patients increased from approximately 104,200 in 1988 to 450,600 in 2012—an average annual growth rate of 6.3 percent.

<sup>23</sup>In 1988, about 14 percent of dialysis patients received peritoneal dialysis and 2 percent received home hemodialysis. In 2012, about 9 percent received peritoneal dialysis and 2 percent received home hemodialysis.

<sup>24</sup>CMS data are limited to Medicare dialysis patients (including some transplant patients), while USRDS data include both Medicare and non-Medicare dialysis patients. According to USRDS, about 89 percent of all dialysis patients in 2012 had Medicare coverage as either a primary or secondary payer.

**Figure 2: Trends in the Use of Home Dialysis, 1988-2012**



Source: GAO analysis of United States Renal Data System (USRDS) data. | GAO-16-125

Note: Analysis includes USRDS data for Medicare and non-Medicare dialysis patients from 1988 through 2012.

Literature we reviewed and stakeholders we interviewed suggested several factors that may have contributed to the trends in home dialysis use from 1988 through 2012. Looking at the initial decline between 1988 and 2008, contributing factors may have included increased capacity to provide in-center hemodialysis and changes in the dialysis population.

- **Increased capacity to provide in-center hemodialysis.** The growth in facilities' capacity to provide in-center hemodialysis from 1988 to 2008 outpaced the growth in the dialysis patient population over the same time period. Specifically, the number of dialysis stations, which include the treatment areas and dialysis machines used to provide in-center hemodialysis, increased at an average annual rate of 7.3 percent during this time period, while the number of patients increased at an average annual rate of 6.8 percent. As a result,

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dialysis facilities may have had a greater financial incentive to treat patients in facilities in an effort to use this expanded capacity, according to literature we reviewed.<sup>25</sup>

- **Changes in the dialysis population.** The increased age and prevalence of comorbidities in the dialysis population may have reduced the portion considered clinically appropriate for home dialysis. Dialysis patients who are older and those with comorbid conditions may be less physically able to dialyze at home. From 1988 to 2008, the mean age of a dialysis patient rose from 52.2 years to 58.6 years. Similarly, the proportion of the dialysis population affected by various comorbid conditions increased during this time period. For example, the percentage of dialysis patients with diabetes as the primary cause of ESRD increased from 24.6 percent in 1988 to 43.1 percent in 2008.

Medicare payment methods and concerns about the effectiveness of peritoneal dialysis may have played a role in the decline in home dialysis use between 1988 and 2008, but changes in both factors may have also contributed to recent increases in use.

- **Medicare payment methods for injectable drugs.** Medicare payment methods prior to 2011 may have given facilities a financial incentive to provide in-center rather than home dialysis. Before 2011, Medicare paid separately for injectable drugs rather than including them in the bundled payment. As a result, Medicare payments to facilities for dialysis care—including the payments for injectable drugs—could have been lower for home patients because of their lower use, on average, of injectable drugs.<sup>26</sup> However, the payment changes in 2011 reduced the incentive to provide in-center

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<sup>25</sup>For example, see D. C. Mendelssohn, “A Skeptical View of Assisted Home Peritoneal Dialysis,” *Kidney International*, vol. 71 (2007), 602-604; and Mohammad Qamar et al., “The United States’ Perspectives on Home Dialysis,” *Advances in Chronic Kidney Disease*, vol. 16, no.3 (May 2009), 189-197.

<sup>26</sup>Compared to hemodialysis patients—the majority of whom receive treatments in a facility—peritoneal dialysis patients need fewer injectable drugs, such as erythropoiesis stimulating agents, to manage anemia. For example, see Francisco Coronel et al., “Erythropoietin Requirements: A Comparative Multicenter Study Between Peritoneal Dialysis and Hemodialysis,” *Journal of Nephrology*, vol. 16, no. 5 (2003), 697-702; and Jon Snyder et al., “Hemoglobin Levels and Erythropoietin Doses in Hemodialysis and Peritoneal Dialysis Patients in the United States,” *Journal of the American Society of Nephrology*, vol. 15, no. 1 (2004), 174-179.

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hemodialysis relative to home dialysis because the Medicare payment for dialysis treatments and related services, such as injectable drugs, no longer differed based on the type of dialysis received by the patient.

- **Concerns about effectiveness of peritoneal dialysis.** Several studies published in the mid-1990s indicated poorer outcomes for peritoneal dialysis compared to hemodialysis, and these studies may have made some physicians reluctant to prescribe peritoneal dialysis, according to stakeholders and literature we reviewed.<sup>27</sup> However, stakeholders identified more recent studies indicating that outcomes for peritoneal dialysis are comparable to hemodialysis.<sup>28</sup> These newer studies may have contributed to the recent increases in home dialysis use by mitigating concerns about the effectiveness of peritoneal dialysis and by making physicians more comfortable with prescribing it.

Estimates from dialysis experts and other stakeholders suggest that further increases in the use of home dialysis are possible over the long term. The home dialysis experts and stakeholders we interviewed indicated that home dialysis could be clinically appropriate for at least half of patients. However, the percentage of patients who could realistically be expected to dialyze at home is lower because of other factors such as patient preferences. For example, at a meeting in 2013, the chief medical officers of 14 dialysis facility chains jointly estimated that a realistic target for home dialysis would be 25 percent of dialysis patients. To achieve this target, they said that changes, such as increased patient education and

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<sup>27</sup>For example, see Wendy E. Bloembergen et al., "A Comparison of Mortality Between Patients Treated with Hemodialysis and Peritoneal Dialysis," *Journal of the American Society of Nephrology*, vol. 6, no. 2 (1995), 177-183; Wendy E. Bloembergen et al., "A Comparison of Cause of Death Between Patients Treated with Hemodialysis and Peritoneal Dialysis," *Journal of the American Society of Nephrology*, vol. 6, no.2 (1995), 184-191; and Canada-USA (CANUSA) Peritoneal Dialysis Study Group, "Adequacy of Dialysis and Nutrition in Continuous Peritoneal Dialysis: Association with Clinical Outcomes," *Journal of the American Society of Nephrology*, vol. 7, no. 2 (1996), 198-207. For an example of literature on the effect of these studies, see Virginia Wang, "Location, Location, Location? A Study of Peritoneal Dialysis Services in the United States" (PhD diss., University of North Carolina Chapel Hill, 2008).

<sup>28</sup>For example, see Rajnish Mehrotra et al., "Similar Outcomes with Hemodialysis and Peritoneal Dialysis in Patients with End-Stage Renal Disease," *Archives of Internal Medicine*, vol. 171, no.2 (January 2011), 110-118; and Eric D. Weinhandl et al., "Propensity-Matched Mortality Comparison of Incident Hemodialysis and Peritoneal Dialysis Patients," *Journal of the American Society of Nephrology*, vol. 21, no.3 (March 2010), 499-506.

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changes to payment policies, would need to occur.<sup>29</sup> As another example, physician stakeholders we interviewed estimated that 15 to 25 percent of dialysis patients could realistically be on home dialysis.

In the short term, however, an ongoing shortage of peritoneal dialysis solution has reduced the use of home dialysis, and this shortage could have a long-term impact as well.<sup>30</sup> Medicare claims data analyzed by CMS show that the percentage of Medicare dialysis patients on home dialysis had reached 10.7 percent in August 2014, when the shortage was first announced, but has since declined to 10.3 percent, as of March 2015. CMS officials attributed this decline to the shortage in the supply of peritoneal dialysis solution because the decline did not occur among facilities owned by one large dialysis facility chain that manufactures its own peritoneal dialysis solution and has not experienced a shortage. Some dialysis facility chains told us that, because of this shortage, they limited the number of new patients on peritoneal dialysis. In addition, one physician association stated that the shortage could have long-term implications. They said that some physicians are reluctant to prescribe this type of dialysis, even when a facility has the capacity to start a patient on peritoneal dialysis, because of uncertainties about peritoneal dialysis supplies.

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<sup>29</sup>Tom Parker III, Doug Johnson, and Allen Nissenson, "The CMO Initiative: Peritoneal dialysis, home dialysis and non-conventional in-center dialysis," *Nephrology News & Issues* (November 2013).

<sup>30</sup>In August 2014, Baxter Healthcare, the largest supplier of peritoneal dialysis solution in the United States, announced supply constraints, which resulted in limits on the number of new patients who could start peritoneal dialysis.

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## Incentives for Facilities to Provide Home Dialysis May Have Limited Impact in Short Term

Medicare payments to dialysis facilities, including those that provided home dialysis, gave them an overall financial incentive to provide dialysis, as shown by their generally positive Medicare margins. The average Medicare margin for all 3,891 freestanding facilities in our analysis was 4.0 percent in 2012—that is, Medicare payments exceeded Medicare allowable costs for dialysis treatments by 4.0 percent.<sup>31</sup> Similarly, the average Medicare margin for the 1,569 freestanding facilities that provided one or both types of home dialysis was 4.20 percent in 2012.<sup>32</sup> (See table 1.) Focusing on those facilities that provided home dialysis, nearly all (94 percent) provided both in-center and one or both types of home dialysis. In addition, although margins were positive, on average, for these facilities, we found that the Medicare margin for large facilities (7.21 percent) was considerably higher, on average, than for small facilities (-3.49 percent). We also found that most of the patient years (81 percent) were devoted to in-center hemodialysis, followed by peritoneal dialysis (15 percent) and home hemodialysis (4 percent).<sup>33</sup> Small and large facilities followed the same pattern.

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<sup>31</sup>Facilities are instructed to report costs in their cost reports that the Medicare program has determined are reasonable for providing in-center and home dialysis care.

<sup>32</sup>The difference in margins between facilities that provide home dialysis and those that do not may be result of multiple factors and may be unrelated to the provision of home dialysis. (See app. I for descriptive information on how Medicare margins varied based on characteristics such as the type of dialysis provided and urban or rural location.)

<sup>33</sup>A patient year is equal to about 156 hemodialysis treatments or 365 days of peritoneal dialysis treatment.

**Table 1: Average Medicare Margin and Characteristics of Facilities That Provided Home Dialysis, 2012**

Category	All facilities	Small facilities	Large facilities
Number of facilities	1,569	785	784
Average Medicare margin	4.20%	-3.49%	7.21%
Average percentage of patient years with Peritoneal dialysis	15%	16%	14%
Average percentage of patient years with Home hemodialysis	4%	4%	4%
Average percentage of patient years with In-center hemodialysis	81%	79%	82%
Average number of patient years (all types of dialysis)	59.8	33.7	85.9

Source: GAO analysis of CMS data. | GAO-16-125

Notes: Analysis is based on 2012 Medicare cost reports from 1,569 freestanding dialysis facilities that provided home dialysis, defined as either home hemodialysis and/or peritoneal dialysis. Medicare margins are weighted by facilities' Medicare patient years. A patient year of treatment is equal to about 156 hemodialysis treatments or 365 days of peritoneal dialysis treatment. Percentages may not add to 100 due to rounding.

Facilities are classified as small or large based on whether their number of Medicare patient years was below or above the median number of patient years among the facilities in our analysis.

In addition to giving an incentive to provide dialysis in general, Medicare payments to facilities likely encourage the use of peritoneal dialysis—the predominant type of home dialysis—over the long term. The payment rate for peritoneal dialysis is the same as the rate for hemodialysis provided in facilities or at home, but the cost of providing peritoneal dialysis is generally lower, according to CMS and stakeholders we interviewed. When CMS established the current payment system, it stated that its decision to have a single payment rate regardless of the type of dialysis would give facilities a powerful financial incentive to encourage the use of home dialysis, when appropriate.<sup>34</sup> Another financial incentive that exists for both peritoneal dialysis and home hemodialysis is that facilities can receive additional months of payments for patients under 65 who undergo home dialysis training. Specifically, for patients under age 65, Medicare coverage typically begins in the fourth month after the patient begins dialysis, but coverage begins earlier if the patient undergoes home dialysis training.<sup>35</sup> This incentive is augmented because payments to facilities are significantly higher during the first 4 months of dialysis.<sup>36</sup>

<sup>34</sup>See ESRD Prospective Payment System, CMS final rule for CY 2011, 75 Fed. Reg. 49030, 49059, 49115 (Aug. 12, 2010) (preamble II.A.7.a.ii, II.F.3.h.)

<sup>35</sup>See 42 U.S.C. § 426-1(b), (c).

<sup>36</sup>Under the bundled payment system, Medicare payments to facilities are 51 percent higher during the first 120 days of dialysis—also referred to as the onset period.

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These incentives to provide home dialysis, compared to in-center hemodialysis, are consistent with CMS's goal of fostering patient independence through greater use of home dialysis among patients for whom it is appropriate.<sup>37</sup>

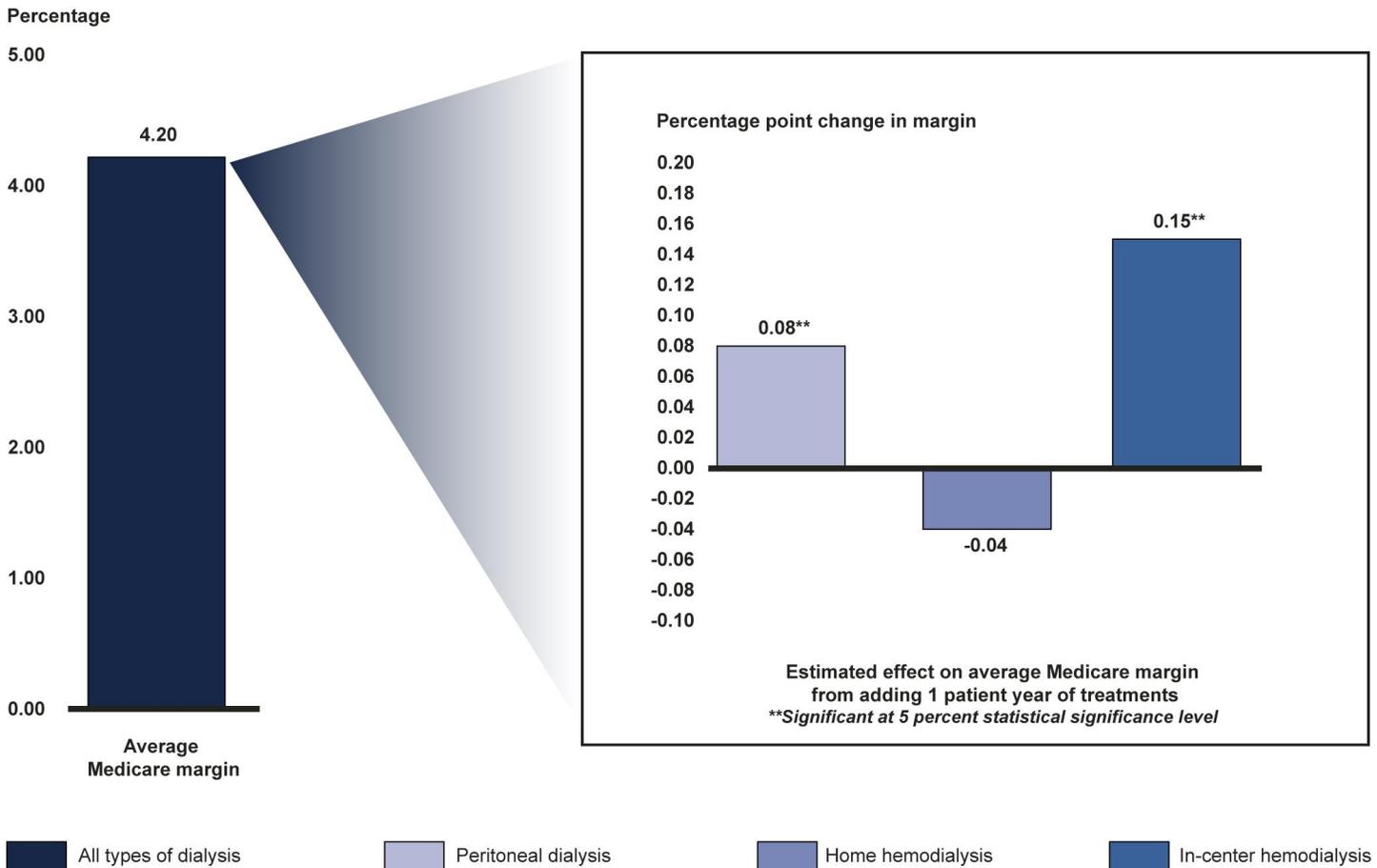
Although over the long term facilities may have a financial incentive to encourage the use of one or both types of home dialysis, the impact of this incentive could be limited in the short term. This is because, in the short term, we found that expanding the provision of in-center hemodialysis at a facility generally tends to increase that facility's Medicare margin and that the estimated increase is more than would result if the facility instead expanded the provision of either type of home dialysis. In particular, we found that, on average, facilities that provided home dialysis could improve their financial position in the short term by increasing their provision of in-center hemodialysis. An additional patient year of in-center hemodialysis improved the margin by an estimated 0.15 percentage points—for example, from 4.20 to 4.35 percent. (See fig. 3.) In contrast, increasing home dialysis resulted in a smaller benefit. Adding a patient year of peritoneal dialysis improved the margin by an estimated 0.08 percentage points and adding a patient year of home hemodialysis had no statistically significant effect on the margin; the estimated 0.04 percentage point reduction on average in the margin was not statistically different from zero. The pattern of the results in figure 3 for the three types of dialysis was similar for small and large facilities.<sup>38</sup> (See results in app. I.)

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<sup>37</sup>In addition to referring to the goal of increasing the use of home dialysis when establishing the single payment rate regardless of the type of dialysis under the current payment system, CMS referred to this goal in connection with fostering patient independence when it previously established its Conditions for Coverage for dialysis facilities and, more recently, in written comments on a draft of this report. See Conditions for Coverage for End-Stage Renal Dialysis Facilities, CMS final rule, 73 Fed. Reg. 20370, 20471 (Apr. 15, 2008) (preamble, VII.B.); and appendix II.

<sup>38</sup>Facilities are classified as small or large based on whether their number of Medicare patient years was below or above the median number of patient years among the facilities in our analysis. For small facilities, the estimated impact of an additional patient year of peritoneal dialysis was not significantly different from the impact for home hemodialysis. For large facilities, the estimated impact of an additional patient year of peritoneal dialysis was not significantly different from the impact for in-center hemodialysis.

**Figure 3: Average Medicare Margin and Estimated Effect from Adding 1 Patient Year of Treatments, by Type of Dialysis, for Facilities That Provided Home Dialysis, 2012**



Source: GAO analysis of CMS data. | GAO-16-125

Notes: Analysis is based on 2012 Medicare cost reports from 1,569 freestanding dialysis facilities that provided home dialysis, defined as either home hemodialysis and/or peritoneal dialysis.

The Medicare margin is weighted by facilities' Medicare patient years. A patient year of treatment is equal to about 156 hemodialysis treatments or 365 days of peritoneal dialysis treatment.

The differences in the estimated percentage point change in the margin for the three types of dialysis were significant at the 5 percent statistical significance level or above.

Our findings on the relative impact of the incentives in the short term are generally consistent with information on the cost of each type of dialysis provided to us by CMS and stakeholders we interviewed. First, consistent with our finding that facilities have a greater short-term incentive for in-center hemodialysis, stakeholders we interviewed said that facilities' costs for increasing their provision of in-center hemodialysis may be lower than

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for either type of home dialysis. For example, although the average cost of an in-center hemodialysis treatment is typically higher than the average cost of a peritoneal dialysis treatment, facilities may be able to add an in-center patient without incurring the cost of an additional dialysis machine because each machine can be used by six to eight patients. In contrast, when adding a home patient, facilities generally incur costs for additional equipment, which is dedicated to a single patient. Second, some stakeholders said that the cost of providing home hemodialysis, in particular, can be higher than other types of dialysis in part because home hemodialysis patients often receive more than three treatments per week and Medicare's policy is not to pay for these additional treatments unless medically justified.<sup>39</sup> Finally, when comparing the two types of home dialysis, CMS and the stakeholders generally reported that the cost of home hemodialysis, including training, was higher than for peritoneal dialysis. They said that home hemodialysis training is more costly because of the greater complexity such as learning to place needles in the vascular access site and to respond to alarms. Stakeholders also told us that Medicare payments cover only a portion of the upfront costs for training a patient, particularly one on home hemodialysis.

CMS increased the training add-on payment beginning in 2014 in response to public comments it received on the cost of home hemodialysis training, but the agency lacks reliable data for determining whether the revised payment is adequate.<sup>40</sup> Specifically, CMS lacks reliable data on the cost of home dialysis treatment and training and on the staff time needed to provide training.

- We found that the cost report data on facilities' costs for each type of dialysis, including costs for home dialysis training, were not sufficiently reliable. Although we determined that data on facilities' total costs across all types of dialysis were sufficiently reliable for purposes of our analysis, stakeholders reported that these total costs were not

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<sup>39</sup>CMS has found variation in how often medical justification was provided for more than three treatments per week for home hemodialysis patients. As a result, CMS recently reiterated that, absent medical justification, the choice of home hemodialysis allows for Medicare payment for no more than three treatments per week. The concept of more frequent dialysis is not applicable to peritoneal dialysis, which is done on a continuous basis throughout the week.

<sup>40</sup>CMS summarized these comments and the agency's response in ESRD Prospective Payment System, CMS final rule for CY 2014, 78 Fed. Reg. 72182-72185 (Dec. 2, 2013).

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accurately allocated to each type of dialysis and to training.<sup>41</sup> One reason for this inaccuracy may be that some facilities allocated certain types of costs, such as dialysis-related drugs and supplies, based on the number of treatments for each type of dialysis. Representatives of these facilities reported that CMS's Medicare Administrative Contractors had approved this allocation method.<sup>42</sup> However, the number of treatments by type of dialysis may not be a reliable basis for allocating such costs. For example, studies have shown that utilization of dialysis-related drugs differs by type of dialysis, and stakeholders reported that supply costs can as well.<sup>43</sup> In addition, CMS officials told us that they do not regularly review the reliability of these data.<sup>44</sup>

- We also found that CMS lacks consistent data on the staff time required to provide home dialysis training even though the agency used the number of hours of nursing time as the basis for its training add-on payment rate. For example, in 2012, CMS acknowledged that 1 hour did not necessarily correspond to the amount of time needed to train a patient, even though CMS used 1 hour as the basis.<sup>45</sup> More recently, despite the fact that CMS increased the training add-on by

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<sup>41</sup>We used cost report data on facilities' total costs to calculate facilities' overall average Medicare margin, and we also used facilities' number of treatments by type of dialysis to estimate the effect from adding 1 patient year of treatment by type of dialysis.

<sup>42</sup>CMS recommends that facilities allocate costs for dialysis-related drugs and certain other types of costs based on the amount charged for each type of dialysis, but a facility can request approval from CMS's Medicare Administrative Contractors to use a different allocation method if the facility believes that change will result in more accurate cost allocations. The Medicare Administrative Contractors are responsible for processing Medicare dialysis facility cost reports and also administer claims submitted by dialysis facilities and other types of Medicare providers.

<sup>43</sup>For example, see Coronel et al., "Erythropoietin Requirements," and Snyder et al., "Hemoglobin Levels and Erythropoietin Doses in Hemodialysis and Peritoneal Dialysis Patients."

<sup>44</sup>CMS officials stated that its periodic audits of dialysis facility cost reports, which are required by the Balanced Budget Act of 1997, do not review the costs of home dialysis or of home dialysis training. Pub. L. No. 105-33, § 4558(a), 111 Stat. 251, 463 (1997) (codified at 42 U.S.C. § 1395rr note). CMS officials could not tell us whether any future audits required by the Protecting Access to Medicare Act of 2014 would review these data. Pub. L. No. 113-93, § 217(e), 128 Stat. 1040, 1063 (2014) (codified at 42 U.S.C. § 1395rr note).

<sup>45</sup>ESRD Prospective Payment System, CMS final rule for CY 2013, 77 Fed. Reg. 67468 (Nov. 9, 2012).

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basing it on 1.5 hours of nursing time, CMS said that the public comments it received did not provide consistent information on the number of hours spent on training; the number of hours reported in these comments varied from 2 to 6 hours per treatment.<sup>46</sup>

The adequacy of training payments could affect facilities' incentives for providing home dialysis, but it is unclear whether these payments are adequate given CMS's lack of reliable data on the cost of training and by type of dialysis. Reliable cost report data are important for CMS to be able to perform effective fiscal management of the program, which involves assessing the adequacy of payment rates. In particular, if the training payments are inadequate, facilities may be less willing to provide home dialysis, which could undermine CMS's goal of encouraging the use of home dialysis when appropriate.

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## Medicare Payment Policies and Limited Nephrology Training May Constrain Physicians' Prescribing of Home Dialysis

Medicare physician payments for dialysis care do not consistently result in incentives for physicians to prescribe home dialysis. In addition, few Medicare patients have used Medicare's KDE benefit, and this low usage may be due to statutory payment limitations on the types of providers permitted to furnish the benefit and on the Medicare patients eligible to receive it. Finally, physicians' limited exposure to home dialysis during nephrology training programs is a third factor that may constrain the extent to which physicians prescribe home dialysis.

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## Medicare Physician Payments May Not Consistently Result in Incentives to Prescribe Home Dialysis

We found that the structure of Medicare's monthly physician payments—one of several factors that could affect the use of home dialysis—may give physicians a disincentive for prescribing home dialysis, which could undermine CMS's goal of encouraging the use of home dialysis when appropriate. CMS, when it established the current method of paying physicians a monthly payment to manage patients' dialysis, stated that this method would encourage the use of home dialysis by giving

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<sup>46</sup>ESRD Prospective Payment System, CMS final rule for CY 2014, 78 Fed. Reg. 72184-72185 (Dec. 2, 2013).

physicians an incentive to manage home patients.<sup>47</sup> According to CMS, this incentive would exist because the monthly payment rate for managing the dialysis care of home patients, which requires a single in-person visit, was approximately equal to the rate for managing and providing two to three visits to in-center patients. However, we found that, in 2013, the rate of \$237 for managing home patients was lower than the average payment of \$266 and maximum payment of \$282 for managing in-center patients. (See table 2.) This difference in payment rates may discourage physicians from prescribing home dialysis.

**Table 2: Monthly Payment Rate and Percentage of Monthly Payments for Physicians' Management of Dialysis Patients' Care, 2013**

Type of dialysis patients	Visits per month	Monthly payment rate	Percentage of monthly payments
In-center patients	One	\$184	6
	Two to three	\$237	22
	Four or more	\$282	72
	<b>Average (any number of visits)</b>	<b>\$266<sup>a</sup></b>	<b>100</b>
Home patients	One or more	\$237	100

Source: GAO analysis of CMS data. | GAO-16-125

Note: Physicians are required to provide at least one visit per month in order to perform a complete assessment of the patient. The payment rates and percentage of monthly payments are for patients ages 20 and older. CMS adjusts a portion of the payment rate to account for geographic differences in the cost of doing business.

<sup>a</sup>This is a weighted average based on the percentage of monthly payments for each category of visits.

Physician associations and other physicians we interviewed told us that Medicare payments may give physicians a disincentive for prescribing home dialysis. They stated that, even though the payment levels for managing home patients are typically lower, the visits with home patients are often longer and more comprehensive; this is in part because physicians may conduct visits with individual home patients in a private setting, but they may be able to more easily visit multiple in-center patients on a single day as they receive dialysis. The physician associations we interviewed also said that they may spend a similar amount of time outside of visits to manage the care of home patients and that they are required to provide at least one visit per month to perform a

<sup>47</sup>Revisions to Payment Policies Under the Physician Fee Schedule for CY 2004, CMS final rule with comment period, 68 Fed. Reg. 63196, 63219 (Nov. 7, 2003) (preamble, II.C.5.)

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complete assessment of the patient.<sup>48</sup> In addition, while physicians can receive a higher payment for providing more than one visit to in-center patients, these additional visits may be provided by nurse practitioners and certain other nonphysician practitioners, who may be less costly.<sup>49</sup> CMS has not revised the overall structure for paying for physicians to manage dialysis patients' care since 2004, although it has addressed some stakeholder concerns such as how it paid physicians when home patients were in the hospital.<sup>50</sup>

In contrast to the monthly payments, Medicare physician payments related to patients' training may provide physicians with financial incentives for prescribing home dialysis. For certain patients who start home training—those under 65 who are eligible for Medicare solely due to ESRD—the monthly payments to physicians can begin in the first month

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<sup>48</sup>The complete assessment of the patient—either a home patient or an in-center patient—includes an examination of the patient's vascular access site and must be provided during a face-to-face visit. If a physician provides more than one visit per month for an in-center patient, those additional visits can be provided via telehealth if the patient is located at originating sites, such as hospitals, that have been designated by CMS. Freestanding dialysis facilities and patients' homes have not been designated as originating sites.

<sup>49</sup>Results from studies we reviewed varied in terms of the relationship between the number of visits per month for in-center hemodialysis patients and differences in patient outcomes. For example, one study found a lower risk for hospitalization among in-center hemodialysis patients with more frequent visits, though another study found no association between hospitalization rates and frequency of physician contact. See Yelena Slinin et al., "Association of Provider-Patient Visit Frequency and Patient Outcomes on Hemodialysis," *Journal of the American Society of Nephrology*, vol. 23, no. 9 (2012), 1560-1567; and Laura C. Plantinga et al., "Frequency of Patient-Physician Contact and Patient Outcomes in Hemodialysis Care," *Journal of the American Society of Nephrology*, vol. 15, no. 1 (2004), 210-218. In addition, one study found that the frequency of visits for in-center hemodialysis patients depends primarily on provider practice patterns rather than on how sick patients are; see Kevin F. Erickson et al., "Variation in Nephrologist Visits to Patients on Hemodialysis across Dialysis Facilities and Geographic Locations," *Clinical Journal of the American Society of Nephrology*, vol. 8, no. 6 (2013), 987-994. If more than one physician or nonphysician practitioner provides visits over the course of the month, Medicare pays the monthly rate to only the physician or practitioner who provided the visit with the complete assessment of the patient and who established the patient's plan of care.

<sup>50</sup>Prior to 2015, CMS reduced the monthly payment by a pro-rated amount according to the number of days that a home patient was in the hospital, even though the physician may have continued to manage the patient's care throughout the month. Starting in 2015, CMS eliminated this reduction in the monthly payment—which stakeholders told us had been an additional disincentive for managing home patients—if the physician has a visit with the home patient during the month. This change is consistent with CMS's payment policies for managing in-center patients who have been hospitalized.

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rather than the fourth month of treatment, which may provide physicians with an incentive to prescribe home dialysis. In addition, Medicare makes a one-time payment of up to \$500 for each patient who has completed home dialysis training under the physician's supervision. One stakeholder told us that this training payment may provide an incentive for physicians to prescribe home dialysis.

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### Payment Limitations on Categories of Providers and Patients for Kidney Disease Education Benefit May Constrain Its Use

Few Medicare patients have used the KDE benefit, which covers the choice of therapy (such as in-center hemodialysis, home dialysis, or kidney transplant) and the management of comorbidities, and stakeholders generally told us this low usage was related to payment limitations on the types of providers who are permitted to furnish the benefit and on the Medicare patients eligible to receive it. According to USRDS, less than 2 percent of eligible Medicare patients used the KDE benefit in 2010 and 2011—the first two years it was available—and use of the benefit has decreased since then.<sup>51</sup>

When CMS implemented the KDE benefit, the agency identified specific categories of providers—physicians, physician's assistants, nurse practitioners, and clinical nurse specialists—as eligible to receive payment for furnishing the benefit.<sup>52</sup> Stakeholders, including physician associations, told us that other categories of trained healthcare providers (such as registered nurses, social workers, and dieticians who may be part of the nephrology practice) are also qualified to provide predialysis

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<sup>51</sup>See United States Renal Data System, *2013 USRDS 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, 2013), 176. USRDS estimated the cumulative probability that Medicare patients received the KDE benefit in the 12 months after being diagnosed with at least Stage IV chronic kidney disease (making the patient eligible for the KDE benefit) or in the 12 months prior to starting dialysis or other ESRD therapy.

According to the Medicare Payment Advisory Commission, Medicare paid for KDE sessions for approximately 4,200 Medicare patients in 2011 and 2012 each, and for approximately 3,600 Medicare patients in 2013. In addition, according to Medicare claims data, Medicare spent \$514,000 to \$537,000 for approximately 8,100 to 8,200 group or individual sessions in 2011 and 2012 each, and Medicare spent \$399,000 for approximately 6,400 sessions in 2013.

<sup>52</sup>In rural areas, hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, and hospices can also provide the benefit, as can hospitals and critical access hospitals paid as if located in a rural area.

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education. However, when asked if other types of providers could be eligible to receive payment, CMS officials said that the statute specified the categories of providers and that the agency was limited to those providers.<sup>53</sup> Dialysis facilities are also not eligible to receive payment for the KDE benefit. Although facility representatives said that they were equipped to provide education to these patients, including education on the choice of type of dialysis,<sup>54</sup> CMS and some other stakeholders said that one reason facilities are not eligible to provide the KDE benefit is their financial interest in treatment decisions. For example, the KDE benefit is designed to provide objective education to patients on steps that can be taken to delay the need for dialysis and on the choice of therapies, which includes kidney transplant, as well as home dialysis and in-center hemodialysis. Some of these options could be contrary to dialysis facilities' financial interest.

Similarly, CMS identified a specific category of patients—those with Stage IV chronic kidney disease—as eligible to receive the KDE benefit. Physician stakeholders said that certain other categories of patients, such as those in Stage III or those in Stage V but who have not started dialysis, may also benefit from Medicare coverage of timely predialysis education. However, when asked if other categories of patients could be eligible to receive the KDE benefit, CMS officials said that the agency was limited by statute to Stage IV patients.<sup>55</sup>

The low usage of the KDE benefit, which may be a result of these payment limitations, suggests that it may be difficult for Medicare patients to receive this education, which is designed to help them make informed treatment decisions. Literature and stakeholders have underscored the value of predialysis education to help patients make informed treatment

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<sup>53</sup>42 U.S.C. § 1395x(ggg)(2)(A).

<sup>54</sup>Facilities currently provide some education to patients who have already started dialysis. Medicare requires facilities to inform current patients about options for both home and in-center hemodialysis and to identify home dialysis plans for patients who are suitable candidates for home dialysis. See 42 C.F.R. §§ 494.70(a)(7), 494.90(a)(7)(i) (2014).

<sup>55</sup>42 U.S.C. § 1395x(ggg)(1)(A).

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decisions, and also indicated that patients who receive it may be more likely to choose home dialysis.<sup>56</sup>

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### Limited Exposure to Home Dialysis during Nephrology Training May Constrain Extent to Which Physicians Prescribe Home Dialysis

Literature we reviewed and nearly all of the stakeholders we interviewed indicated that physicians have limited exposure to home dialysis during nephrology training programs and thus may not feel comfortable prescribing it. One study found that 56 percent of physicians who completed training said they felt well trained and competent in the care of peritoneal dialysis patients, and 16 percent felt this way in the care of home hemodialysis patients.<sup>57</sup> Furthermore, another study found that physicians who felt more prepared to care for peritoneal dialysis patients were more likely to prescribe it.<sup>58</sup>

Literature we reviewed and stakeholders identified two main factors that may limit physicians' exposure to home dialysis while they undergo nephrology training:

- The nephrology board certification examination administered by the American Board of Internal Medicine does not emphasize home dialysis, particularly home hemodialysis. The examination blueprint published by the board shows that approximately 9 percent of the board certification examination is dedicated to questions regarding ESRD, which may include hemodialysis and peritoneal dialysis but, according to one board official, is unlikely to include home hemodialysis. Literature and stakeholders suggested that greater emphasis on home dialysis on certification examinations might lead to a greater emphasis on home dialysis in nephrology training.

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<sup>56</sup>For example, see Eduardo Lacson Jr et al., "Effects of a Nationwide Predialysis Educational Program on Modality Choice, Vascular Access, and Patient Outcomes," *American Journal of Kidney Diseases*, vol. 58, no. 2 (2011), 235-242; Braden J. Manns et al., "The Impact of Education on Chronic Kidney Disease Patients' Plans to Initiate Dialysis with Self-Care dialysis: A Randomized Trial," *Kidney International*, vol. 68 (2005), 1777-1783; and Rajnish Mehrotra et al., "Patient Education and Access of ESRD Patients to Renal Replacement Therapies Beyond In-center Hemodialysis," *Kidney International*, vol. 68 (2005), 378-309.

<sup>57</sup>Jeffrey S. Berns, "A Survey-Based Evaluation of Self-Perceived Competency after Nephrology Fellowship Training," *Clinical Journal of the American Society of Nephrology*, vol. 5, no.3 (March 2010), 490-496.

<sup>58</sup>Joseph R. Merighi et al., "Insights into Nephrologist Training, Clinical Practice, and Dialysis Choice," *Hemodialysis International*, vol. 16 (2012), 242-251.

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- According to an Institute of Medicine report, the way Medicare provides graduate medical education payments may discourage nephrology training outside of the hospital, and one stakeholder said this system may impede physician exposure to home patients.<sup>59</sup> Medicare pays teaching hospitals directly to help cover the costs of graduate medical education, including the salaries of the physicians in training.<sup>60</sup> Hospitals have the option to allow physicians to train at a second, off-site location—for example, a dialysis facility with a robust home dialysis program—if the hospital continues to pay the physicians’ salaries. However, the stakeholder said that hospitals may be reluctant to allow physicians to train at a second, off-site location, such as a dialysis facility, because patients at such locations may not be served primarily by the hospital.

The American Society of Nephrology has acknowledged that nephrology training in home dialysis needs to improve. As a result, the society has developed and disseminated guidelines identifying training specific to home dialysis and providing suggestions on curriculum organization to increase physician exposure to home patients.<sup>61</sup> For example, the guidelines suggest physicians in training should demonstrate knowledge of the infectious and noninfectious complications specific to peritoneal dialysis and home hemodialysis. They also suggest a program’s curriculum should include observation of and participation in a patient’s training to conduct home dialysis.

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## Conclusions

The number and percentage of patients choosing to dialyze at home have increased in recent years, and our interviews with home dialysis experts and stakeholders indicated potential for future growth. To realize this potential, it is important for the incentives associated with Medicare payments to facilities and physicians to be consistent with CMS’s goal of

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<sup>59</sup>See Institute of Medicine, *Graduate Medical Education That Meets the Nation’s Health Needs* (Washington, D.C.: The National Academies Press, 2014).

<sup>60</sup>Medicare also provides an indirect medical education payment adjustment to teaching hospitals, in recognition of the fact that teaching hospitals tend to have higher costs because they treat sicker patients and have other inefficiencies associated with a training environment. These payments are add-on payments for every Medicare discharge under the inpatient prospective payment system.

<sup>61</sup>See American Society of Nephrology, *Home Dialysis Benchmarks Workgroup* (Washington, D.C.: American Society of Nephrology, 2014).

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encouraging the use of home dialysis among patients for whom it is appropriate. One aspect of payment policy—training add-on payments to facilities—has a direct impact on facilities’ incentives for providing home dialysis. However, whether these training payments are adequate continues to be unclear because CMS lacks reliable data on the cost of home dialysis treatment and training for assessing payment adequacy. If training payments are inadequate, facilities may be less willing to provide home dialysis. In addition, the way Medicare pays physicians to manage the care of dialysis patients may be discouraging physicians from prescribing home dialysis. Finally, the limited use of the KDE benefit suggests that it may be difficult for Medicare patients to receive this education, which is designed to help them make informed decisions related to their ESRD treatment, including decisions on the choice of the type of dialysis, as well as options such as kidney transplant and steps to delay the need for dialysis.

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## Recommendations

- To determine the extent to which Medicare payments are aligned with costs for specific types of dialysis treatment and training, the Administrator of CMS should take steps to improve the reliability of the cost report data for treatment and training associated with specific types of dialysis.
- The Administrator of CMS should examine Medicare policies for monthly payments to physicians to manage the care of dialysis patients and revise them if necessary to ensure that these policies are consistent with CMS’s goal of encouraging the use of home dialysis among patients for whom it is appropriate.
- To ensure that patients with chronic kidney disease receive objective and timely education related to this condition, the Administrator of CMS should examine the Kidney Disease Education benefit and, if appropriate, seek legislation to revise the categories of providers and patients eligible for the benefit.

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## Agency and Third Party Comments and Our Evaluation

We received written comments on our draft report from the Department of Health and Human Services (HHS). These comments are reprinted in appendix II. Because Medicare payments for home dialysis have implications for patients and the dialysis industry, we also obtained comments on our draft from groups representing home dialysis patients, large and small dialysis facility chains and independent facilities, and nephrologists. Following is our summary of and response to comments from HHS and these patient and industry groups.

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## Comments from HHS

In written comments on a draft of this report, HHS reiterated its goal of fostering patient independence through greater use of home dialysis among patients for whom it is appropriate and pointed out that home dialysis use has increased since 2011 when the bundled payment system was implemented. HHS concurred with two of our three recommendations. In response to our first recommendation that CMS improve the reliability of cost report data for training and treatment associated with specific types of dialysis, HHS said that it is willing to consider reasonable modifications to the cost report that could improve the reliability of cost report data. HHS also stated that it was conducting audits of cost reports as required by the Protecting Access to Medicare Act of 2014. HHS also concurred with our second recommendation to examine Medicare policies for monthly payments to physicians to manage patients' dialysis to ensure that these policies are consistent with CMS's goal of encouraging home dialysis use when appropriate. HHS said that it would review these services through CMS's misvalued code initiative, which involves identifying and evaluating physician services that may not be valued appropriately for Medicare payment purposes and then adjusting Medicare payment as needed. We believe that this examination and any resulting revisions to these payment policies have the potential to address our recommendation.

HHS did not concur with our third recommendation that CMS examine the KDE benefit and, if appropriate, seek legislation to revise the categories of providers and patients eligible for the benefit. HHS said that CMS works continuously to appropriately pay for ESRD services and must prioritize its activities to improve care for dialysis patients. While we acknowledge the need for HHS to prioritize its activities to improve dialysis care, it is important for HHS to help ensure that Medicare patients with chronic kidney disease understand their condition, how to manage it, and the implications of the various treatment options available, particularly given the central role of patient choice in dialysis care. The limited use of the KDE benefit suggests that it may be difficult for Medicare patients to receive this education and underscores the need for CMS to examine and potentially revise the benefit.

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## Comments from Groups Representing Patients and the Dialysis Industry

We received comments from five groups: (1) Home Dialyzors United (HDU), which represents home dialysis patients; (2) the National Renal Administrators Association (NRAA), which represents small dialysis facility chains and independent facilities; (3) DaVita, which is one of the two large dialysis facility chains; (4) Fresenius, which is the other large dialysis facility chain; and (5) the Renal Physicians Association (RPA), which represents nephrologists. The groups expressed appreciation for

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the opportunity to review the draft, and the three groups that commented on the quality of the overall report stated that it accurately addressed issues related to the use of home dialysis.

Three of the groups commented on some or all of our recommendations, while the remaining two groups did not comment specifically on this aspect of our report. Specifically, HDU, NRAA, and RPA agreed with our first recommendation that CMS improve the reliability of cost report data for treatment and training associated with specific types of dialysis. A fourth group—Fresenius—expressed concern about the reliability of data on the costs of home dialysis, which was consistent with our recommendation that CMS needs to improve the reliability of these data. RPA, in addition to agreeing with this recommendation, questioned the reliability of the data on total facility costs that we used for our analysis. Although it was beyond the scope of our report to verify the accuracy of each facility's cost report, we took several steps to assess the cost report data that we analyzed. These steps included verifying the cost report data for internal consistency and checking the number of dialysis treatments reported against Medicare claims. The fact that implementing these steps caused us to exclude some facilities' data from our analysis suggests that the potential exists to improve the accuracy of these data. CMS's implementation of our recommendation and auditing of cost reports under the Protecting Access to Medicare Act of 2014 create the opportunity for CMS to begin addressing this issue. NRAA, another group that agreed with our first recommendation, recommended that we or CMS develop mechanisms in addition to the cost reports to more accurately capture the resources devoted to providing home dialysis to each patient, but developing such mechanisms was beyond the scope of this report.

One group (HDU) agreed with our second recommendation that CMS examine and, if necessary, revise Medicare payment policies for physicians to manage the care of dialysis patients, but a second group (RPA) urged us to reconsider the recommendation out of concern that implementing it could lead to cuts in physician payments for home dialysis. While RPA agreed that the current payment method gives physicians a disincentive for prescribing home dialysis, the group emphasized that it was only one of numerous factors that affect this treatment decision. RPA also stated that it would support certain payment changes that would increase physicians' incentives to prescribe home dialysis, which could include using performance measures to promote home dialysis use. However, RPA expressed concern that the process CMS may use for examining and potentially revising this payment method could lead to cuts in physician payments for home dialysis, which RPA asserted would further discourage its use and be contrary to the intent of

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our recommendation. We agree that Medicare's current method of paying physicians to manage patients' dialysis care is one of several factors that could influence physicians' decisions to prescribe home dialysis and described these factors in our report. In addition, while we do not know what changes, if any, CMS will make to physician payments for managing patients' dialysis care, we believe the intent of our recommendation—to ensure that these payments are consistent with CMS's goal to encourage the use of home dialysis when appropriate—is clear.

Three groups (HDU, NRAA, and RPA) agreed with our third recommendation that CMS examine the KDE benefit and if appropriate seek revisions to the categories of providers and patients eligible for the benefit. RPA also emphasized its agreement with our findings that the statutory limitations on the providers and patients eligible for the benefit have contributed to the limited use of the benefit. These groups also urged other changes to the KDE benefit such as removing the requirement for a copayment and making documentation requirements more flexible. The limitations in the categories of eligible providers and patients were cited in our interviews with stakeholders as the main reasons for the limited use of the KDE benefit, but we acknowledge that other opportunities may exist for improving the benefit's design. NRAA also pointed out that facilities currently educate patients with chronic kidney disease on the choice of type of dialysis but are not reimbursed by Medicare for doing so. We stated in the report that, according to the large and small dialysis facility chains we interviewed, they have the capacity to educate such patients about their condition. However, we also reported the concern raised by CMS and certain other stakeholders that the education provided by facilities may not be objective because they have a financial interest in patients' treatment decisions.

The patient and industry groups also made several comments in addition to those described above.

- DaVita, NRAA, and RPA stated that the use of telehealth by physicians to manage the care of dialysis patients could facilitate the use of home dialysis. We noted in the report that certain visits for managing in-center patients can be provided via telehealth. CMS has established a process for identifying other services—such as managing home patients—that could be provided via telehealth under Medicare, and examining this process was beyond the scope of this report.
- HDU, NRAA, and RPA stressed the importance of patient-centered dialysis care and of ensuring that patients have sufficient information to make informed decisions on the type of dialysis. We agree that

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patient preferences and patient education are central to decisions regarding the type of dialysis and have described these and other factors that could affect these decisions.

- DaVita and RPA stressed the impact of the ongoing shortage of peritoneal dialysis solution. In particular, DaVita said the shortage is the biggest barrier to the use of home dialysis. We agree that this shortage could have a long-term impact on the use of home dialysis and revised the report to incorporate this perspective.
- DaVita and HDU asserted that Medicare's method of paying for dialysis care separately from other services, such as inpatient care, could affect incentives for providing home dialysis. For example, DaVita suggested that the incentive to provide home hemodialysis could increase if a single entity were financially responsible for all Medicare services provided to a Medicare patient. This incentive could increase because, according to DaVita, the cost of inpatient care may be lower for home hemodialysis patients than for in-center hemodialysis patients. We agree that choosing one type of dialysis over another could affect the use of other types of Medicare services, but examining such implications was beyond the scope of this report.
- NRAA and RPA appreciated that our report addressed the role of nephrology training programs in the use of home dialysis, and both groups said that we or CMS should further examine how physicians can receive greater exposure to home dialysis through these programs. RPA said that this examination could also address the role of Medicare payments for graduate medical education. While we acknowledge the importance of these issues, further examination of them was beyond the scope of our report.

In addition to the comments described above, the patient and industry groups provided technical comments on the draft, which we incorporated as appropriate.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health & Human Services and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

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If you or your staff have any questions about this report, please contact me at (202) 512-7114, or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of our report. GAO staff who made key contributions to this report are listed in appendix III.

A handwritten signature in black ink, appearing to read 'James Cosgrove', written in a cursive style.

James Cosgrove  
Director, Health Care

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# Appendix I: Data and Methods for Analysis of Facilities' Medicare Margins

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This appendix describes the data and methods we used for our analysis of Medicare margins, which was part of our effort to examine incentives associated with Medicare payments to dialysis facilities.

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## Medicare Cost Report Data

We analyzed Medicare cost report data for 2012 from freestanding facilities located in the 50 states and the District of Columbia. We took steps to restrict our analysis to data from facilities with similar cost and payment structures. We did not include hospital-based facilities in our analysis because these facilities' reported costs may be driven in part by hospitals' methods for allocating overhead costs within these hospitals rather than by the costs of the dialysis facility itself.<sup>1</sup> Because of possible differences in cost structures, we excluded facilities that (1) provided any pediatric or intermittent peritoneal dialysis treatments, (2) were government-owned, or (3) had cost reporting periods not equal to calendar year 2012, which generally occurred when facilities changed ownership, opened, closed, or changed Medicare status during the year. Because of possible differences in payment structures, we also limited our analysis to facilities that elected to be paid fully under the bundled payment system. Implementing these steps resulted in the exclusion of approximately 19 to 20 percent of the 5,380 freestanding facilities originally in the cost report data set.

We also took several steps to assess the reliability of facilities' cost report data on total costs, total Medicare payments, and the number of dialysis treatments provided. In particular, we checked for and excluded facilities with internal inconsistencies among variables such as reporting that they provided more treatments to Medicare patients than to Medicare and non-Medicare patients combined or reporting negative treatment numbers. In addition, we excluded facilities that reported unusually high or low average costs or average Medicare payments, which may be indicative of

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<sup>1</sup>In 2012, 91 percent of dialysis facilities were freestanding and 9 percent were hospital-based.

data entry errors.<sup>2</sup> Finally, we compared the number of Medicare-covered treatments reported on the cost reports to similar data from Medicare claims on the number of paid treatments, and we excluded facilities with inconsistencies.<sup>3</sup> Implementing these steps to assess the reliability of the data resulted in the exclusion of an additional approximately 8 to 9 percent of the 5,380 freestanding facilities originally in the cost report data set, leaving 3,891 (72 percent) of these facilities in our analysis. We focused our analysis primarily on the 1,569 of these 3,891 freestanding facilities that provided home dialysis (defined as either home hemodialysis and/or peritoneal dialysis) to Medicare dialysis patients in 2012. We determined that the data on total costs, total Medicare payments, and number of dialysis treatments provided were sufficiently reliable for the purposes of our analysis.

## Calculating Average Medicare Margins

Using the Medicare cost report data described above, we calculated each facility's Medicare margin. First, we estimated the costs each facility incurred to provide dialysis to Medicare patients. The cost reports do not differentiate between costs for Medicare and non-Medicare patients, so we estimated Medicare costs by multiplying total costs by the proportion of all dialysis treatments that were provided to Medicare patients. We then calculated each facility's Medicare margin as follows:

$$\frac{(\text{Medicare payments} - \text{Estimated Medicare costs})}{\text{Medicare payments}}$$

<sup>2</sup>We excluded outlier values using the outer fence method, which involved first calculating the difference between the 25th and 75th percentiles for the average cost per treatment and for the average Medicare payment per treatment. We then excluded facilities with an average cost per treatment or average Medicare payment per treatment that was above the 75th percentile plus three times that difference or that was below the 25th percentile minus three times that difference. As a result, we excluded 124 facilities (2 percent of the 5,380 freestanding facilities originally in the cost report data set) that reported an average cost per treatment above \$413 or below \$78 (the median was \$243) or that reported an average Medicare payment per treatment above \$323 or below \$173 (the median was \$247). This method is similar to the one used by CMS when developing the bundled payment system. See U.S. Department of Health and Human Services, *Report to Congress: A Design for a Bundled End Stage Renal Disease Prospective Payment System* (2008).

<sup>3</sup>We excluded 234 facilities (4 percent of the 5,380 freestanding facilities originally in the cost report data set) where the number and, if applicable, the proportion of treatments were inconsistent between what the facilities reported and the claims data on the number of paid treatments. We did these comparisons across all types of dialysis and for the different types of dialysis.

We calculated the Medicare margin for all facilities that provided home dialysis. (See table 3.) When calculating the average margin for facilities in our analysis, we weighted the average by the total number of Medicare-covered patient years of dialysis.<sup>4</sup> We classified facilities as small or large based on whether their number of Medicare patient years was below or above the median number of patient years among the facilities in our analysis that provided home dialysis.

**Table 3: Medicare Margins of Facilities That Provided Home Dialysis, 2012**

Facility characteristic	SubCharacteristic	Number of facilities	Average Medicare margin (percentage)
Type of dialysis	Only peritoneal dialysis	41	14.14
	Only home hemodialysis	9	-14.38
	Mix of types of dialysis	1,519	4.21
Size of facilities <sup>a</sup>	Small	785	-3.49
	Large	784	7.21
Location of facilities	Urban	1,291	5.02
	Rural	278	-0.74
Affiliation of facilities	Affiliated with large dialysis facility chain	1,342	3.67
	Not affiliated with large dialysis facility chain	227	7.21
<b>All facilities that provided home dialysis</b>		<b>1,569</b>	<b>4.20<sup>b</sup></b>
<b>All facilities in our analysis, including those that did not provide home dialysis</b>		<b>3,891</b>	<b>4.00<sup>b</sup></b>

Source: GAO analysis of CMS data. | GAO-16-125

Notes: Analysis is based on 2012 Medicare cost reports from 3,891 freestanding dialysis facilities, including 1,569 that provided home dialysis, defined as either home hemodialysis and/or peritoneal dialysis.

Medicare margins are weighted by facilities' Medicare patient years. A patient year of treatment is equal to about 156 hemodialysis treatments or 365 days of peritoneal dialysis treatment.

<sup>a</sup>Facilities are classified as small or large based on whether their number of Medicare patient years was below or above the median number of patient years among the facilities in our analysis.

<sup>b</sup>The difference in margins between facilities that provide home dialysis and those that do not may be result of multiple factors and may be unrelated to the provision of home dialysis.

<sup>4</sup>A patient year of treatment is equal to about 156 hemodialysis treatments or 365 days of peritoneal dialysis treatment.

**Estimating How Facilities' Medicare Margins Are Associated with Home and In-center Hemodialysis**

To examine incentives associated with each type of dialysis, we used multiple linear regression analysis to estimate the extent to which adding a patient year of peritoneal dialysis, home hemodialysis, and in-center hemodialysis was associated with an increase or decrease in facilities' Medicare margins. The explanatory variables of our regression model included, for each type of dialysis, a binary variable for whether or not the facility provided that type of dialysis and a continuous variable with the number of patient years for that type of dialysis. To control for other factors that could affect a facility's Medicare margin, our model also included binary variables for whether or not the facility was located in an urban area or whether or not the facility was affiliated with a large dialysis facility chain. See table 4 for more information about the characteristics included in the model.

**Table 4: Characteristics of Facilities That Provided Home Dialysis, 2012**

Facility characteristic	SubCharacteristic	Size of facilities <sup>a</sup>		
		All facilities (N=1,569)	Small (N=785)	Large (N=784)
Whether facility provides each type of dialysis (%)	Peritoneal dialysis	95%	95%	95%
	Home hemodialysis	42%	36%	47%
	In-center hemodialysis	94%	89%	99%
Number of Medicare patient years (average)	Peritoneal dialysis	8.8	5.5	12.1
	Home hemodialysis	2.5	1.4	3.5
	In-center hemodialysis	48.5	26.8	70.3
Location of facility in urban area (%)	NA	82%	77%	88%
Affiliation of facility with large dialysis facility chain (%)	NA	86%	84%	87%

Source: GAO analysis of CMS data. | GAO-16-125

Notes: Analysis is based on 2012 Medicare cost reports from 1,569 freestanding dialysis facilities that provided home dialysis, defined as either home hemodialysis and/or peritoneal dialysis.

A patient year of treatment is equal to about 156 hemodialysis treatments or 365 days of peritoneal dialysis treatment.

<sup>a</sup>Facilities are classified as small or large based on whether their number of Medicare patient years was below or above the median number of patient years among the facilities in our analysis.

As shown in table 5 and discussed further in the report, the results of our regression model show the effect on facilities' Medicare margin from adding one patient year of a given type of dialysis.

**Table 5: Estimated Effects of Characteristics on Medicare Margins for Facilities That Provided Home Dialysis, 2012**

Facility characteristic	Subcharacteristic	Size of facilities <sup>a</sup>		
		All facilities (N=1,569)	Small (N=785)	Large (N=784)
Coefficient estimate for intercept (Prob >  t )	na	-0.74 (0.79)	-10.51 (0.01)	-1.13 (0.84)
Coefficient estimate for whether facility provides each type of dialysis (Prob >  t )	Peritoneal dialysis	3.16 (0.05)	4.39 (0.09)	2.32 (0.24)
	Home hemodialysis	-0.99 (0.14)	-0.83 (0.51)	-1.90 (0.02)
	In-center hemodialysis	-9.98 (<.0001)	-24.46 (<.0001)	-0.04 (0.99)
Coefficient estimate for number of Medicare patient years (Prob >  t )	Peritoneal dialysis	0.08 (0.01)	0.48 (<.0001)	0.04 (0.20)
	Home hemodialysis	-0.04 (0.17)	0.22 (0.24)	-0.03 (0.33)
	In-center hemodialysis	0.15 (<.0001)	0.71 (<.0001)	0.08 (<.0001)
Coefficient estimate for location in urban area (Prob >  t )	Na	3.93 (<.0001)	1.99 (0.11)	3.76 (0.00)
Coefficient estimate for affiliation with large dialysis facility chain (Prob >  t )	na	-2.26 (0.01)	-0.95 (0.50)	-3.35 (0.00)
Adjusted R-square	na	0.19	0.23	0.10

Source: GAO analysis of CMS data. | GAO-16-125

Notes: Analysis is based on 2012 Medicare cost reports from 1,569 freestanding dialysis facilities that provided home dialysis, defined as either home hemodialysis and/or peritoneal dialysis.

A patient year of treatment is equal to about 156 hemodialysis treatments or 365 days of peritoneal dialysis treatment.

<sup>a</sup>Facilities are classified as small or large based on whether their number of Medicare patient years was below or above the median number of patient years among the facilities in our analysis.

# Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

SEP 21 2015

James Cosgrove  
Director, Natural Resources and Environment  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis" (GAO-15-751).

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

Sincerely,

A handwritten signature in cursive script that reads "Jim R. Esquea".

Jim R. Esquea  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: END-STAGE RENAL DISEASE: MEDICARE PAYMENT REFINEMENTS COULD PROMOTE INCREASED USE OF HOME DIALYSIS (GAO-15-751)**

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the GAO's draft report. HHS is committed to moving our health care system to one that values quality over quantity and focuses on reforms to align payments with better outcomes.

HHS has established a goal of fostering patient independence through greater use of home dialysis among End-Stage Renal Disease (ESRD) patients for whom it is appropriate. Since moving to the ESRD Prospective Payment System in 2011, there has been an increase in utilization of home dialysis modalities.

The ESRD Quality Incentive Program ties Medicare payments directly to dialysis facility performance on quality measures, resulting in better care at lower cost for over 503,000 Medicare beneficiaries with ESRD. In addition, the Centers for Medicare and Medicaid Innovation announced in 2013 that they will test a new Comprehensive ESRD Care model. Through the Comprehensive ESRD Care initiative, CMS will partner with health care providers and suppliers to test the effectiveness of a new payment and service delivery model in providing beneficiaries with patient-centered, high-quality care.

On June 26, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that will update payment policies and rates under the ESRD Prospective Payment System (PPS) for renal dialysis services furnished to beneficiaries for 2016. This rule also proposes new quality and performance measures to improve the quality of care by dialysis facilities treating patients with end-stage renal disease.

**GAO Recommendation**

To determine the extent to which Medicare payments are aligned with costs for specific types of dialysis treatment and training, the Administrator of CMS should take steps to improve the reliability of the cost report data for treatment and training associated with specific types of dialysis.

**HHS Response**

HHS concurs with GAO's recommendation. HHS is willing to consider reasonable modifications to the cost report that could improve the reliability of cost report data. In addition, HHS is conducting ESRD cost report audits required by section 217(e) of the Protecting Access to Medicare Act of 2014 that will review a representative sample of dialysis facilities' cost report data for 2012.

**GAO Recommendation**

The Administrator of CMS should examine Medicare policies for monthly payments to physicians to manage the care of dialysis patients and revise them if necessary to ensure that these policies are consistent with CMS's goals of encouraging the use of home dialysis among patients for whom it is appropriate.

**HHS Response**

HHS concurs with GAO's recommendation. HHS will prioritize the review of the payment rates for monthly capitation payment (MCP) services under the misvalued code initiative so that the relative

resource costs of the services are accurately considered under Physician Fee Schedule payment methodologies. As noted in the report, HHS recently revised payment rules for greater consistency between facility-based and home dialysis MCP services under partial month scenarios.

**GAO Recommendation**

To ensure that patients with chronic kidney disease receive objective and timely education related to this condition, the Administrator of CMS should examine the Kidney Disease Education benefit and, if appropriate, seek legislation to revise the categories of providers and patients eligible for the benefit.

**HHS Response**

HHS non-concurs with GAO's recommendation. CMS continuously works to make appropriate payments for ESRD services and must prioritize activities to improve care for ESRD patients. The Fiscal Year 2016 President's budget does not include a proposal to revise the categories of providers and patients eligible for Kidney Disease Education.

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# Appendix III: GAO Contact and Staff Acknowledgments

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## GAO Contact

James Cosgrove, (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov)

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## Staff Acknowledgments

In addition to the contact named above, William Black, Assistant Director; George Bogart; Andy Johnson; Corissa Kiyon; Hannah Marston Minter; Richard Lipinski; Elizabeth T. Morrison; Vikki Porter; and Eric Wedum made key contributions to this report.

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# Appendix IV: Accessible Data

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## Agency Comment Letter

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Text of Appendix II:  
Comments from the  
Department of Health and  
Human Services

Page 1

SEP 21, 2015

James Cosgrove

Director, Natural Resources and Environment

U.S. Government Accountability Office 441 G Street NW

Washington, DC 20548

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Sincerely,

Assistant Secretary for Legislation

Attachment

Page 2

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: END-STAGE RENAL DISEASE: MEDICARE PAYMENT REFINEMENTS

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COULD PROMOTE INCREASED USE OF HOME DIAALYSIS (GAO-15-751)

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**GAO Recommendation**

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**HHS Response**

HHS concurs with GAO's recommendation. HHS will prioritize the review of the payment rates for monthly capitation payment (MCP) services under the misvalued code initiative so that the relative

Page 3

resource costs of the services are accurately considered under Physician Fee Schedule payment methodologies. As noted in the report, HHS recently revised payment rules for greater consistency between facility-based and home dialysis MCP services under partial month scenarios.

**GAO Recommendation**

To ensure that patients with chronic kidney disease receive objective and timely education related to this condition, the Administrator of CMS should examine the Kidney Disease Education benefit and, if appropriate, seek legislation to revise the categories of providers and patients eligible for the benefit.

**HHS Response**

HHS non-concurs with GAO's recommendation. CMS continuously works to make appropriate payments for ESRD services and must prioritize activities to improve care for ESRD patients. The Fiscal Year 2016 President's budget does not include a proposal to revise the categories of providers and patients eligible for Kidney Disease Education.

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## Public Affairs

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