

March 2011

# END-STAGE RENAL DISEASE

## CMS Should Assess Adequacy of Payment When Certain Oral Drugs Are Included and Ensure Availability of Quality Monitoring Data



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## Why GAO Did This Study

For most individuals with end-stage renal disease (ESRD), Medicare purchases a bundle of dialysis-related services using a single payment. In 2014, the Centers for Medicare & Medicaid Services (CMS) plans to include in this bundled payment “oral-only” ESRD drugs used to treat mineral and bone disorder. Currently, Medicare generally pays for these drugs only if the beneficiary has Part D prescription drug coverage. This report (1) describes the rationales for including oral-only ESRD drugs in the bundled payment, (2) examines dialysis organizations’ recent experience providing oral-only ESRD drugs and their future ability to provide these drugs, (3) examines the data sources that CMS could use to account for oral-only ESRD drugs in the bundled payment, and (4) examines CMS’s ability to monitor treatment of mineral and bone disorder. GAO interviewed CMS officials, experts in mineral and bone disorder, and representatives of 4 large and 16 small dialysis organizations. GAO also reviewed ESRD payment regulations, related reports, clinical guidelines, and state pharmacy licensure requirements in 10 selected states.

## What GAO Recommends

GAO recommends that CMS assess payment adequacy when oral-only ESRD drugs are included in the bundled payment and ensure availability of reliable data for monitoring treatment of mineral and bone disorder. CMS agreed with GAO’s recommendations.

View [GAO-11-365](#) or key components. For more information, contact James C. Cosgrove at (202) 512-7114 or [cosgrovej@gao.gov](mailto:cosgrovej@gao.gov).

## END-STAGE RENAL DISEASE

### CMS Should Assess Adequacy of Payment When Certain Oral Drugs Are Included and Ensure Availability of Quality Monitoring Data

## What GAO Found

There are three key reasons for including oral-only ESRD drugs in the bundled payment for dialysis care. First, including these drugs could promote more efficient dialysis care, because organizations that provide this care receive a fixed payment and gain financially to the extent they reduce their costs for the items and services included in the bundle. Second, including the oral-only ESRD drugs could promote clinically appropriate care. Currently, dialysis organizations gain financially if beneficiaries receive oral-only ESRD drugs instead of drugs that are in the bundle because this reduces costs without reducing the payment these organizations receive. Including oral-only ESRD drugs in the bundle would remove financial incentives under the payment system to use certain drugs over others. Finally, including oral-only ESRD drugs in the bundled payment could improve access to these drugs for certain beneficiaries, such as those who currently lack separate prescription drug coverage for these drugs.

Three of the 4 large dialysis organizations interviewed by GAO reported that they provided oral-only ESRD drugs to some of the beneficiaries they served in 2010. In contrast, all of the 16 small dialysis organizations that GAO interviewed reported that they did not provide these drugs in 2010. Regardless of their recent experience providing oral-only ESRD drugs, the large and small organizations GAO interviewed identified issues that could affect their ability to provide these drugs in 2014. For example, most organizations expressed concern about whether the bundled payment for dialysis care would adequately cover the costs of providing oral-only ESRD drugs.

To account for oral-only ESRD drugs in the payment bundle in 2014, CMS officials noted that they would be limited to using data on payments for these drugs under Medicare Part D. However, these data may understate the costs that dialysis organizations would incur to provide these drugs, in part, because Medicare currently pays for these drugs primarily for those beneficiaries with Part D coverage. Although CMS does not know whether the bundled payment in 2014 will be sufficient to cover the costs that efficient dialysis organizations would incur to provide the entire bundle of dialysis-related items and services, a potential underestimate of the total cost to provide oral-only ESRD drugs raises questions about payment adequacy beginning in 2014. GAO and others have stated that inadequate payments could lead to access and quality of care issues for beneficiaries on dialysis.

CMS is developing new, consensus-based measures that it could use to monitor treatment of mineral and bone disorder. CMS is also developing a new Web-based system to collect data for such measures. However, full implementation of this new system has been delayed repeatedly, and dialysis organizations and others GAO interviewed expressed concern about the reliability of data collected using this system. Recognizing the importance of timely and reliable quality monitoring under bundled payment systems, CMS officials told GAO that they intend to collect data using an alternative mechanism in 2011.

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## Abbreviations

AAKP	American Association of Kidney Patients
AKF	American Kidney Fund
CKD-MBD	chronic kidney disease-mineral and bone disorder
CMS	Centers for Medicare & Medicaid Services
CPM	Clinical Performance Measure
CROWNWeb	Consolidated Renal Operations in a Web-Enabled Network
ESRD	end-stage renal disease
KCC	Kidney Care Council
KDIGO	Kidney Disease: Improving Global Outcomes
K/DOQI	Kidney Disease Outcomes Quality Initiative
MedPAC	Medicare Payment Advisory Commission
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
NKF	Nation Kidney Foundation
NQF	National Quality Forum
NRAA	National Renal Administrators Association
PDP	prescription drug plan
PPACA	Patient Protection and Affordable Care Act
PTH	parathyroid hormone
QIP	Quality Incentive Program
RPA	Renal Physicians Association
USRDS	United States Renal Data System

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United States Government Accountability Office  
Washington, DC 20548

March 23, 2011

### Congressional Committees

Regardless of age, most individuals with end-stage renal disease (ESRD), a condition of permanent kidney failure, are eligible for health care coverage under Medicare.<sup>1,2</sup> Since the implementation of Medicare's ESRD benefit in 1973, hundreds of thousands of lives have been extended through Medicare-covered dialysis treatment—a process that removes excess fluids and toxins from the bloodstream. According to the Centers for Medicare & Medicaid Services (CMS), the agency within the Department of Health and Human Services that administers Medicare, in 2007, Medicare spent about \$9.2 billion on dialysis treatment and related items and services for approximately 329,000 beneficiaries on dialysis.<sup>3</sup>

Medicare pays dialysis organizations<sup>4</sup> a single rate for providing dialysis treatment and certain related items and services, which is a common form of Medicare payment known as bundling. Medicare pays the bundled rate per dialysis treatment—generally for three treatments per week. Effective

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<sup>1</sup>Medicare coverage generally begins in the fourth month after patients start dialysis. For individuals who have employer group coverage, Medicare is the secondary payer for the first 30 months of Medicare entitlement, after which Medicare becomes the primary payer. 42 U.S.C. § 1395y(b)(1)(C).

<sup>2</sup>Most individuals diagnosed with ESRD are eligible to receive Medicare benefits under Medicare Part A, Part B, and Part D. 42 U.S.C. §§ 426-1, 1395w-101(a)(3)(A). Medicare Part A covers inpatient hospital, skilled nursing facility, and hospice care, as well as some home health care, and generally does not require a monthly premium. In addition, individuals diagnosed with ESRD who choose to enroll in Medicare Part B and/or 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.

<sup>3</sup>The expenditures we report include beneficiary cost-sharing amounts. The \$9.2 billion that Medicare spent on dialysis treatment and related items and services in 2007 includes about \$8.8 billion in Medicare Part B spending in addition to about \$0.4 billion that Medicare spent under Part D for certain oral ESRD drugs. CMS was unable to provide us with data that were more recent than 2007.

<sup>4</sup>For purposes of this report, we define a dialysis organization as an organization that owns at least one facility that provides dialysis services. The dialysis industry is very concentrated, with many facilities owned and operated by a few organizations. For example, about 61 percent of the approximately 5,600 dialysis facilities are owned by three large organizations.

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January 1, 2011, the bundled payment for dialysis care expanded to include payment for some additional items and services.<sup>5</sup> As a result, the bundled payment covers the following under Medicare Part B: (1) dialysis treatment and associated routine services, such as nursing, equipment, supplies, and ESRD-related laboratory tests; (2) injectable drugs used to treat complications related to ESRD; and (3) oral ESRD drugs that have injectable equivalents.<sup>6</sup>

This payment change was consistent with our previous recommendation that the bundled payment for dialysis care be expanded to include all ESRD services in order to improve efficiency and remove financial incentives to provide more injectable ESRD drugs than necessary.<sup>7</sup> However in a subsequent report, we noted that bundled payment systems may give providers an incentive to underserve the most costly beneficiaries to avoid financial losses.<sup>8</sup> We emphasized that beneficiaries on dialysis are particularly vulnerable to any disruptions in care because of their need for life-sustaining dialysis. As a result, we recommended that CMS monitor access to and quality of dialysis care to identify any adverse effects of this payment system change on beneficiaries.

The current Medicare bundled payment for dialysis care covers most, but not all, of the items and services typically provided to dialysis patients. In particular, this bundled payment does not include oral ESRD drugs that do not have injectable equivalents, which consist of two classes of drugs—calcimimetics and phosphate binders—and are used to treat a complication of ESRD known as mineral and bone disorder. CMS plans to include oral-only ESRD drugs in the bundled payment for dialysis care

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<sup>5</sup>Throughout this report, we use the term bundled payment for dialysis care to refer to the base bundled payment rate to which CMS has not made any adjustments to account for factors such as beneficiary characteristics that are associated with the cost of dialysis care.

<sup>6</sup>Prior to January 2011, Medicare's bundled payment for dialysis care covered dialysis treatment and certain associated routine services. Injectable ESRD drugs were paid for separately under Part B, and oral ESRD drugs were generally covered under Part D. Dialysis organizations have the option of transitioning to the current payment system over 4 years by being paid through a combination of the previous and current payment systems.

<sup>7</sup>See GAO, *End-Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility*, [GAO-07-77](#) (Washington, D.C.: Nov. 13, 2006).

<sup>8</sup>See GAO, *End-Stage Renal Disease: CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System*, [GAO-10-295](#) (Washington, D.C.: Mar. 31, 2010).

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beginning in 2014.<sup>9,10</sup> At that time, dialysis organizations will be responsible for providing these drugs to beneficiaries.

The Patient Protection and Affordable Care Act (PPACA) requires us to examine issues associated with including oral-only ESRD drugs in Medicare's bundled payment for dialysis care.<sup>11</sup> As discussed with the committees of jurisdiction, this report: (1) describes the rationales for including oral-only ESRD drugs in the bundled payment for dialysis care, (2) examines dialysis organizations' recent experience with providing oral-only ESRD drugs and their ability to provide these drugs under the bundled payment system, (3) examines the data sources that CMS could use to account for oral-only ESRD drugs in the bundled payment system, and (4) examines CMS's ability to monitor treatment of mineral and bone disorder under the bundled payment system.

To describe the rationales for including oral-only ESRD drugs in the bundled payment for dialysis care, we conducted interviews with CMS officials responsible for the design of the payment system as well as experts on treatment of mineral and bone disorder. In addition, we reviewed CMS's recently published proposed and final rules for the current bundled payment system in order to understand the payment system's design. We also reviewed related reports by the Medicare Payment Advisory Commission (MedPAC) and others as well as the clinical literature on dialysis and oral-only ESRD drugs.

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<sup>9</sup>CMS, in the preamble to the proposed rule for the current ESRD prospective payment system, included oral-only ESRD drugs in the bundled payment for dialysis care. *Medicare Program; End-Stage Renal Disease Prospective Payment System*, 74 *Fed. Reg.* 49,922, 49,941 (proposed Sept. 29, 2009). In the preamble to the final rule for the ESRD prospective payment system, CMS noted its decision to delay the inclusion of these drugs until 2014. CMS's decision was due in part to allow dialysis organizations additional time to develop the necessary arrangements or infrastructure to provide oral-only ESRD drugs and negotiate prices with drug manufacturers and pharmacies. In addition, CMS needed additional time to thoroughly educate beneficiaries, dialysis organizations, and pharmacies on aspects of the bundled payment system involving the provision of oral-only ESRD drugs. *Medicare Program; End-Stage Renal Disease Prospective Payment System*, 75 *Fed. Reg.* 49,030, 49,044 (Aug. 12, 2010).

<sup>10</sup>For purposes of this report, we use the term bundled payment system for dialysis care to refer to the Medicare Part B ESRD Prospective Payment System.

<sup>11</sup>Pub. L. No. 111-148, § 10336, 124 Stat. 119, 974.

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To examine dialysis organizations' recent experience with providing oral-only ESRD drugs and their ability to provide these drugs under the bundled payment system, we conducted semistructured interviews with representatives from 20 dialysis organizations—4 large and 16 small organizations. We selected the 4 large dialysis organizations because they owned the largest number of dialysis facilities nationwide. At the time of our study, these large dialysis organizations reported that they owned about 150 to 1,750 dialysis facilities and served about 12,400 to 130,500 dialysis patients. In addition, 3 of these organizations collectively owned about 61 percent of dialysis facilities and served about 63 percent of dialysis patients in 2008. We randomly selected the 16 small dialysis organizations from 10 states: California, Florida, Georgia, Illinois, New York, North Dakota, Ohio, Pennsylvania, Texas, and Utah.<sup>12</sup> These 10 states were located in all four census regions and accounted for about 50 percent of all beneficiaries on dialysis as of December 31, 2008. We selected the 16 small dialysis organizations based on data from Medicare's Dialysis Facility Compare database.<sup>13</sup> Each of these 16 small dialysis organizations contained 1 to 112 dialysis facilities and served 23 to about 6,200 dialysis patients.<sup>14</sup> We selected at least 2 small dialysis organizations from each of the 5 largest states in our review and 1 small organization from each of the other 5 states in our review. Seven of the 16 small dialysis organizations were hospital-based and 10 of these 16 small organizations owned at least 1 facility in an urban area.<sup>15</sup> The 16 small dialysis organizations in our review did not constitute a representative sample.

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<sup>12</sup>We selected 8 of these 10 states because they contained the most beneficiaries on dialysis. We selected the other 2 states—North Dakota and Utah—because large dialysis organizations in these states constituted the smallest portion of the dialysis market.

<sup>13</sup>Dialysis Facility Compare is a database on Medicare's Web site that allows users to compare dialysis facilities nationwide based on factors such as the types of services and quality of care provided.

<sup>14</sup>Dialysis facilities can be freestanding or hospital-based and for-profit or not-for-profit. In 2009, about 89 percent were freestanding and about 81 percent were for-profit. Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: March 2010).

<sup>15</sup>We defined hospital-based organizations as those where the organization was owned by a hospital. We defined urban areas as those areas that are classified either as Metropolitan Statistical Areas or Micropolitan Statistical Areas. Metropolitan Statistical Areas have at least one urbanized area with a population of 50,000 or more, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties. Micropolitan Statistical Areas have at least one urban cluster with a population of at least 10,000 but less than 50,000, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties.



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Because dialysis organizations likely would need to comply with state pharmacy licensure requirements to directly provide oral-only ESRD drugs, we reviewed these requirements in each of the 10 states we selected and interviewed state officials responsible for compliance with these requirements. We also conducted interviews with representatives of professional organizations and beneficiary advocacy organizations.

To examine the data sources that CMS could use to account for oral-only ESRD drugs in the bundled payment system, we conducted interviews with CMS officials responsible for designing this payment system. We also reviewed provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA),<sup>16</sup> which requires the implementation of the current bundled payment system, as well as CMS's proposed and final rules for this payment system. As part of this review, we analyzed the potential implications that these data sources could have on the extent to which payments will be adequate when CMS expands the bundled payment to include oral-only ESRD drugs.

To examine CMS's ability to monitor treatment of mineral and bone disorder under the bundled payment system, we reviewed relevant documentation from CMS and clinical practice guidelines for care related to the treatment of mineral and bone disorder. In addition, we conducted interviews with CMS officials responsible for the quality monitoring of dialysis care; nephrology clinicians with expertise in the treatment of mineral and bone disorder, including individuals who helped develop quality measures and guidelines for the treatment of this condition; representatives of dialysis organizations; and officials from organizations that represent nephrology clinicians, researchers, and beneficiaries on dialysis.

We conducted this performance audit from July 2010 through March 2011 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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<sup>16</sup>Pub. L. No. 110-275, § 153, 122 Stat. 2494, 2553 (codified at 42 U.S.C. § 1395rr).

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## Background

Treatment options for ESRD include kidney transplantation and dialysis.<sup>17</sup> Kidney transplants are not a practical option on a wide scale, as suitable donated organs are scarce. In contrast, dialysis is the treatment used by most beneficiaries with ESRD. Hemodialysis, the most common form of dialysis, is generally administered three times a week at facilities that provide these services.<sup>18,19</sup> During hemodialysis, a machine pumps blood through an artificial kidney and returns the cleansed blood to the body.

One common complication of ESRD is mineral and bone disorder, which can result in a variety of negative clinical conditions in ESRD patients, including weak and brittle bones and cardiovascular disease. Because mineral and bone disorder is associated with abnormal calcium, phosphorus, and parathyroid hormone (PTH) levels in the blood, treatment of mineral and bone disorder typically involves monitoring the levels of these substances in the blood and providing a combination of medications to control these levels.<sup>20</sup> The medications that are generally provided to treat mineral and bone disorder are vitamin D,<sup>21</sup> calcimimetics, and phosphate binders. Vitamin D and calcimimetics are used to help maintain normal levels of calcium and PTH, while phosphate binders are used to reduce excessive phosphorus levels. Vitamin D is generally administered intravenously, although a small number of patients—usually those who receive dialysis in their home—are treated with the oral form of

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<sup>17</sup>ESRD is the last of five stages of chronic kidney disease. Chronic kidney disease is typically observed as a gradual decline in kidney function.

<sup>18</sup>In 2008, approximately 93 percent of all dialysis patients underwent hemodialysis therapy. United States Renal Data System (USRDS), *USRDS 2010 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, 2010).

<sup>19</sup>Patients can also receive hemodialysis in their home, but only about 1 percent of all dialysis patients did so in 2008. Peritoneal dialysis is the other treatment method and generally occurs in the home. Peritoneal dialysis utilizes the peritoneal membrane, which surrounds the patient's abdomen, as a natural blood filter. Patients remove wastes and excess fluids from their abdomen manually throughout the day, or a machine automates the process while patients sleep at night. About 7 percent of all dialysis patients in 2008 received peritoneal dialysis. USRDS, *USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*.

<sup>20</sup>PTH is produced by the parathyroid glands, which are located in the neck. PTH controls calcium, phosphorus, and vitamin D levels within the blood and bone. High levels of PTH in the blood can lead to a condition known as secondary hyperparathyroidism.

<sup>21</sup>Throughout this report, we use the term vitamin D to refer to the active form of this vitamin, which is generally not available without a prescription. The nonactive form of vitamin D is available over the counter in the form of a dietary supplement.

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the drug. Calcimimetics and phosphate binders are available only in oral form.

Under the bundled payment system for dialysis care, dialysis organizations are responsible for providing injectable ESRD drugs as well as oral ESRD drugs with injectable equivalents.<sup>22</sup> Dialysis organization personnel typically administer injectable ESRD drugs to beneficiaries when they come in for their dialysis treatments. In contrast, dialysis organization personnel generally are not licensed to dispense oral ESRD drugs with injectable equivalents. As a result, dialysis organizations may operate or contract with a community or mail-order pharmacy to provide these drugs to beneficiaries.<sup>23</sup> Because dialysis organizations are not currently responsible for providing oral-only ESRD drugs under the bundled payment system for dialysis care, beneficiaries typically have coverage for these drugs through other sources, such as Medicare Part D prescription drug plans (PDP) and employer- or union-sponsored drug plans.

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## Medicare Payment for Dialysis Care

CMS implemented the bundled payment system for Medicare-covered dialysis care in 1983. CMS has also developed bundled payment systems for other Medicare-covered services in several settings, including inpatient hospitals, skilled nursing facilities, and home health agencies. When implementing a bundled payment system, CMS may determine what services will be covered under the bundle and what the payment rate to providers will be for those services. This rate is generally designed to cover the costs that an efficient provider would incur to provide the bundled services.<sup>24</sup>

As required by MIPPA, in January 2011, CMS made the most substantial change in Medicare's bundled payment for dialysis care since this bundled payment system was implemented in 1983—expanding the bundled

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<sup>22</sup>Dialysis organizations are responsible for providing bundled services such as ESRD drugs either directly to beneficiaries or through contracts with other entities.

<sup>23</sup>Mail-order pharmacies may send drugs to beneficiaries at their homes or dialysis facilities.

<sup>24</sup>MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: March 1999). The payment rate under bundled payment systems may be adjusted based on beneficiary characteristics and other factors associated with the cost of care, such as geographic differences in wages.

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payment to cover additional items and services. The bundled payment will be expanded further in 2014.

- **Prior to 2011**, Medicare's bundled payment covered dialysis treatment and certain associated items and services under Part B.<sup>25</sup> This bundled payment did not cover all dialysis-related items and services. Specifically, Medicare paid separately under Part B for injectable ESRD drugs.<sup>26</sup> In addition, for beneficiaries who were enrolled in Medicare Part D PDPs, Medicare covered oral ESRD drugs under Part D.<sup>27</sup>
- **For 2011 through 2013**, the bundled payment for dialysis care was expanded to cover, under Part B, additional dialysis-related items and services such as injectable ESRD drugs and oral ESRD drugs with injectable equivalents.<sup>28,29</sup> Medicare continues to cover oral-only ESRD drugs under Part D.

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<sup>25</sup>This bundled payment was referred to as the composite rate.

<sup>26</sup>These drugs were not covered under the bundled payment prior to 2011 because they were either not routine or not available when CMS first implemented the bundled payment system in 1983. Injectable ESRD drugs include erythropoiesis stimulating agents, injectable iron, and injectable vitamin D. Erythropoiesis stimulating agents and injectable iron are commonly used to treat anemia, a condition in which an insufficient number of red blood cells are available to carry oxygen throughout the body.

<sup>27</sup>Of the approximately \$9.2 billion in Medicare expenditures on dialysis care in 2007, dialysis treatment and other services covered under the bundled payment accounted for about 61.7 percent, injectable ESRD drugs accounted for about 29.2 percent, oral-only ESRD drugs accounted for about 4.8 percent, oral ESRD drugs with injectable equivalents accounted for about 0.1 percent, and other items and services accounted for the remaining 4.2 percent.

<sup>28</sup>The base bundled rate is \$229.63 in 2011 and is adjusted based on factors such as beneficiaries' characteristics such as age and comorbid conditions that are associated with the cost of dialysis care. Medicare pays amounts in addition to the bundled payment for beneficiaries whose dialysis care is unusually costly. Dialysis organizations may choose to transition to the new payment system over a 4-year phase-in period during which these organizations would be paid under a combination of the previous and current payment systems.

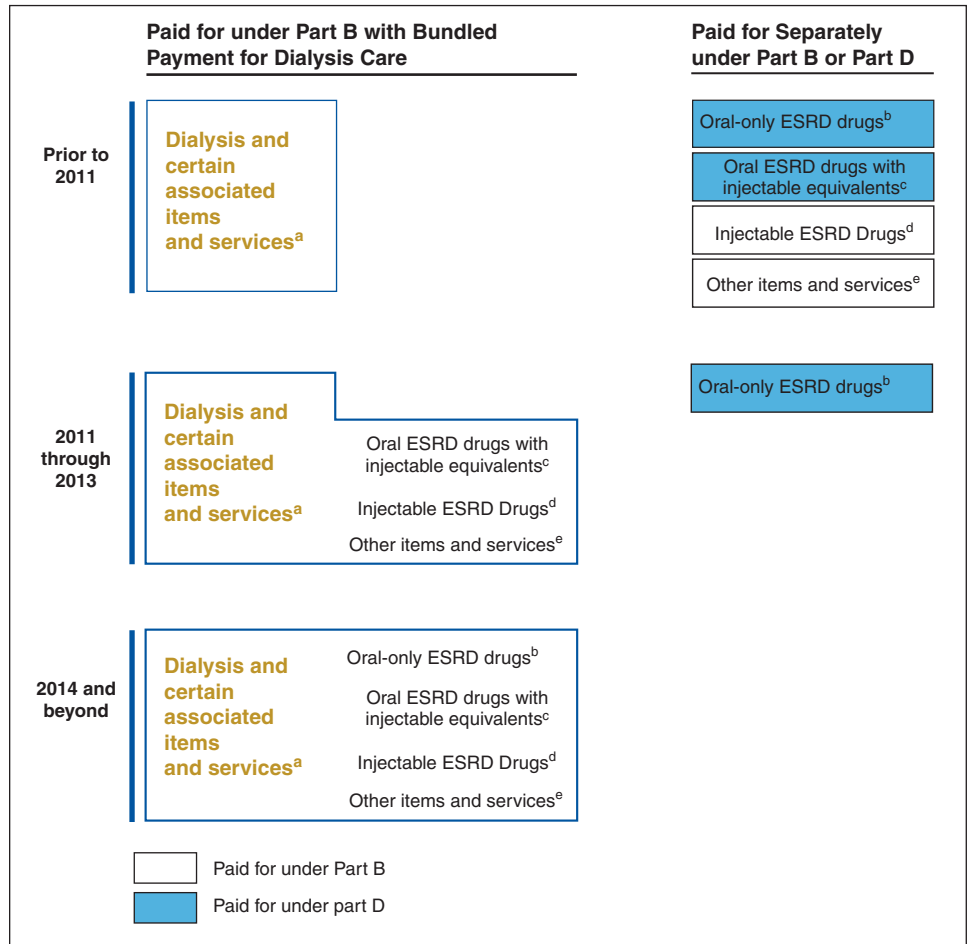
<sup>29</sup>The oral ESRD drugs with injectable equivalents that are currently covered under the bundled payment are oral vitamin D and levocarnitine.

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- **Beginning in 2014**, the bundled payment will be expanded again—this time to include coverage for oral-only ESRD drugs.<sup>30</sup> As a result, Medicare will begin paying for these drugs with the bundled payment under Part B rather than covering them under Part D. (See fig. 1 for a summary of changes over time in Medicare’s payment methods for dialysis and related items and services.)

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<sup>30</sup>The oral-only ESRD drugs that Medicare plans to cover under the bundled payment beginning in 2014 are calcimimetics and phosphate binders. *75 Fed. Reg.* at 49,042.

**Figure 1: Summary of Changes in Medicare Payment Methods through 2014 for Dialysis and Related Items and Services**



Source: Medicare Program: End-Stage Renal Disease Prospective Payment System, 75 Fed. Reg. 49,030 (Aug. 12, 2010).

<sup>a</sup>Dialysis and certain associated services include dialysis treatment and associated routine items and services, such as nursing, equipment, and supplies.

<sup>b</sup>Oral-only ESRD drugs consist of calcimimetics and phosphate binders.

<sup>c</sup>Oral ESRD drugs with injectable equivalents are oral vitamin D and oral levocarnitine (used to address a deficiency in carnitine, which helps the body produce energy).

<sup>d</sup>Injectable ESRD drugs include erythropoiesis stimulating agents, injectable iron, injectable vitamin D, and other injectable drugs such as levocarnitine and vancomycin (an antibiotic used for treatment of certain infections).

<sup>e</sup>Other items and services include, for example, medical equipment and ESRD-related laboratory tests.

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## Monitoring the Quality of Dialysis Care

In response to a provision in the Balanced Budget Act of 1997, which required CMS to develop a method to measure and report on the quality of dialysis care provided under the Medicare program, CMS developed the ESRD Clinical Performance Measures (CPM) Project.<sup>31-32</sup> Through the CPM Project, CMS develops quality measures for monitoring various aspects of dialysis care and collects data to support these quality measures. From 1999 through 2008, CMS's CPM Project collected data to support its quality measures annually using a random national sample of beneficiaries and a paper data collection form completed by dialysis facilities.<sup>33</sup> However, because CMS's CPM Project collected data for only a national sample of beneficiaries, CMS was limited to using these data to monitor the quality of dialysis care at the national level and not the facility level.

Due in part to the limited amount of data that CMS could collect through the paper data collection form, CMS has been developing a new Web-based data collection system—referred to as the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb). CROWNWeb is designed to collect data for all Medicare beneficiaries receiving dialysis care, rather than for a sample of beneficiaries, and to allow CMS to monitor the quality of dialysis care at both the national level and the facility level. In general, CMS plans for facilities that are part of large dialysis organizations participating in Medicare to transmit data for their patients from the organization's data management system to CROWNWeb

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<sup>31</sup>Pub. L. No. 105-33, § 4558(b) 111 Stat. 215, 463-64.

<sup>32</sup>State survey agencies also participate in monitoring the quality of dialysis care when they periodically evaluate dialysis organizations' adherence to Medicare's Conditions for Coverage for ESRD Facilities. The conditions for coverage are the minimum health and safety rules that dialysis facilities participating in Medicare must meet. 42 C.F.R. Part 494 (2010). In particular, the conditions for coverage direct dialysis facilities to develop, implement, and maintain an ongoing internal quality oversight program that focuses on indicators related to improved health outcomes. 42 C.F.R. § 494.110 (2010). In addition, as required, CMS plans to promote the quality of dialysis care by linking payments for dialysis care to performance beginning in 2012. *Medicare Program; End-Stage Renal Disease Quality Incentive Program*, 76 *Fed. Reg.* 628 (Jan. 5, 2011). This initiative, the Quality Incentive Program, will reduce payments to dialysis facilities by up to 2 percent if the care furnished by a facility does not meet certain quality standards established by CMS.

<sup>33</sup>Electronic data for some of the data elements were accepted from certain large dialysis organizations. These electronically submitted data were printed onto paper forms and these paper forms were sent to facilities to supply the data not already provided on the form.

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using an automated process—referred to as “batch” submission.<sup>34</sup> In contrast, CMS plans for facilities that are part of small dialysis organizations participating in Medicare to submit data for their patients to CROWNWeb by manually entering data via the Web.

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## Including Oral-Only ESRD Drugs in the Bundled Payment Could Promote Efficiency, Clinically Appropriate Care, and Access to These Drugs

There are three key reasons for including oral-only ESRD drugs in the bundled payment for dialysis care: to encourage more efficient care, to encourage more clinically appropriate care, and to increase access to these drugs for certain beneficiaries. As we and others have noted, bundling payments for items and services related to dialysis care is designed to give dialysis organizations an incentive to provide care more efficiently because organizations retain the difference if Medicare’s bundled payment exceeds the cost of providing such items and services.<sup>35</sup> Therefore, including oral-only ESRD drugs in the bundled payment for dialysis care could introduce an incentive for organizations to select the oral-only ESRD drugs and associated doses that lead to efficient dialysis care in order to increase the amount of money they retain from the bundled payment.<sup>36</sup>

Including oral-only ESRD drugs in the bundled payment for dialysis care could also promote clinically appropriate care by removing the financial incentive to use these drugs instead of drugs currently included in the bundled payment. Specifically, dialysis organizations are not responsible for the cost of phosphate binders and calcimimetics because these drugs currently are not included in the bundled payment for dialysis care. As a result, dialysis organizations gain financially if beneficiaries receive these drugs to treat mineral and bone disorder instead of drugs included in the

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<sup>34</sup>The batch submission process is currently in a pilot phase. Although the majority of data for large dialysis organizations that participate in this process is automatically transmitted to CROWNWeb, representatives from these organizations must manually enter certain data for their patients, such as demographic data.

<sup>35</sup>See, for example, GAO, *End-Stage Renal Disease: Bundling Medicare’s Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility*, [GAO-07-77](#) (Nov. 13, 2006); MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: March 2010); and 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>36</sup>Under the bundled payment system, CMS expects ESRD facilities will evaluate the potential use of less expensive yet equally effective ESRD items and services, where those alternatives are available and not contraindicated by the patient’s clinical status. *75 Fed. Reg.* at 49,041.



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bundled payment, such as vitamin D, even though doing so may not always represent the most clinically appropriate care. For example, two experts on treatment of mineral and bone disorder who we interviewed noted that this financial incentive under the current bundled payment system could lead to increased use of calcimimetics and decreased use of vitamin D to control beneficiaries' PTH levels. Although calcimimetics can be effective at lowering PTH levels, these drugs may not be appropriate for all beneficiaries and could result in adverse side effects for some beneficiaries.<sup>37</sup>

Finally, including oral-only ESRD drugs in the bundled payment for dialysis care could improve access to these drugs for certain beneficiaries, including beneficiaries who do not currently have prescription drug coverage and beneficiaries with Part D prescription drug coverage whose annual drug costs are within a certain range. Approximately 17 percent of all Medicare beneficiaries on dialysis did not have any prescription drug coverage in 2007.<sup>38</sup> Studies have shown that, due to the higher out-of-pocket drug costs they incur, individuals who lack prescription drug coverage are less likely to use prescription drugs than individuals with drug coverage.<sup>39</sup> Furthermore, beneficiaries on dialysis with standard drug coverage through Part D may be subject to increased cost sharing for oral-only ESRD drugs when these beneficiaries' total annual spending on all prescription drugs falls between \$2,840 and \$6,448—a coverage gap

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<sup>37</sup>See, for example, Official Journal of the International Society of Nephrology, *Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD)*, vol. 76, supplement 113 (August 2009); Piergiorgio Messa, et al., "The OPTIMA Study: Assessing a New Cinacalcet (Sensipar/Mimpara) Treatment Algorithm for Secondary Hyperparathyroidism," *The American Society of Nephrology* (2008); and Sharon M. Moe, et al., "Achieving NKF-K/DOQI Bone Metabolism and Disease Treatment Goals with Cinacalcet HCl," *Kidney International*, vol. 67 (2005).

<sup>38</sup>See Wendy St. Peter, et al., "Sources of Drug Coverage among Medicare Beneficiaries with End-Stage Renal Disease" (poster presented at the American Society of Nephrology Renal Week meeting, Denver, Colo., November 2010).

<sup>39</sup>See, for example, Laurie E. Felland and James D. Reschovsky, "More Nonelderly Americans Face Problems Affording Prescription Drugs," *Center for Studying Health System Change, Results from the Community Tracking Study*, no. 22 (January 2009); Yuriy Pylypchuk, "Adverse Selection and the Effect of Health Insurance on Utilization of Prescribed Medicine Among Patients with Chronic Conditions," *Advances in Health Economics and Health Services Research*, vol. 22 (2010); and Dana Gelb Safran, et al., "Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey," *Health Affairs* (2005).

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sometimes called the “doughnut hole.”<sup>40,41</sup> However, when oral-only ESRD drugs are included in the bundled payment, all beneficiaries on dialysis will be eligible for coverage for these drugs under Medicare Part B, and will not be subject to the Medicare Part D coverage gap for these drugs.

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## Most Large Dialysis Organizations Provided Oral-Only ESRD Drugs to Some Beneficiaries in 2010; Both Large and Small Organizations Identified Potential Issues with Providing These Drugs in 2014

Three of the 4 large dialysis organizations in our review reported that they provided oral-only ESRD drugs to some of the Medicare beneficiaries they served in 2010. In contrast, all 16 of the small dialysis organizations in our review reported that they did not provide these drugs to beneficiaries in 2010. Regardless of their experience with providing these drugs to beneficiaries, the large and small dialysis organizations in our review identified several issues that could affect their ability to provide these drugs to beneficiaries in 2014.

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<sup>40</sup>This total annual spending amount is calculated based on spending by the Part D PDP on behalf of the beneficiary as well as the beneficiary’s total out-of-pocket costs.

<sup>41</sup>In 2007, approximately 60 percent of Medicare beneficiaries with Part D coverage who were on dialysis reached the Part D coverage gap. See Wendy L. St. Peter, “Medication Trends in Dialysis Patients—Focus on Medicare Part D” (presentation at the American Society of Nephrology Renal Week meeting, Denver, Colo., November 2010). Prior to 2011, beneficiaries were responsible for 100 percent of the cost of drugs while they were subject to the coverage gap. Beginning in 2011, provisions in the health care reform law will gradually reduce the amount that Part D beneficiaries are required to pay for drugs while they are subject to the coverage gap by phasing in different levels of subsidies for these drugs. For example, in 2014, beneficiaries will be responsible for approximately 48 percent of the cost of brand-name drugs and 72 percent of the cost of generic drugs while they are subject to the coverage gap. By 2020, beneficiaries will be responsible for only 25 percent of the cost of both brand-name and generic drugs while they are subject to the coverage gap.

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### Three Large Dialysis Organizations Provided Oral-Only ESRD Drugs to Some Beneficiaries in 2010, While Small Organizations We Interviewed Did Not Provide These Drugs

The four large dialysis organizations in our review generally had some experience with providing oral-only ESRD drugs to Medicare beneficiaries. Specifically, three of the large dialysis organizations in our review reported that they provided oral drugs, including oral-only ESRD drugs, to some of their patients in 2010.<sup>42</sup> Representatives from these three large dialysis organizations explained that their organizations operated community or mail-order pharmacies and provided oral drugs to about 2 to 22 percent of their patients, including some Medicare beneficiaries who were enrolled in a Part D PDP. For example, representatives from one of these large dialysis organizations noted that their organization operated a mail-order pharmacy and provided oral drugs to about 26,000 of its 120,000 patients. These representatives told us that their dialysis organization's pharmacy typically mailed oral drugs to patients either at their homes or at dialysis facilities. The representatives also said that their dialysis organization's pharmacy promoted and monitored patients' adherence to their prescriptions by, among other things, sending reminders to patients when their prescriptions needed to be refilled and notifying clinicians when patients did not fill their prescriptions on schedule.

In contrast to most of the large dialysis organizations in our review, all 16 of the small dialysis organizations in our review reported that they did not provide oral-only ESRD drugs to Medicare beneficiaries in 2010. The National Renal Administrators Association (NRAA), a nonprofit organization that represents small dialysis organizations throughout the United States, also told us that small dialysis organizations generally did not provide oral-only ESRD drugs or any other oral drugs in 2010. However, small dialysis organizations—including those in our review—may have recently gained some experience with providing oral ESRD drugs that have injectable equivalents. Since January 2011, under the bundled payment system for dialysis care, all dialysis organizations—large and small—are responsible for providing oral ESRD drugs that have injectable equivalents to all of the Medicare beneficiaries they serve who need these drugs. However, the small dialysis organizations in our review generally noted that less than 2 percent of their patients had prescriptions

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<sup>42</sup>These three large dialysis organizations served about 63 percent of dialysis patients nationwide in 2008. USRDS, *USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*.

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for oral ESRD drugs that have injectable equivalents, while most of their patients had prescriptions for oral-only ESRD drugs.<sup>43,44</sup>

In addition to having different experiences with providing oral-only ESRD drugs to Medicare beneficiaries in 2010, the large and small dialysis organizations in our review generally reported that they were at different stages of planning for providing these drugs to beneficiaries in 2014. Specifically, the same 3 large dialysis organizations that provided oral-only ESRD drugs to some beneficiaries in 2010 reported that they had started planning for providing these drugs in 2014. Representatives from 2 of these 3 large dialysis organizations reported that their organizations planned to use their own mail-order pharmacies to provide these drugs to beneficiaries in 2014. The third large dialysis organization was still considering whether to use its own mail-order pharmacy or to contract with another mail-order pharmacy to provide these drugs to beneficiaries in 2014. In contrast, representatives from only 1 of the 16 small dialysis organizations in our review reported that their organization had plans for providing oral-only ESRD drugs to beneficiaries in 2014. Specifically, representatives from a small hospital-based dialysis organization reported that their organization planned to use the hospital's pharmacy to provide oral-only ESRD drugs to beneficiaries.<sup>45</sup>

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### Both Large and Small Dialysis Organizations Identified Several Issues That Could Affect Their Ability to Provide Oral-Only ESRD Drugs in 2014

Both the large and small dialysis organizations in our review identified several issues that could affect their ability to provide oral-only ESRD drugs in 2014. One issue that both the large and small dialysis organizations in our review generally expressed concern about was the uncertainty surrounding Medicare's bundled payment amount for dialysis care. Specifically, 3 of the 4 large dialysis organizations and 11 of the 16 small dialysis organizations in our review noted that they were concerned

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<sup>43</sup>Nine of the 16 small dialysis organizations in our review reported that less than 2 percent of their patients needed oral ESRD drugs with injectable equivalents. An additional 3 small organizations noted that from 5 to 15 percent of their patients needed these drugs. The other 4 small organizations in our review did not provide exact data on the percentage of their patients who needed these drugs.

<sup>44</sup>Nearly 80 percent of beneficiaries with ESRD enrolled in Medicare Part D PDPs in 2007 needed phosphate binders—a common oral-only ESRD drug. USRDS, *USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*.

<sup>45</sup>Five of the other six hospital-based small dialysis organizations in our review reported that their hospitals' pharmacies were not licensed to provide oral drugs to outpatients.

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about the extent to which the bundled payment for dialysis care would cover their costs of obtaining oral-only ESRD drugs and providing these drugs to beneficiaries. For example, representatives from 2 of the 20 dialysis organizations in our review indicated that, if the bundled payment amount for dialysis care was inadequate, beneficiaries might not receive certain high-cost oral-only ESRD drugs—even if these drugs were the most clinically effective. Additionally, experts on mineral and bone disorder noted that, to minimize costs, dialysis organizations could choose to increase their provision of calcium-based phosphate binders, which tend to be relatively inexpensive. However, the use of calcium-based phosphate binders could increase beneficiaries' blood calcium levels, which could have adverse clinical effects.<sup>46</sup> Furthermore, representatives from 2 of the small dialysis organizations in our review noted that the weaker purchasing power of small dialysis organizations relative to that of large dialysis organizations would make it difficult for them to negotiate competitive prices for oral-only ESRD drugs with drug manufacturers and pharmacies.

In addition to their concerns about payment adequacy, all 4 of the large dialysis organizations in our review told us that complying with different state pharmacy licensure requirements in multiple states could pose challenges. Similarly, 9 of the 16 small dialysis organizations in our review noted that the need to comply with these requirements would make it difficult for them to operate their own pharmacies. These requirements generally pertain to staffing, drug storage, security, and delivery. For example, all 10 states we selected for our review required that

1. a pharmacist be in charge of a pharmacy;<sup>47</sup>
2. a pharmacist supervise drug dispensing at a pharmacy;
3. a pharmacy meet drug storage standards, such as securely storing drugs in a designated space; and

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<sup>46</sup>See, for example, David J.A. Goldsmith and Adrian Covic, "Calcium and the Saga of the Binders: Accumulating Controversy, or Building Consensus?" *International Urology and Nephrology*, vol. 40 (December 2008); Goce B. Spasovski, "Bone Health and Vascular Calcification Relationships in Chronic Kidney Disease," *International Urology and Nephrology*, vol. 39 (December 2007); and Marcello Tonelli, Neesh Pannu, and Braden Manns, "Oral Phosphate Binders in Patients with Kidney Failure," *The New England Journal of Medicine*, vol. 362 (April 2010).

<sup>47</sup>Four of the 10 states in our review also required that a pharmacist work at only one pharmacy.

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4. a pharmacy follow security procedures, such as restricting access to a pharmacy when a pharmacist is off duty.

Representatives from the 3 large dialysis organizations that operated pharmacies in 2010 said that providing oral-only ESRD drugs to all of the Medicare beneficiaries they will serve in 2014 would be challenging. These representatives noted that complying with drug delivery requirements would be challenging because certain states prohibited particular drug delivery methods. For example, officials from the Board of Pharmacy in 2 states—Georgia and Ohio—told us that their states generally prohibited pharmacies in their states from mailing drugs to beneficiaries at dialysis facilities. Representatives from 1 of these 3 large dialysis organizations also noted that, although their dialysis organization operated a pharmacy, the pharmacy served only about 2 percent of the dialysis organization’s current patients and served patients in only 1 of the 27 states in which the dialysis organization operated. As a result, this dialysis organization would need to comply with the pharmacy licensure requirements of the other 26 states to provide oral-only ESRD drugs to the Medicare beneficiaries it will serve in these states. Furthermore, representatives from 9 of the small dialysis organizations in our review indicated that state pharmacy licensure requirements would make it difficult to operate their own pharmacies. Some of the representatives from these small dialysis organizations indicated that it would be more feasible for their dialysis organizations to contract with community or mail-order pharmacies to provide oral-only ESRD drugs to Medicare beneficiaries.

Another potential issue raised by all 4 of the large dialysis organizations and 11 of the 16 small dialysis organizations in our review was related to the need for additional resources to implement organizational changes associated with providing oral-only ESRD drugs to Medicare beneficiaries. Specifically, representatives from 1 of the large dialysis organizations and 5 of the small dialysis organizations in our review noted that their organizations may need to hire or train staff to, among other things, assist with the distribution of oral-only ESRD drugs to beneficiaries or monitor beneficiaries’ adherence to their prescriptions for these drugs. Additionally, representatives from all 4 of the large dialysis organizations and 3 of the 16 small dialysis organizations in our review indicated that their organizations may need to develop new systems for various purposes, such as billing or monitoring beneficiary adherence to prescriptions.

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Finally, some of the large and small dialysis organizations in our review identified other issues that could affect their ability to provide oral-only ESRD drugs to Medicare beneficiaries. For example, 2 of the 4 large dialysis organizations and 1 of the 16 small dialysis organizations in our review expressed concern that including oral-only ESRD drugs in the bundled payment for dialysis care could lead to additional fragmentation of care because beneficiaries would receive prescription drug coverage from multiple, unconnected sources.<sup>48</sup> Representatives from these dialysis organizations noted that, if beneficiaries obtain their oral-only ESRD drugs from their dialysis organizations but obtain their other prescription drugs from another source such as their Medicare Part D PDPs, then their PDPs could lack information on the oral-only ESRD drugs that these beneficiaries take. These representatives expressed concern that this lack of information could impair the ability of PDPs to identify potential negative drug interactions.

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## CMS Is Limited to Using Part D Data to Account for Oral-Only ESRD Drugs in the Bundled Payment; These Data May Understate Dialysis Organizations' Costs

According to CMS officials, CMS is limited to using data on payments under Medicare's Part D program to account for oral-only ESRD drugs in the bundled payment. In particular, CMS officials stated that federal law limits the agency to using data on payments under Medicare for dialysis and related items and services such as oral-only ESRD drugs in 2007, 2008, or 2009 to calculate the bundled payment for dialysis care. In addition, federal law limits the estimated total payments that CMS may use when implementing the new bundled payment system in 2011 to 98 percent of what total payments under Medicare would have been if the previous

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<sup>48</sup>A small percentage of beneficiaries may already experience fragmentation of care with regard to oral prescription drugs because oral ESRD drugs with injectable equivalents are currently included in the bundled payment. According to CMS, from 2007 through 2009 about 9 to 10 percent of ESRD beneficiaries who had Part D coverage received oral ESRD drugs with injectable equivalents. *75 Fed. Reg.* 49,030 (Aug. 12, 2010).

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system had remained in place.<sup>49,50</sup> CMS officials told us that they had identified two potential sources of data on payments under Medicare for oral-only ESRD drugs that they could use to account for these drugs in the bundled payment—payments for these drugs under Medicare’s Part D and Retiree Drug Subsidy programs.<sup>51</sup> Part D payment data represent PDP payments to pharmacies for each medication provided to beneficiaries, and these data also include information on beneficiary cost-sharing and the amounts beneficiaries paid for drugs while they were in the coverage gap.<sup>52</sup> Retiree Drug Subsidy data represent the total amounts that Medicare paid to groups such as employers or unions to subsidize the drug coverage of Medicare beneficiaries in these groups. However, CMS officials stated that it would not be feasible to use Retiree Drug Subsidy data because these data do not indicate which payments were for oral-only ESRD drugs for beneficiaries on dialysis.

Although CMS is limited to using data on payments under Part D for oral-only ESRD drugs to account for oral-only ESRD drugs in the bundled payment, certain aspects of these data suggest that the data on total payments under Part D for 2007 through 2009 may understate the costs that dialysis organizations would incur to provide these drugs. Specifically:

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<sup>49</sup>42 U.S.C. § 1395rr(b)(14). To make this determination, this provision requires that CMS use per-patient utilization data for 2007, 2008, or 2009, whichever year has the lowest per patient utilization. To calculate the bundled payment rate under the current bundled payment system for dialysis care, CMS (1) calculated the average payment per dialysis treatment based on total payments under Medicare Part B and Part D for dialysis and related items and services in the bundle and (2) adjusted this amount to account for changes between 2007 and 2011 in the prices of these items and services. *75 Fed. Reg.* at 49,074.

<sup>50</sup>According to CMS officials, MIPPA did not specify the data sources that CMS could use to account for changes in drug prices between the data collection year and the year in which the drugs would be included in the bundle.

<sup>51</sup>The Retiree Drug Subsidy program subsidizes drug coverage that is sponsored by groups such as employers or unions. Under this program, Medicare pays 28 percent of the allowable cost of drug coverage for beneficiaries in plans that are eligible to receive the subsidy. In 2007, Medicare made approximately \$3.8 billion in subsidy payments on behalf of about 16 percent of all Medicare beneficiaries.

<sup>52</sup>Medicare does not pay directly for prescription drugs for beneficiaries in Part D PDPs. Instead, Medicare pays these PDPs a single rate per beneficiary per month to subsidize the drug coverage of each beneficiary enrolled in Part D. Part D PDPs then pay pharmacies per prescription to provide a given drug to a beneficiary, and this amount includes the cost of the drug and of dispensing the medication.



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- **Part D data for 2007 through 2009 accounted for only about two-thirds of beneficiaries on dialysis.**<sup>53</sup> In 2007, for example, Part D payments for oral-only ESRD drugs for beneficiaries on dialysis with Part D coverage totaled about \$445 million; however, this amount did not include payments for oral-only ESRD drugs for the approximately one-third of beneficiaries on dialysis who lacked Part D coverage. Because it is unclear whether or to what extent beneficiaries with and without Part D coverage are comparable in their utilization of oral-only ESRD drugs, using Part D data to account for beneficiaries without Part D coverage presents challenges.<sup>54</sup> If the two groups of beneficiaries were comparable in their utilization of oral-only ESRD drugs, total spending on these drugs for all beneficiaries on dialysis—including the approximately one-third of beneficiaries without Part D coverage—could have been an estimated \$216 million higher in 2007.<sup>55</sup>
  - **Part D drug coverage in 2007 through 2009 generally was less comprehensive than the coverage that dialysis organizations will be required to provide.** Most stand-alone Part D PDPs during this time did not cover drugs when beneficiaries' annual drug costs were in the coverage gap.<sup>56,57</sup> However, beginning in 2014, dialysis organizations will be responsible for covering the cost of oral-only ESRD drugs for beneficiaries

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<sup>53</sup>CMS found that 67 to 69 percent of beneficiaries on dialysis in 2007, 2008, or the first three quarters of 2009 had Part D prescription drug coverage. *75 Fed. Reg.* at 49,071.

<sup>54</sup>CMS officials noted that they did not have reason to believe that the utilization of oral-only ESRD drugs for beneficiaries with Part D coverage differed from beneficiaries without such coverage. However, they did not provide any evidence that utilization of oral-only ESRD drugs was similar for these two groups of beneficiaries.

<sup>55</sup>To calculate this \$216 million estimate, we assumed that Part D payments per dialysis treatment for oral-only ESRD drugs for beneficiaries without Part D coverage were the same (i.e., \$18) as payments per treatment for beneficiaries with this coverage.

<sup>56</sup>Jack Hoadley et al., *Medicare Part D 2009 Data Spotlight: The Coverage Gap*, The Henry J. Kaiser Family Foundation (November 2008).

<sup>57</sup>A PDP can either be a stand-alone plan or be part of a Medicare Advantage plan, which also provides Medicare services covered under Part A and Part B. However, beneficiaries with ESRD are not eligible for most Medicare Advantage plans unless they develop the disease while enrolled in a Medicare Advantage plan. 42 U.S.C. § 1395w-21(a)(3)(B).

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on dialysis.<sup>58</sup> Moreover, some studies suggest that more comprehensive coverage of oral-only ESRD drugs, which dialysis organizations will be required to provide, could lead to greater use of and adherence to prescriptions for these drugs.<sup>59</sup> As a result, beneficiaries' use of oral-only ESRD drugs, and therefore dialysis organizations' costs of providing these drugs, could be higher than the historical Part D data indicate.

- **Part D data reflect payment rates that may be lower than dialysis organizations' costs.** Part D data reflect payment rates that PDPs negotiated with drug manufacturers and pharmacies. Because PDPs generally have larger numbers of beneficiaries than dialysis organizations and are providing a wider range of drugs, these plans may be able to negotiate larger volume discounts for purchasing oral-only ESRD drugs.<sup>60,61</sup> Furthermore, these Part D data do not account for PDPs' administrative costs of providing prescription drugs, including oral-only ESRD drugs.<sup>62</sup>

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<sup>58</sup>CMS addressed this shortcoming and the lack of payment data for beneficiaries without Part D coverage when it used Part D data to include oral ESRD drugs with injectable equivalents in the 2011 bundled payment. Specifically, CMS first calculated the average Part D payment per dialysis treatment for these drugs for beneficiaries on dialysis who had Part D coverage. In doing so, CMS included beneficiary payments, including those made while in the coverage gap, as well as payments made by PDPs. CMS then added the average payment for these drugs to the bundled payment amount for all beneficiaries on dialysis—including beneficiaries without Part D coverage.

<sup>59</sup>See Vicki Fung et al., "Falling into the Coverage Gap: Part D Drug Costs and Adherence for Medicare Advantage Prescription Drug Plan Beneficiaries with Diabetes," *Health Services Research*, vol. 45, no. 2 (April 2010); Patricia Neuman et al., "Medicare Prescription Drug Benefit Progress Report: Findings from a 2006 National Survey of Seniors," *Health Affairs*, vol. 26, no. 5 (2007); Shawn X. Sun., Kwan Y. Lee, and Meghana Aruru, "Examining Part D Beneficiaries' Medication Use in the Doughnut Hole," *The American Journal of Pharmacy Benefits*, vol. 1, no. 1 (Spring 2009); and Yuting Zhang et al., "The Impact of Medicare Part D on Medication Adherence Among Older Adults Enrolled in Medicare-Advantage Products," *Medical Care*, vol. 48, no. 5 (May 2010).

<sup>60</sup>Average beneficiary enrollment in Part D PDPs in 2007—one of the years of data that CMS could use—was about 168,000. In contrast, the large dialysis organizations in our study served about 12,000 to 130,000 patients, and some of the small organizations we interviewed noted that they served fewer than 50 patients.

<sup>61</sup>According to CMS officials, the inclusion of oral-only ESRD drugs may provide the opportunity for dialysis organizations to affiliate to enhance their purchasing power.

<sup>62</sup>Although Part D data do not account for the administrative costs associated with providing Part D drugs, CMS officials noted that these data do include the payments PDPs made to pharmacies for dispensing these drugs.

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CMS does not know whether the payment amount for the entire bundle of items and services, including oral-only ESRD drugs, will be adequate—that is, whether it will cover the costs incurred by an efficient dialysis organization to supply oral-only ESRD drugs in addition to the range of other items and services included in the bundle. However, the possibility that Part D data may understate the costs of providing oral-only ESRD drugs raises questions about the adequacy of the overall bundled payment rate. We and others have noted that inadequate payments under bundled payment systems could impair the ability of providers such as dialysis organizations to furnish beneficiaries with access to high-quality care.<sup>63</sup> CMS officials stated that they had not yet determined what the bundled payment rate will be when oral-only ESRD drugs are included, because CMS was focused on implementing the current payment system for dialysis care. As a result, CMS does not know whether or the extent to which the bundled payment rate will be adequate when, beginning in 2014, CMS includes oral-only ESRD drugs in the bundled payment for dialysis care.

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## CMS Is Developing New Quality Measures Related to Mineral and Bone Disorder; However, CMS’s System for Collecting Data for Its Quality Measures Has Been Delayed

CMS is currently developing new quality measures for monitoring treatment of mineral and bone disorder in order to identify measures for which a consensus target level can be proposed based on the clinical evidence available. CMS is also developing a new data collection system, called CROWNWeb, which the agency plans to use to collect data to support these new measures. However, due to repeated implementation delays and data reliability issues associated with CROWNWeb, it is uncertain when CMS will be able to rely on CROWNWeb to collect data for these measures.

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<sup>63</sup>For example, see GAO, *End-Stage Renal Disease: CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System*, [GAO-10-295](#) (Washington, D.C.: Mar. 31, 2010); MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: March 1999); and Joseph P. Newhouse, Melinda Beeuwkes Buntin, and John D. Chapman, “Risk Adjustment and Medicare: Taking a Closer Look,” *Health Affairs*, vol. 16, no. 5 (1997).

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## CMS Is Developing New Quality Measures Related to Mineral and Bone Disorder

CMS is developing new quality measures related to treatment of mineral and bone disorder in order to identify measures for which a consensus target level can be proposed based on the clinical evidence available. CMS's current quality measures use target levels for serum calcium and serum phosphorus that are based on clinical guidelines recommended by the 2003 Kidney Disease Outcomes Quality Initiative (K/DOQI) Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease.<sup>64</sup> However, more recent clinical guidelines issued in 2009 state that there is insufficient clinical evidence to support target levels for serum calcium and serum phosphorus, such as those recommended by the K/DOQI guidelines.<sup>65</sup> Furthermore, four of the five experts we interviewed also noted that there is a lack of clinical evidence to support target levels for these indicators.

CMS's current quality measures for monitoring treatment of mineral and bone disorder are:<sup>66</sup>

1. The percentage of patients in a dialysis facility with serum calcium measured at least once within the month.
2. The percentage of patients in a dialysis facility with serum phosphorus measured at least once within the month.
3. The percentage of patients in a dialysis facility with mean serum calcium between 8.4 and 10.2 milligrams per deciliter (mg/dL).
4. The percentage of patients in a dialysis facility with mean serum phosphorus between 3.5 and 5.5 mg/dL.

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<sup>64</sup>K/DOQI was established by the National Kidney Foundation to develop clinical practice guidelines for dialysis and other aspects of kidney disease. The National Kidney Foundation is a nonprofit health organization which advocates for individuals affected by kidney disease.

<sup>65</sup>See the Official Journal of the International Society of Nephrology, *KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD)*, vol. 76, supplement 113 (August 2009).

<sup>66</sup>CROWNWeb is designed to collect data for all four of these measures; however, only the first two measures are currently included in the CPM Project. CMS officials told us that they plan to use the data collected in CROWNWeb to refine CMS's quality measures over time.

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CMS does not currently have a quality measure related to PTH; however, all of the experts we interviewed noted that PTH is an important indicator for monitoring treatment of mineral and bone disorder.<sup>67</sup>

As part of its efforts to develop new quality measures, CMS recently submitted two new mineral and bone disorder measures, in addition to measures related to other aspects of dialysis care, to an independent consensus-building body known as the National Quality Forum (NQF).<sup>68</sup> NQF evaluates quality measures to determine which ones should be endorsed—that is, recognized—as national standards.<sup>69</sup> The measures related to treatment of mineral and bone disorder that CMS submitted to NQF are:

1. The percentage of patients in a dialysis facility with a 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.
2. The percentage of patients in a dialysis facility with a 3-month rolling average of serum phosphorus less than 2.5 mg/dL.

In January 2011, the NQF ESRD Steering Committee recommended that the measure related to serum calcium continue through the consensus development process toward possible endorsement by NQF but did not recommend that the measure related to serum phosphorus continue

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<sup>67</sup>CMS officials stated that CMS has not focused on developing a measure for PTH because of the lack of consensus around PTH levels and measures. Laboratories differ in the assays, or measures, they use to assess PTH levels, and PTH levels vary depending on the assays used.

<sup>68</sup>NQF is a nonprofit organization that endorses national consensus standards for measuring and publicly reporting on health care performance. The measures that CMS submitted to NQF were recommended by a panel of experts that CMS convened in March 2010. CMS did not submit a measure related to PTH to NQF; however, CROWNWeb is designed to collect data on PTH levels when it is fully implemented and CMS officials stated that they may use these data in the future if an appropriate quality measure related to PTH is developed.

<sup>69</sup>NQF's process of endorsing quality measures includes: (1) issuing a call for organizations to submit measures to NQF for consideration; (2) using a steering committee and, if applicable, a technical advisory panel to evaluate the measures submitted to NQF; (3) allowing the public to comment on the measures proposed by the steering committee for endorsement; (4) allowing members of NQF to vote on the measures proposed by the steering committee for endorsement; and (5) gaining the approval of both the NQF Consensus Standards Approval Committee and the NQF Board of Directors on the final measures proposed for endorsement.

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through this process.<sup>70</sup> A final decision on whether NQF will endorse these and other quality measures is scheduled for June 2011. Once this process is complete, CMS plans to decide how it will incorporate any NQF-endorsed quality measures into its quality monitoring activities.<sup>71</sup>

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### CMS's System for Collecting Data for Its Quality Measures Has Been Delayed

Due in part to repeated implementation delays, it is uncertain when CMS will be able to rely on CROWNWeb to collect the data it needs to support its quality measures related to treatment of mineral and bone disorder, as well as other aspects of dialysis care. Beginning in 2009, CMS stopped collecting data via a paper data collection form for the quality measures included in the CPM Project because CMS intended to begin collecting data for these measures from all dialysis facilities in CROWNWeb in February 2009. However, CMS officials told us that full, national implementation of CROWNWeb was delayed because a contractor tasked with designing and implementing CROWNWeb performed poorly. CMS officials told us that CMS hired a new contractor in September 2009 and scheduled full implementation of CROWNWeb for December 2009. According to CMS officials, full implementation of CROWNWeb was delayed again because CMS needed to update CROWNWeb to address security requirements for federal data systems.<sup>72</sup> Due in part to these delays, CMS modified the implementation of CROWNWeb to a “phase-in” approach whereby the number of facilities submitting data to CROWNWeb increases in phases until full implementation is achieved.<sup>73</sup> Specifically,

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<sup>70</sup>The Steering Committee noted that the phosphorus measure would apply to less than 1 percent of the population receiving dialysis and is a measure of nutrition rather than mineral and bone disorder.

<sup>71</sup>A CMS official noted that CMS may use a serum phosphorus measure for monitoring the quality of mineral and bone disorder despite the lack of NQF endorsement at this time.

<sup>72</sup>See CMS, QualityNet System Security Policy, Version 6.0 (November 2009). CMS officials told us that initially CMS planned to allow dialysis organization personnel to access CROWNWeb using a personalized username and password. However, because of the new security requirements, CROWNWeb users will also be required to input a randomly generated one-time password that is valid for 12 hours and is sent to them via e-mail, telephone, or text message.

<sup>73</sup>Eight dialysis facilities participated in Phase 1 of CROWNWeb implementation, which began in February 2009. Approximately 180 facilities are participating in Phase 2—the current phase—which began in August 2009. CMS plans to expand Phase 2 participation to approximately 630 dialysis facilities beginning in April 2011. CMS officials noted that Phase 3 and Phase 4 of CROWNWeb implementation—which will be combined—are scheduled to begin in November 2011 and full, national implementation of CROWNWeb is currently scheduled for February 2012. Once national implementation of CROWNWeb is achieved, CMS estimates approximately 5,600 dialysis facilities will participate in CROWNWeb.

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about 180 dialysis facilities currently submit data to CROWNWeb, and CMS planned to begin collecting data from all dialysis facilities—approximately 5,600—in June 2011. However, due to continued implementation challenges, CMS recently delayed the full, national implementation of CROWNWeb until February 2012.

In addition to concerns about implementation delays,<sup>74</sup> dialysis organizations and others we spoke with expressed concern about the reliability of the data in CROWNWeb. For example, 9 of the 20 dialysis organizations we interviewed expressed concern about the reliability of manually entered data and CMS noted that there is a data error rate of over 20 percent for data submitted to CROWNWeb via the batch submission process in the current phase of CROWNWeb implementation.<sup>75</sup> According to CMS officials, CMS has contracted with two vendors that are responsible for evaluating the accuracy and reliability of data in CROWNWeb. However, the results of this evaluation will not be available until CROWNWeb is fully implemented.

CMS officials told us that, due to the delays with the implementation of CROWNWeb, from 2008 through 2010 data for quality measures related to mineral and bone disorder and other aspects of dialysis care were collected through a project—referred to as the Elab Project—administered by the ESRD Network Program.<sup>76</sup> The ESRD Network Program, which was established in 1978, consists of 18 ESRD Networks,

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<sup>74</sup>Eleven of the 16 small dialysis organizations in our review noted that the process of entering data manually in CROWNWeb would be administratively burdensome. CMS is working with NRAA to develop the capacity for NRAA to act as a third-party Health Information Exchange that will allow small dialysis organizations to have their data uploaded directly to CROWNWeb. The Health Information Exchange would allow small dialysis organizations to submit their data to NRAA, which would then format and submit the data to CROWNWeb. CMS officials told us that CMS does not expect to have this capacity available until 2012 or later.

<sup>75</sup>CMS did not specify the error rate associated with manually entered data.

<sup>76</sup>The Elab Project was established by ESRD Network 11 in 1999 to determine whether or not electronic laboratory data, which the Network used for quality improvement purposes, could be collected directly from the corporate offices of large dialysis organizations or national laboratory chains to decrease the data submission burden on dialysis facilities. Beginning in 2002, the project stopped collecting data directly from national laboratory chains and all facilities not affiliated with a large dialysis organization were required to submit their data via an electronic data collection form. The Elab Project uses quality measures related to treatment of mineral and bone disorder that identify the percentages of dialysis patients with serum calcium and serum phosphorus levels maintained within certain ranges.

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covering each U.S. state, territory, and the District of Columbia, which are responsible for helping CMS monitor the quality of dialysis care provided by dialysis facilities in their geographic area.<sup>77</sup> Through the Elab Project, the ESRD Networks collected data for nearly 100 percent of dialysis patients in the United States in 2009, the most recent year for which data are available.<sup>78</sup> The ESRD Networks used these data to monitor the quality of dialysis care at both the national level and the facility level.<sup>79</sup> Given the implementation challenges associated with CROWNWeb, CMS officials noted that they plan to continue the Elab Project in 2011 and that it may be necessary to continue this initiative in subsequent years.<sup>80</sup>

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## Conclusions

Expanding the bundled payment for dialysis care to include oral-only ESRD drugs has the potential to promote efficiency, clinically appropriate care, and access to these drugs for the over 300,000 beneficiaries on dialysis. However, Part D data, which CMS officials noted they were limited to using to expand the bundled payment to include oral-only ESRD drugs, may understate the costs that dialysis organizations would incur to provide these drugs. This raises questions about whether, in its entirety, the bundled payment for dialysis care will provide adequate payments for dialysis organizations when, beginning in 2014, CMS uses the payment to cover the provision of oral-only ESRD drugs, along with other services.

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<sup>77</sup>Each network is charged with monitoring and promoting the quality of dialysis care in a specific geographic area, which generally covers one or more states.

<sup>78</sup>In 2009, the Elab Project collected data on about 97 percent of patients on dialysis in the United States.

<sup>79</sup>Officials from ESRD Network 11 noted that the most recent test of the reliability of the data collected by the Elab Project revealed that the data were reliable approximately 95 percent of the time.

<sup>80</sup>In addition to CMS's quality monitoring activities such as the Elab Project, CMS officials noted that they recently began conducting surveillance using Medicare claims data to identify changes in health outcomes and the use of dialysis-related items and services that could be associated with the recent change in Medicare's payment method for dialysis care. For example, to examine changes related to treatment of mineral and bone disorder, CMS is reviewing data on Medicare items and services provided under Part A, Part B, and Part D to identify changes in incidences of bone fractures, as well as changes in the use of vitamin D, phosphate binders, and calcimimetics. This effort is part of a broader CMS effort to examine changes in health outcomes and the use of health care items and services associated with changes in Medicare payment policy. A CMS official leading this effort noted that, in contrast to CMS's quality monitoring activities, this effort does not evaluate whether the level of an outcome or the use of an item or service represents good quality care.



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Because inadequate payments could impair the ability of dialysis organizations to provide beneficiaries with access to high-quality dialysis care, it will be important for CMS to know—before implementing this payment change—whether or to what extent the bundled payment for dialysis care will be adequate when the payment also includes oral-only ESRD drugs.

In addition to the need to assess payment adequacy, the importance of quality monitoring under bundled payment systems has been well established to help ensure that any improvements in efficiency associated with these payment systems are not realized by compromising the quality of dialysis care for beneficiaries. Specifically, we emphasized in our March 2010 report the need for CMS to monitor beneficiaries' quality of dialysis care as soon as possible after the payment system for dialysis care was implemented in January 2011. CMS recognizes the importance of monitoring the quality of dialysis care, including treatment of mineral and bone disorder, and the agency has conducted such monitoring for decades. However, the substantial and repeated delays associated with CROWNWeb, in addition to potential problems with data reliability associated with that system, raise questions about when CMS will be able to rely on the data collected in CROWNWeb to monitor the quality of dialysis care. Due to significant recent changes in CMS's method for paying for dialysis care, it is imperative that CMS identify an alternate source of data for quality monitoring until CROWNWeb is fully operational. CMS officials recognize the need for an alternate data source and intend to continue the Elab Project in 2011. These officials also recognize that, given the uncertainties with CROWNWeb implementation, it may be necessary to continue the Elab Project in future years.

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## Recommendations for Executive Action

To help ensure that Medicare beneficiaries have access to high-quality dialysis care, we recommend that the Administrator of CMS assess the extent to which the bundled payment for dialysis care will be sufficient to cover an efficient dialysis organization's costs to provide such care when the bundled payment expands to cover oral-only ESRD drugs. The Administrator should conduct this assessment before implementing this expanded bundled payment.

In order to ensure effective monitoring of treatment of mineral and bone disorder, we recommend that the Administrator of CMS continue collecting data for quality measures related to this condition from sources such as the Elab Project until CROWNWeb is fully implemented and concerns about its data reliability have been adequately addressed.

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## Agency and Other Comments and Our Evaluation

We received written comments on our draft report from the Department of Health and Human Services on behalf of CMS. These comments are reprinted in appendix I. We also obtained oral comments on our draft report from groups representing ESRD patients, large and small dialysis organizations, and nephrologists.

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### Comments from CMS

In written comments on a draft of this report, CMS agreed with both of our recommendations. In response to our recommendation that CMS assess the adequacy of the bundled payment when oral-only ESRD drugs are included, CMS stated that it would carefully analyze data on the utilization of these drugs before including them under the bundled payment. CMS also noted that, before implementing this payment change, the agency would allow for public comment through the rulemaking process and would carefully examine any concerns expressed by the public to ensure that beneficiaries continue to have access to needed medications. Furthermore, CMS stated that it was confident that the additional amount to be included in the ESRD prospective payment system to account for oral-only ESRD drugs would be adequate to account for the average patient's oral drug needs. They noted that particular aspects of the payment system are intended to account for the higher drug costs of some patients. Consistent with our findings, CMS also noted that including oral-only ESRD drugs in the payment bundle would be advantageous because it would allow for the selection of drugs that are in the best clinical interests of the patients without regard to financial incentives.

With regard to our recommendation that CMS ensure the availability of data for monitoring the treatment of mineral and bone disorder, CMS noted that it plans to include measures related to mineral and bone disorder in the ESRD Quality Incentive Program (QIP). Recognizing the importance of collecting data on ESRD quality measures, CMS noted that it has collected and used data through a number of quality initiatives over the last two decades and currently collects such information through multiple sources. In its comments CMS also explained that although the agency plans to eventually collect patient-level quality data through CROWNWeb and another mechanism developed in consultation with the NRAA, the Elab Project will be funded for the year 2011. According to CMS the agency plans to make continuing the project a funding priority until other data sources are available, making the project redundant. CMS emphasized that all of these data collection vehicles include clinical indicators on mineral and bone metabolism. CMS also provided an updated schedule for national CROWNWeb implementation and noted that

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data validity and reliability issues will be addressed over this period. CMS also provided technical comments which we incorporated as appropriate.

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## Comments from Groups Representing the Dialysis Industry and Patients

In their oral comments to us regarding our draft report, representatives from the American Association of Kidney Patients (AAKP), the American Kidney Fund (AKF), the Kidney Care Council (KCC), the National Renal Administrators Association (NRAA), and the Renal Physicians Association (RPA) generally agreed with our message and recommendations to CMS. The representatives generally noted that our draft report was well-written and balanced and that they appreciated that we collected data and perspectives from a variety of organizations. The groups also underscored our findings related to dialysis organizations' ability to provide oral-only ESRD drugs. Specifically, representatives from all of the groups reiterated some of the possible challenges we described in our draft report related to providing these drugs, including the complexity of complying with state pharmacy licensure requirements, the potential for fragmentation of care, and the potential influence of the payment change on physician prescribing behaviors for oral-only ESRD drugs. The groups representing large and small dialysis providers also expressed unease about the additional costs they will incur to provide these drugs. The five groups' comments on our draft report generally focused on three areas of concern: (1) the reasons for including oral-only ESRD drugs in the bundled payment system, (2) the data CMS intends to use to account for oral-only ESRD drugs in the bundled payment system, and (3) CMS's ability to monitor the quality of care provided to dialysis beneficiaries. Industry and patient group representatives also provided technical comments, which we incorporated as appropriate.

In commenting on our findings related to the reasons for including oral-only ESRD drugs in the bundled payment, representatives of RPA, NRAA, and AKF expressed concern that potential increases in beneficiaries' out-of-pocket costs for oral-only ESRD drugs could affect beneficiaries' access to these drugs when they are included in the bundled payment. For example, representatives of RPA and NRAA commented that beneficiaries' cost sharing for these drugs could be higher than it would be if the drugs remained covered under Part D because the Part D coverage gap will be reduced.<sup>81</sup> In addition, representatives of AKF noted that some

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<sup>81</sup>Beginning in 2011, provisions in the health care reform law will gradually reduce the amount that Part D beneficiaries are required to pay for drugs while they are subject to the coverage gap by phasing in different levels of subsidies for these drugs.

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beneficiaries currently receive financial assistance to help cover their out-of-pocket costs for Part D drugs and once oral-only ESRD drugs are included in the Part B payment bundle, these beneficiaries will no longer receive this assistance.

We did not assess the extent to which beneficiaries' cost sharing will change when oral-only ESRD drugs are included in the bundled payment system because doing so was beyond the scope of our study. Although beneficiaries' out-of-pocket costs for drugs covered under Part D will decrease once the Part D coverage gap is eliminated, beneficiaries will continue to be responsible for cost sharing for Part D-covered drugs. As noted in the preamble to the final rule for the design of the bundled payment system for dialysis care, whether a particular beneficiary's cost sharing for oral-only ESRD drugs increases or decreases when these drugs are included in the bundled payment will depend on his or her individual circumstances.<sup>82</sup> However, as we noted in the report, beneficiaries who currently lack any prescription drug coverage could experience a reduction in out-of-pocket costs related to oral-only ESRD drugs when these drugs are included in the bundled payment.

In commenting on our findings related to the Part D data CMS intends to use to account for oral-only ESRD drugs in the bundled payment for dialysis care, representatives from RPA, NRAA, KCC, and AAKP restated the potential limitations of these data that we identified in the draft report. Representatives from RPA and NRAA commented that these data may not reflect changes in treatment patterns since 2007. In addition, representatives from KCC commented that MIPPA did not limit CMS to using Part D data from 2007, 2008, or 2009 to account for oral-only ESRD drugs in the bundled payment. KCC representatives also asserted that it was not CMS's position that MIPPA limited the agency to using these data to expand the bundled payment to include oral-only ESRD drugs. They noted further that in the proposed rule for the new payment system, CMS calculated \$14 per dialysis treatment to account for oral-only ESRD drugs in the bundled payment amount. However, KCC's estimate of the cost of providing these drugs was \$45 per treatment. KCC representatives suggested that we note the true cost of providing oral-only ESRD drugs in the report. Representatives of NRAA also commented that if the amount of the bundled payment were not adequate, small dialysis organizations

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<sup>82</sup>75 *Fed. Reg.* at 49,041.

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could go out of business, which could create access problems for beneficiaries.

In our draft report, we noted the potential limitations of Part D data and recommended that CMS assess the extent to which the bundled payment for dialysis care would be sufficient to cover an efficient dialysis organization's costs to provide these drugs. CMS asserted that MIPPA limited the agency to using data on Medicare payments for oral-only ESRD drugs in 2007, 2008, or 2009 to account for these drugs in the bundled payment system. In addition, CMS officials also reiterated that they were limited to using data from the Part D program. However, assessing the true cost of providing oral-only ESRD drugs and CMS's interpretation of MIPPA was beyond the scope of our study. Of most concern is whether the payment for the entire bundle of services will be adequate to cover the costs of efficient dialysis organizations. We agree that if the bundled payment is not adequate, access problems for beneficiaries could result. In our report, we recommended that CMS assess the adequacy of the bundled payment amount before expanding the bundled payment to include oral-only ESRD drugs.

Finally, in commenting on our findings related to CMS's ability to monitor the quality of care provided to dialysis beneficiaries under the bundled payment system, representatives of RPA and AKF agreed with our finding that there is not consensus around appropriate quality measures for monitoring treatment of mineral and bone disorder. In addition, representatives of RPA, KCC, and AAKP commented that the report should place stronger emphasis on the CROWNWeb implementation challenges and representatives of RPA and KCC underscored their concerns about the reliability of the data in CROWNWeb.

In our draft report, we noted that CMS submitted two new quality measures related to treatment of mineral and bone disorder to NQF in an effort to identify measures for which a target level can be proposed based on the clinical evidence available. Although the phosphorus measure submitted by CMS has been rejected by NQF, the calcium measure submitted by CMS was still under consideration when we conducted the data collection for this report. In addition, we highlighted in our draft report the challenges associated with CROWNWeb implementation—including repeated and significant delays with national implementation and concerns about data reliability—and recommended that CMS continue to collect data for quality measures related to treatment of mineral and bone disorder from sources such as the Elab Project until CROWNWeb is fully operational.

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We are sending copies of this report to the Administrator of CMS. In addition, the report is available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [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 this report. GAO staff who made major contributions to this report are listed in appendix II.

A handwritten signature in black ink, appearing to read "James C. Cosgrove". The signature is stylized with large, sweeping loops and a prominent initial "J".

James C. Cosgrove  
Director, Health Care

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# Appendix I: 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

MAR 17 2011

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

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled, "End-Stage Renal Disease: CMS Should Assess Adequacy of Payment When Certain Oral Drugs Are Included and Ensure Availability of Quality Monitoring Data" (GAO 11-369).

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 (GAO) DRAFT REPORT ENTITLED, "END STAGE RENAL DISEASE: CMS SHOULD ASSESS ADEQUACY OF PAYMENT WHEN CERTAIN ORAL DRUGS ARE INCLUDED AND ENSURE AVAILABILITY OF QUALITY MONITORING DATA" (GAO-11-365)**

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

GAO found that while there were positive aspects of including oral-only end stage renal disease (ESRD) drugs in the ESRD bundled payment, there were concerns that the payment amount included might be understated. The report also indicated that the Centers for Medicare and Medicaid Services (CMS) is developing new, consensus-based measures to monitor bone and mineral disorders and could be collecting data using alternative mechanisms in 2011 until the new Web-based system is operational. GAO payment findings were based on interviews with 4 large dialysis organizations and 16 small dialysis organizations.

**GAO Recommendation**

To help ensure that Medicare beneficiaries have access to high-quality dialysis care, we recommend that the Administrator of CMS assess the extent to which the bundled payment for dialysis care will be sufficient to cover an efficient dialysis organization's costs to provide such care when the bundled payment expands to cover oral-only ESRD drugs. The Administrator should conduct this assessment before implementing this expanded bundled payment.

**CMS Response:**

CMS concurs with this recommendation. Before payment for these drugs is included in the bundle, we will carefully analyze the data on usage, and include a proposed payment change based on the data, in a notice of proposed rulemaking. The public will be given 60 days to comment and to express any concerns about the proposal. CMS will then review those concerns carefully to ensure that beneficiaries continue to have access to the medications they need. We continue to assess the usage of oral-only drugs and will continue to do so prior to their implementation in the bundled payment. We are confident that the additional amount to be included in the ESRD Prospective Payment System (PPS) per treatment base rate to account for oral-only ESRD-related drugs will be adequate to account for the average patient's oral drug needs. We would note that the ESRD PPS base rate amount is multiplied by the applicable case-mix and facility adjusters to arrive at the bundled payment amount for each patient. The ESRD PPS adjustment factors were developed to reflect the higher costs of some patients which include higher costs for drugs. Finally, the intent of the outlier policy is primarily to account for the higher drug costs for some patients.

One advantage of including oral-only ESRD drugs in the payment bundle is that doing so creates a level playing field for the selection of drugs that are in the best clinical interests of the patients, without regard to financial incentives posed by including some drugs and excluding others from the ESRD PPS.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "END STAGE RENAL DISEASE: CMS SHOULD ASSESS ADEQUACY OF PAYMENT WHEN CERTAIN ORAL DRUGS ARE INCLUDED AND ENSURE AVAILABILITY OF QUALITY MONITORING DATA" (GAO-11-365)**

**GAO Recommendation**

In order to ensure effective monitoring of treatment of mineral and bone disorder, we recommend that the Administrator of CMS continue collecting data for quality measures related to this condition from sources such as the Elab Project until CROWNWeb is fully implemented and concerns about its data reliability have been adequately addressed.

**CMS Response:**

CMS concurs with this recommendation. We plan to include treatment of mineral and bone disorder in the ESRD Quality Incentive Program (QIP). We are developing measures and will have a vehicle to collect data.

CMS recognizes the importance of collecting data for ESRD quality measures. CMS has collected and used data as part of a number of quality initiatives over the last two decades. CMS clinical quality data is currently collected via claims, administrative forms, the ESRD Network Quality Improvement Elab Project, PQRI, and the ESRD Networks. CMS plans to collect patient level quality data from all dialysis facilities using the CROWNWeb system that is slated for national release in early 2012. In addition, CMS is working with the National Renal Administrators Association to put in place a National Health Information Network (NHIN) Electronic Health Record reporting system that will collect patient level data. The Elab project will be funded for the current year and we plan to make it a funding priority and continue the project until other data sources make this effort redundant. Each of these data collection vehicles (CROWNWEB, NHIN, and Elab) includes the collection of bone and mineral metabolism clinical indicators. The Elab project has collected serum phosphorus and calcium data since 1998.

The implementation date for the national release of CROWNWeb has been delayed beyond June 2011 due to ongoing efforts to address security and interoperability issues. CROWNWeb Phase III (version 4.0) is scheduled for pilot release late November 2011; its national release is scheduled for early 2012. We anticipate that all CROWNWeb data validity and reliability issues will be addressed over this next year.

Monitoring clinical care in order to assure quality of care and access to care are key components to meeting the needs and expectations of beneficiaries. Consequently, CMS plans to continue the monitoring of mineral and bone disorder through data from Elab project until CROWNWeb is fully implemented and any concerns about its data reliability have been adequately addressed.

We appreciate the effort that went into this draft report and look forward to working with GAO on this and other issues in the future.

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# Appendix II: GAO Contact and Staff Acknowledgments

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## GAO Contact

James C. 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, Jessica Farb, Assistant Director; William Black; Manuel Buentello; Krister Friday; David Grossman; Aubrey Naffis; and Jennifer Whitworth made key contributions to this report.

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