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END-STAGE RENAL DISEASE

CMS Plans for Including Phosphate Binders in the Bundled Payment

GAO-24-106288

GAO Highlights

Highlights of GAO-24-106288, a report to congressional committees

November 2023

END-STAGE RENAL DISEASE:

CMS Plans for Including Phosphate Binders in the Bundled Payment

Why GAO Did This Study

Dialysis services provide life-sustaining treatment for individuals with end-stage renal disease. In 2021, Medicare covered dialysis treatment under Part B for nearly 332,000 beneficiaries with the disease who were enrolled in Medicare's traditional fee-for-service program. Currently, phosphate binders are covered under Medicare's prescription drug benefit (Part D). In 2020, Medicare Part D plans paid almost $1 billion for these drugs.

The American Taxpayer Relief Act of 2012 includes a provision for GAO to review issues associated with the inclusion of phosphate binders in the bundled payment.

This report describes (1) CMS's plans to include phosphate binders in the bundled payment; (2) dialysis organizations' views on their capacity to dispense phosphate binders once these drugs are included in the bundled payment; and (3) CMS's plans to monitor phosphate binder treatment once these drugs are included in the bundled payment.

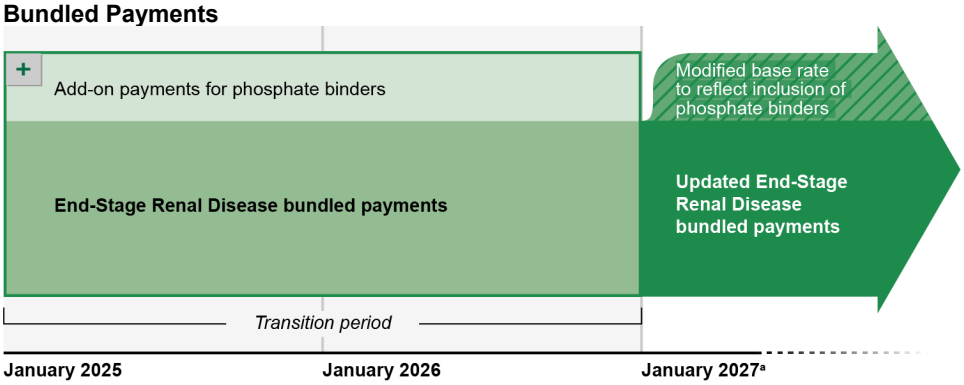
GAO reviewed regulations, statutes, and relevant CMS documentation. GAO interviewed CMS officials, five large dialysis organizations that comprised over 85 percent of dialysis facilities in fiscal year 2022, an association representing over 100 small dialysis organizations, and associations representing nephrologists and dialysis patients.

View GAO-24-106288. For more information, contact Leslie V. Gordon, (202) 512-7114 or gordonlv@gao.gov

What GAO Found

Phosphate binders are oral drugs commonly used by Medicare beneficiaries with end-stage renal disease to treat mineral and bone disorder, which may result in weak and brittle bones. Currently, these drugs are paid for separately from the bundled payment that the Centers for Medicare & Medicaid Services (CMS) established for dialysis and most end-stage renal disease-related treatment under Medicare's traditional fee-for-service program. The bundled payment is designed to incentivize efficient care, because dialysis organizations retain the difference if Medicare's bundled payment exceeds the cost of providing services. Congress has delayed until 2025 the inclusion of phosphate binders in the bundled payment. Beginning in 2025, CMS plans to pay for phosphate binders using an add-on payment for at least 2 years. Subsequently, CMS plans to modify the bundled payment to account for the cost and utilization of phosphate binders but has not yet finalized its approach for doing so.

Timing of CMS's Plans for Including Phosphate Binders in End-Stage Renal Disease Bundled Payments



Source: GAO analysis of Centers for Medicare & Medicaid (CMS) information. | GAO-24-106288

[a]CMS's proposal is to pay for phosphate binders for at least 2 years using an add-on payment to dialysis organizations. CMS officials said they may extend the transition period to a third year for CMS to collect sufficient claims data to accurately set the payment rate.

When CMS includes phosphate binders in the bundled payment, dialysis organizations will be responsible for dispensing these drugs to beneficiaries. All dialysis organization representatives GAO interviewed anticipate needing to expand their existing capacity to dispense oral drugs. They attributed this need, in part, to the high volume of phosphate binder prescriptions. In addition, these dialysis organization representatives expressed concerns that the modified bundled payment may not fully account for the costs of acquiring, shipping, and dispensing phosphate binders. CMS officials expect that it will be feasible for dialysis organizations to make necessary operational changes. CMS officials said they would assess the adequacy of payments. Agency officials also said they would examine concerns raised by the public through the rulemaking process to ensure continued access to these medications.

CMS plans to monitor beneficiary utilization of phosphate binders and health outcomes related to phosphate binder treatment once these drugs are included in the bundled payment.

Contents

Letter		1
	Background	4
	CMS Plans to Modify the ESRD Bundled Payment to Include Phosphate Binders after a Transition Period	11
	Dialysis Organizations Anticipate That Dispensing a High Volume of Phosphate Binders Will Require Expanding Existing Capacity	14
	CMS Plans to Monitor Utilization and Health Outcomes as Phosphate Binders Are Included in the Bundled Payment	20
	Agency Comments	22
Appendix I	GAO Contact and Staff Acknowledgments	25

Figures

Figure 1: Components of the Bundled Payment to Organizations Providing Dialysis Care 7

Figure 2: Expansion of Bundled Payment for Dialysis Care through 2025 8

Figure 3: Timing of CMS's Plans for Including Phosphate Binders in End-Stage Renal Disease Bundled Payments 11

Figure 4: Process Generally Used by Dialysis Organizations to Dispense Oral Drugs Included in Bundled Payment to Medicare Beneficiaries 15

Abbreviations

CMS	Centers for Medicare & Medicaid Services
ESRD	end-stage renal disease
USRDS	United States Renal Data System

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Congressional Committees

Individuals with end-stage renal disease (ESRD)—a condition of permanent kidney failure—rely on dialysis services for life-sustaining treatment and most are eligible for Medicare benefits, regardless of age. Dialysis treatment removes excess fluids and toxins from the bloodstream. In 2021, Medicare's traditional fee-for-service program covered dialysis treatment under Part B for nearly 332,000 beneficiaries with ESRD and spent $10.0 billion for outpatient dialysis services.[1]

The Centers for Medicare & Medicaid Services (CMS)—the agency that administers Medicare—pays dialysis organizations a single, bundled payment for dialysis treatments and most ESRD-related treatment. This payment covers ESRD-related injectable drugs, oral drugs with an injectable equivalent, laboratory services, and medical equipment and supplies. Paying for dialysis care with a bundled payment is designed to give dialysis organizations a financial incentive to provide this care efficiently. This is because organizations retain the difference if Medicare's bundled payment exceeds the cost of providing such items and services. At present, this bundled payment does not cover oral ESRD drugs without an injectable equivalent—called oral-only drugs.

In 2025, CMS plans to begin including oral-only drugs, which currently only include phosphate binders, in the bundled payment. Phosphate binders are used to treat mineral and bone disorder, a common complication in ESRD patients. Currently, phosphate binders are covered under Medicare Part D, under which beneficiaries typically fill prescriptions at pharmacies, including retail or mail-order pharmacies. Once phosphate binders are included in the bundled payment, dialysis organizations will be responsible for dispensing these drugs to

[1]Beneficiaries in Medicare's traditional fee-for-service program generally receive Medicare benefits under Part A (inpatient hospital coverage), Part B (outpatient medical coverage, including dialysis treatments), and Part D (prescription drug coverage). See 42 U.S.C. §§ 426-1(a), 1395w-101(a)(3)(A). Beneficiaries may also receive benefits provided under Medicare Parts A and B through the Medicare Advantage program, a private plan alternative to traditional Medicare. Since 2021, individuals with ESRD have been eligible to enroll in the Medicare Advantage program. However, this report focuses on services under traditional Medicare, which covers the majority of beneficiaries with ESRD. See 21st Century Cures Act, Pub. L. No. 114-255, § 17006, 130 Stat. 1033, 1334 (2016) (amending 42 U.S.C. § 1395w-21(a)(3)).

beneficiaries. CMS delayed the inclusion of phosphate binders in the bundled payment in part to give dialysis organizations more time to develop the capacity necessary to assume this additional responsibility, and Congress subsequently delayed their inclusion further.[2]

In 2011, we reported that including oral-only ESRD drugs, such as phosphate binders, in the bundled payment would encourage more efficient and appropriate care and increase access to these drugs for certain beneficiaries.[3] In addition, we recommended that CMS assess the extent to which the bundled payment—once it is expanded to cover oral-only ESRD drugs—would be sufficient to cover an efficient dialysis organization's costs. CMS agreed with our recommendation but had not implemented it as of June 2023. CMS is not yet able to assess payment adequacy because the agency has not yet determined what the bundled payment will be once phosphate binders are included. We also reported on CMS's activities to enable monitoring of care related to these drugs.

The American Taxpayer Relief Act of 2012 includes a provision for us to review payment, capacity, and monitoring issues associated with including phosphate binders in Medicare's bundled payment that were previously described in our 2011 report.[4] In this report, we describe:

1. CMS's plans to include phosphate binders in the bundled payment;
2. dialysis organizations' views on their capacity to dispense phosphate binders once these drugs are included in the bundled payment; and

[2]In 2010, CMS delayed the inclusion of oral-only ESRD drugs in the bundled payment until 2014. Medicare Program; End-Stage Renal Disease Prospective Payment System, 75 Fed. Reg. 49, 030 (Aug. 12, 2010). Congress further delayed the inclusion of oral-only ESRD drugs in the bundled payment to 2025. American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 632(b), 126 Stat. 2313, 2354 (2013); Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 217(a)(1), 128 Stat. 1040, 1061 (2014); Stephen Beck, Jr., ABLE Act of 2014, Pub. L. No. 113-295, div. B, § 204, 128 Stat. 4010, 4065 (2014).

[3]The 2011 report covered oral-only ESRD drugs, which at the time included phosphate binders and calcimimetics. Since the Food and Drug Administration approved an injectable form of calcimimetics in 2017, phosphate binders have been the sole oral-only ESRD drug. Therefore, we refer specifically to phosphate binders throughout this report and not oral-only ESRD drugs. GAO, *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 (Washington, D.C.: March 23, 2011).

[4]Pub. L. No. 112-240, § 632(d), 126 Stat. at 2354 (2013) (as amended by GAO Mandates Revision Act of 2016, Pub. L. No. 114-301, § 3(c), 130 Stat. 1514, 1515 (2016)).

3. CMS's plans to monitor phosphate binder treatment once these drugs are included in the bundled payment.

To describe CMS's plans to include phosphate binders in the bundled payment, we interviewed CMS officials responsible for rulemaking associated with the bundled payment. We reviewed statutes and regulations related to the timing and process for including phosphate binders in the bundled payment. We also reviewed CMS's proposed and final rules for the bundled payment that were published in the Federal Register, as well as other CMS documentation related to the process for including other ESRD-related drugs in the bundled payment. As part of our review, we describe data issues that we identified in our 2011 report and how, if at all, CMS's plans have the potential to address them.[5]

To describe dialysis organizations' views on their capacity to provide phosphate binders under the bundled payment, we interviewed a nongeneralizable selection of representatives from five large dialysis organizations and an association representing small dialysis organizations.[6] We interviewed representatives from these organizations about processes they currently use to provide oral ESRD-related drugs and any adjustments or challenges they anticipate in dispensing phosphate binders. The five large dialysis organizations we selected each operated between 200 and 2,900 dialysis facilities in fiscal year 2022 and together accounted for 85 percent of all dialysis facilities.[7] The association representing small dialysis organizations represented 120 small and independent dialysis organizations across a majority of states.[8] To gain additional insight into the implications of including phosphate binders in the bundled payment and dialysis organizations' capacity to do so, we interviewed a nongeneralizable selection of stakeholders, including associations representing dialysis patients, nephrologists, and dialysis organizations. Finally, we reviewed relevant documentation from CMS and interviewed CMS officials to obtain their perspective on

[5]GAO-11-365.

[6]In this report, we refer to the association representing small dialysis organizations as "small dialysis organizations." In addition, we refer to the five large dialysis organizations and an association representing small dialysis organizations as "all dialysis organizations."

[7]We selected the five large dialysis organizations based on data from CMS's Medicare Dialysis Facility Compare database. This database allows users to compare dialysis facilities nationwide based on factors such as the type of services and quality of care.

[8]This association represents both freestanding and hospital-based dialysis facilities.

challenges that dialysis organizations anticipate in dispensing phosphate binders.

To describe CMS's plans to monitor phosphate binder treatment under the bundled payment, we reviewed relevant documentation from CMS and clinical practice guidelines for the treatment of mineral and bone disorder. We conducted interviews with CMS officials about current and planned efforts to monitor quality and access. We also interviewed a nongeneralizable selection of stakeholder groups representing various perspectives and that were knowledgeable about mineral and bone disorder treatment and monitoring, including associations representing nephrologists, dialysis patients, and dialysis organizations.

We conducted this performance audit from October 2022 to November 2023 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.

Background

End-Stage Renal Disease Treatment

ESRD is a condition of permanent kidney failure for which treatment options include kidney transplantation or dialysis.[9] Dialysis is the treatment used by most Medicare beneficiaries with ESRD. Hemodialysis, the most common form of dialysis, is generally administered three times a week at dialysis facilities.[10] During hemodialysis, a machine pumps blood through an artificial kidney and returns the cleansed blood to the body.

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

[10]In 2020, approximately 61 percent of all patients with ESRD underwent hemodialysis therapy. United States Renal Data System, *2022 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States* (Bethesda, Md.: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases).

Patients may also receive dialysis at home.[11] About 14 percent of all ESRD patients received dialysis at home in 2020.[12]

One common complication of ESRD is mineral and bone disorder, which can result in a variety of clinical conditions in ESRD patients, including weak and brittle bones and cardiovascular disease. Mineral and bone disorder is associated with abnormal calcium, phosphorus, and parathyroid hormone levels in the blood. Therefore, 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 them. For instance, the phosphorous levels of individuals with ESRD may build up over time as their kidneys can no longer filter and remove excess phosphorous.[13] These high phosphorous levels can also adversely affect parathyroid hormone and calcium levels.

One common treatment of mineral and bone disorder is the use of phosphate binders to reduce elevated phosphorous levels.[14] Currently, phosphate binders are oral-only ESRD drugs and, as noted above, are covered under Medicare's outpatient prescription drug benefit (Part D). In 2020, over 60 percent of Medicare ESRD dialysis patients with Part D coverage were prescribed phosphate binders, and Medicare Part D plans paid almost $1 billion for these drugs.[15] Because phosphate binders prevent the body from absorbing the phosphorus individuals consume through food, these drugs are generally prescribed to be taken with every meal or snack.

[11]Home dialysis may be hemodialysis or peritoneal dialysis. 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.

[12]United States Renal Data System, *2022 USRDS Annual Data Report*.

[13]Phosphorous is naturally occurring in many foods, such as meat, beans, and dairy. Phosphorous is also used as an additive or preservative in processed foods.

[14]Other strategies for managing phosphorous levels may include reduction of dietary phosphorus and removal of phosphorus by dialysis.

[15]United States Renal Data System, *2022 USRDS Annual Data Report*.

There are several different types of phosphate binders, including calcium-based and non-calcium-based.[16] In 2020, the two most commonly dispensed phosphate binders were sevelamer carbonate–a non-calcium-based option—and calcium acetate—a calcium-based option.[17] Several types of prescription phosphate binders—including the most commonly used types—are available in generic versions, typically at a lower price.[18]

Medicare Payment for Dialysis Care

Medicare pays dialysis organizations a bundled payment for dialysis treatment provided to ESRD beneficiaries in Medicare's traditional fee-for-service program.[19] CMS calculates the bundled payment through a series of steps.

- Each bundled payment starts with the base payment rate. In 2023, the base rate is $266 per treatment. This payment is intended to cover all operating and capital costs that efficient providers would incur in furnishing dialysis treatments.
- For each treatment a beneficiary receives, CMS adjusts the base rate to account for various factors that are associated with the cost of dialysis care, including beneficiary characteristics (such as age and comorbid conditions) and facility characteristics (such as facilities that furnish a low volume of dialysis treatments).

[16]Calcium acetate is a calcium-based phosphate binder. Calcium carbonate, which is available over the counter, is also considered a calcium-based phosphate binder. Non-calcium-based phosphate binders include sevelamer carbonate, sucroferric oxyhydroxide, ferric citrate, lanthanum carbonate, and sevelamer hydrochloride. A patient's phosphate binder prescription may take into account various factors such as cost, pill burden, and effects on patient health. For instance, clinical treatment guidelines recommend limiting the use of calcium-based phosphate binders to avoid excessive exposure to calcium. Kidney Disease: Improving Global Outcomes, "Kidney Disease: Improving Global Outcomes 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder," *Kidney International Supplements*, vol. 7 no. 1 (2017).

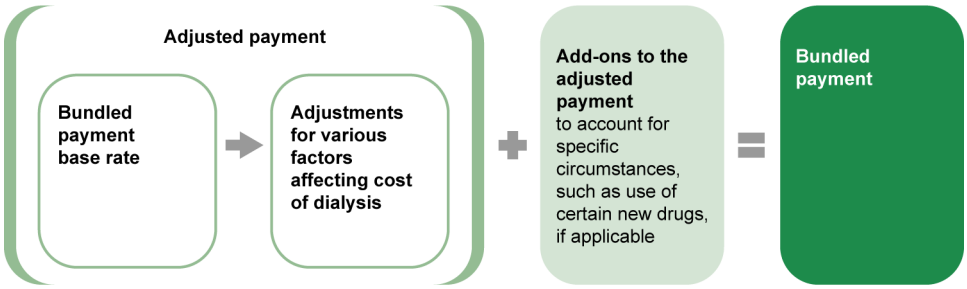
[17]In 2020, sevelamer carbonate was dispensed to 62 percent of beneficiaries on hemodialysis with Part D coverage who were prescribed phosphate binders, and calcium acetate was dispensed to 35 percent. United States Renal Data System, *2022 USRDS Annual Data Report.*

[18]Generic options are available for sevelamer carbonate, calcium acetate, lanthanum carbonate, and sevelamer hydrochloride. Generic options are not available for sucroferric oxyhydroxide and ferric citrate.

[19]The bundled payment does not apply to Medicare Advantage. Medicare Advantage plans are required to cover the same dialysis services that are included in the bundled payment. However, CMS is prohibited from requiring that Medicare Advantage plans use a particular price structure to pay contracted providers. See 42 U.S.C. § 1395w-24(a)(6)(B)(iii).

- CMS includes additional payments in the bundled payment based on specific circumstances that may affect the cost of dialysis care. These include high-cost outlier payments if a beneficiary's care is unusually costly or an add-on payment adjustment for new ESRD drugs.[20] See figure 1.

Figure 1: Components of the Bundled Payment to Organizations Providing Dialysis Care



Source: GAO analysis of Centers for Medicare & Medicaid (CMS) information. | GAO-24-106288

CMS has modified the ESRD bundled payment over time by including additional services and treatments. This has expanded the types of drugs that dialysis organizations provide.

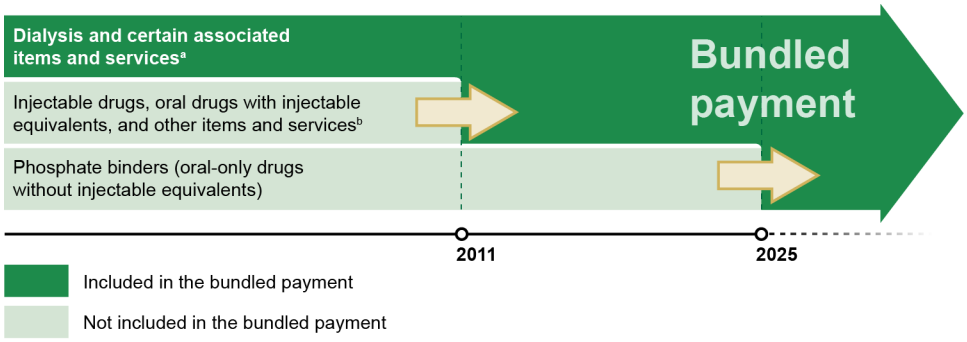
- **Prior to 2011**. The bundled payment covered dialysis treatment and some, but not all dialysis-related items and services during this time. Medicare paid dialysis organizations separately under Part B for injectable ESRD drugs, and oral ESRD drugs were covered under Part D.
- **2011 through 2024**. CMS modified the bundled payment to include additional dialysis-related items and services such as injectable ESRD drugs and oral ESRD drugs with injectable equivalents—such as vitamin D. In 2018, CMS included oral and injectable calcimimetics in the bundled payment after the Food and Drug Administration

[20]In response to a requirement that CMS establish a process for including new drugs in the bundled payments, the agency created this add-on payment that would be paid for a new drug during a transition period until CMS collects sufficient claims data for rate setting analysis. After the transition period ends, CMS may modify the bundled payment to account for the new drug. CMS has outlined under what circumstances it will and will not modify the bundled payment after the transition period. For instance, CMS will not modify the bundled payment if the new ESRD drug falls into certain existing drug categories that are already covered under the bundle. See 42 C.F.R. § 413.234 (2022).

approved an injectable equivalent to oral calcimimetics (making it no longer an oral-only ESRD drug).[21]

- **Beginning in 2025**. CMS plans to expand the bundled payment in 2025 to include phosphate binders, the only remaining oral-only ESRD drug.[22] As a result, Medicare will begin covering phosphate binders with the bundled payment under Part B rather than under Part D. See figure 2.

Figure 2: Expansion of Bundled Payment for Dialysis Care through 2025



Source: GAO analysis of Centers for Medicare & Medicaid (CMS) information. | GAO-24-106288

[a]Dialysis and certain associated services include dialysis treatment and associated routine items and services, such as nursing, equipment, and supplies.

[b]Injectable ESRD drugs include erythropoiesis stimulating agents, injectable iron, injectable vitamin D, and other injectable drugs. Other items and services include, for example, medical equipment and ESRD-related laboratory tests.

Monitoring Dialysis Treatment

The bundled payment system is intended to encourage efficient treatment, and monitoring can help to identify any unintended consequences to beneficiaries of adding a new item or service to the bundled payment. Such unintended consequences may include underutilization of drugs or other medically necessary treatments and potentially related detrimental effects on beneficiary health outcomes. We and others have noted the importance of monitoring quality of and access

[21]Like phosphate binders, calcimimetics are also used treat beneficiaries with mineral and bone disorder.

[22]See Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model, 87 Fed. Reg. 67,136, 67,180 (Nov. 7, 2022).

to care under bundled payment systems to help ensure that beneficiaries receive appropriate care.[23]

CMS monitors dialysis treatment under the bundled payment by collecting and reviewing relevant data from dialysis facilities. CMS has been monitoring dialysis treatment and health outcomes—like hospitalizations—since the bundled payment was established in 2011. CMS reported it has observed changes in the utilization of ESRD drugs when they were included in the bundled payment as a result of the bundled payment's incentives to provide care efficiently.[24] The agency reported that it has not observed any sustained increase in adverse health outcomes related to the inclusion of these drugs in the bundled payment. [25]

CMS also administers the Quality Incentive Program that links a dialysis facility's bundled payments to its performance on certain quality measures, which are evidence-based metrics used to assess aspects of health care quality. CMS scores facilities on these measures—for instance, using data that facilities submit through the agency's ESRD Quality Reporting System, which includes monthly data on patients' calcium and phosphorous levels.[26] CMS is required to include a quality

[23]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); GAO, *Skilled Nursing Facilities: Medicare Payment Changes Require Provider Adjustments but Maintain Access*, GAO/HEHS-00-23 (Washington, D.C.: Dec. 14, 1999); Melinda Beeuwkes Buntin, et al., *Inpatient Rehabilitation Facility Care Use Before and After Implementation of the IRF Prospective Payment System* (Santa Monica, Calif.: RAND Health, 2006); Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C., March 2000); and Department of Health and Human Services Office of Inspector General, *Effect of the Home Health Prospective Payment System on the Quality of Home Health Care*, OEI-01-04-00160 (January 2006).

[24]See 87 Fed. Reg. at 67,181.

[25]See 87 Fed. Reg. at 67,181.

[26]The ESRD Quality Reporting System is CMS's data collection system for dialysis facility, patient demographics, and clinical data. The beneficiary clinical data submitted by facilities are verified by comparing a sample of the clinical data submitted to facility patient records each year.

measure related to mineral and bone disorder in the Quality Incentive Program.[27]

CMS has developed two quality measures related to mineral and bone disorder: (1) an outcome measure that assesses the share of a facility's patients that have calcium levels above an established threshold (called hypercalcemia); and (2) a process measure that assesses whether a facility reported monthly data on patients' phosphorous levels (called phosphorous reporting). These measures have been subject to criticism because CMS's contractor for evaluating quality measures determined that they are "topped out"—meaning that dialysis facilities generally perform well on these measures leaving limited room for improvement.[28] As a result, CMS has modified the hypercalcemia measure and removed the phosphorous reporting measure from the Quality Incentive Program.[29]

[27]The requirement for measures specific to conditions treated with oral-only drugs states that the measure should be an outcome measure to the extent feasible. Outcome measures track the results of health care. Process measures assess the extent to which providers have taken steps or implemented processes of care that have been proven to benefit patients. The requirement also provides that measures should be endorsed (meaning a measure has been recognized as the best available for a given aspect of care) by CMS's contractor for evaluating quality measures called the consensus-based entity. See 42 U.S.C. § 1395rr(h)(2)(E).

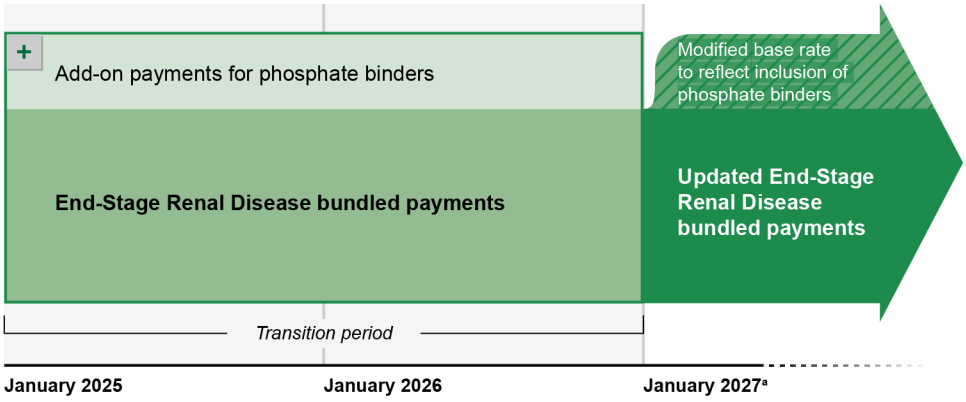
[28]Because these measures were topped out, CMS's contractor changed its endorsement of both measures to an inactive endorsement. This means the measures remain reliable and valid, but the measures no longer address high leverage areas for accountability purposes.

[29]In response to criticism of the hypercalcemia measure, CMS converted it to a process measure (called hypercalcemia reporting) to continue to meet the mineral and bone disorder measure requirement in the Quality Incentive Program beginning with calendar year 2023. This measure assesses the number of months in which a dialysis facility reports a patient's calcium levels. See 87 Fed. Reg. 67,136, 67,250 (Nov. 7, 2022). Previously, starting with calendar year 2019, CMS removed the phosphorous reporting measure because it determined that its outcome measure of hypercalcemia was a superior indicator of appropriate mineral and bone disorder treatment. See Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS, 83 Fed. Reg. 56,922, 56,986 (Nov. 14, 2018).

CMS Plans to Modify the ESRD Bundled Payment to Include Phosphate Binders after a Transition Period

CMS intends to finalize its plans to include phosphate binders in the bundled payment through its annual rulemaking process for updating the bundled payment. The agency's general plans include paying for this class of drugs using an add-on payment during a transition period of at least 2 years beginning in 2025.[30] Upon completion of this transition period, CMS plans to modify the bundled payment to reflect the inclusion of phosphate binders. See figure 3 for the proposed timing of these changes for phosphate binders.

Figure 3: Timing of CMS's Plans for Including Phosphate Binders in End-Stage Renal Disease Bundled Payments



Source: GAO analysis of Centers for Medicare & Medicaid (CMS) information. | GAO-24-106288

[a]CMS would modify the bundled payment to include phosphate binders after January 2027 if the agency extends the transition period.

Add-on payment during transition period. CMS plans to pay dialysis organizations for phosphate binders provided to Medicare fee-for-service beneficiaries using an add-on payment during the transition period.[31] The add-on payment for drugs added to the bundled payment is 100 percent

[30]In the calendar year 2023 final rule, CMS described the agency's general plans for including phosphate binders in the ESRD bundled payment beginning in 2025. See 87 Fed. Reg. 67,136, 67,180 (Nov. 7, 2022). CMS's proposed and final rules for calendar year 2025 ESRD payments are expected to be published in 2024.

[31]See 87 Fed. Reg. at 67,180. CMS established the add-on payment and transition period to help dialysis facilities incorporate into dialysis treatment new drugs and biological products, such as oral-only ESRD drugs. It also helps them make appropriate changes in their businesses to adopt such products, provides additional payments for associated costs, and promote competition among the products with similar functions, while focusing Medicare resources on products that are innovative.

of the average sales price for that drug, per regulation.[32] According to agency officials, during this transition period, CMS will collect utilization data for each type of phosphate binder through monthly claims that dialysis organizations submit to CMS for payment purposes.[33] CMS officials said they will analyze the utilization data to determine if it is necessary to extend the transition period to a third year in order to collect sufficient claims data to accurately set a payment rate. For example, CMS extended the transition period for calcimimetics to a third year because of the introduction of generic calcimimetics. CMS officials told us that an extension for a third year, if needed, would be proposed and finalized in the agency's annual updates to the bundled payment.

Modifying bundled payment after transition period. Once the transition period is complete, CMS plans to modify the bundled payment to account for the cost and utilization of phosphate binders. CMS officials said they will finalize the modification in the annual outpatient ESRD bundled payment rulemaking process.[34] CMS officials said that, to include phosphate binders in the bundled payment, they may use the same process the agency used to include calcimimetics in the bundled payment.[35] See text box for details on the process CMS used to include calcimimetics in the bundled payment.

[32]42 C.F.R. § 413.234(c) (2022).

[33]Medicare pays dialysis organizations for each dialysis treatment provided during a month.

[34]In the calendar year 2023 final rule, CMS reported that the agency will use the most recently available data as required by statute, in establishing payment for phosphate binders under the ESRD payment system. 87 Fed. Reg. 67,136, 67,180 (Nov. 7, 2022). The process for creating federal rules generally includes three main phases: initiating rulemaking, developing proposed rules, and developing final rules.

[35]CMS's process for including calcimimetics in the ESRD bundled payment is described in the agency's drug designation process at 42 C.F.R. § 413.234(f) (2022).

Centers for Medicare & Medicaid Services' Process for Modifying the Bundled Payment to Include Calcimimetics

Following the approval of an injectable calcimimetic, CMS began paying dialysis organizations for injectable and oral calcimimetics using an add-on payment as part of their ESRD bundled payment in January 2018.

CMS paid an add-on payment for 2 years and then decided to extend the transition period for calcimimetics to a third year. CMS extended the transition period because, due to the introduction of generic calcimimetics, CMS had not collected sufficient utilization data.

On January 1, 2021, CMS increased the base rate of the bundled payment for the inclusion of calcimimetics. Specifically, CMS

- determined the total expenditures for each type of calcimimetic—oral calcimimetics (generic and brand combined) and injectable calcimimetics—by multiplying utilization for each type of calcimimetics from July 1, 2018, through December 31, 2019, by the most recent average sales price for each type of calcimimetics, and then
- calculated the per-treatment increase to the bundled payment base rate by dividing the total expenditures for both types of calcimimetics by the total number of paid dialysis treatments for all Medicare fee-for-service beneficiaries during this same time period.

Source: GAO. I GAO 24-106288

We reported in 2011 that, according to CMS officials, the agency was limited to using Part D data on payments for oral-only ESRD drugs to account for these drugs in the bundled payment. As a result, the utilization and price data CMS would have used to modify the bundled payment may understate dialysis organizations' costs of providing these drugs because they (1) only reflected the utilization of Medicare fee-for-service beneficiaries with ESRD who were enrolled in a Part D plan; and (2) reflected the prices Part D plans negotiated with drug manufacturers, which could be lower than the prices paid by dialysis organizations.[36] If CMS uses the same process to modify the bundled payment to incorporate phosphate binders as the one used with calcimimetics, the process has the potential to address both of these data limitations in the following ways.

- First, the agency would use data on phosphate binder utilization collected during the transition period for all Medicare fee-for-service beneficiaries—not just those with Part D coverage—to determine by how much to modify the bundled payment to reflect the inclusion of phosphate binders.
- Second, the agency would use the most recent average sales price for phosphate binders to calculate the amount to increase the bundled payment base rate to reflect the inclusion of phosphate binders. The average sales price reflects the prices for each type of phosphate

[36]In 2020, approximately 79 percent of fee-for-service beneficiaries with ESRD were enrolled in a Medicare Part D plan. The prices negotiated by Part D plans could have been lower than what dialysis organizations would pay because dialysis organizations may have less negotiating power for oral-only ESRD drugs prices than Part D plans. Part D plans generally have larger numbers of beneficiaries than dialysis organizations and are providing a wider range of drugs.

binder paid to drug manufacturers by all purchasers, not just Part D plans.

While CMS has not finalized the process it will use to modify the bundled payment to include phosphate binders, the agency plans to use the most recently available data to do so, as required by statute.[37]

Dialysis Organizations Anticipate That Dispensing a High Volume of Phosphate Binders Will Require Expanding Existing Capacity

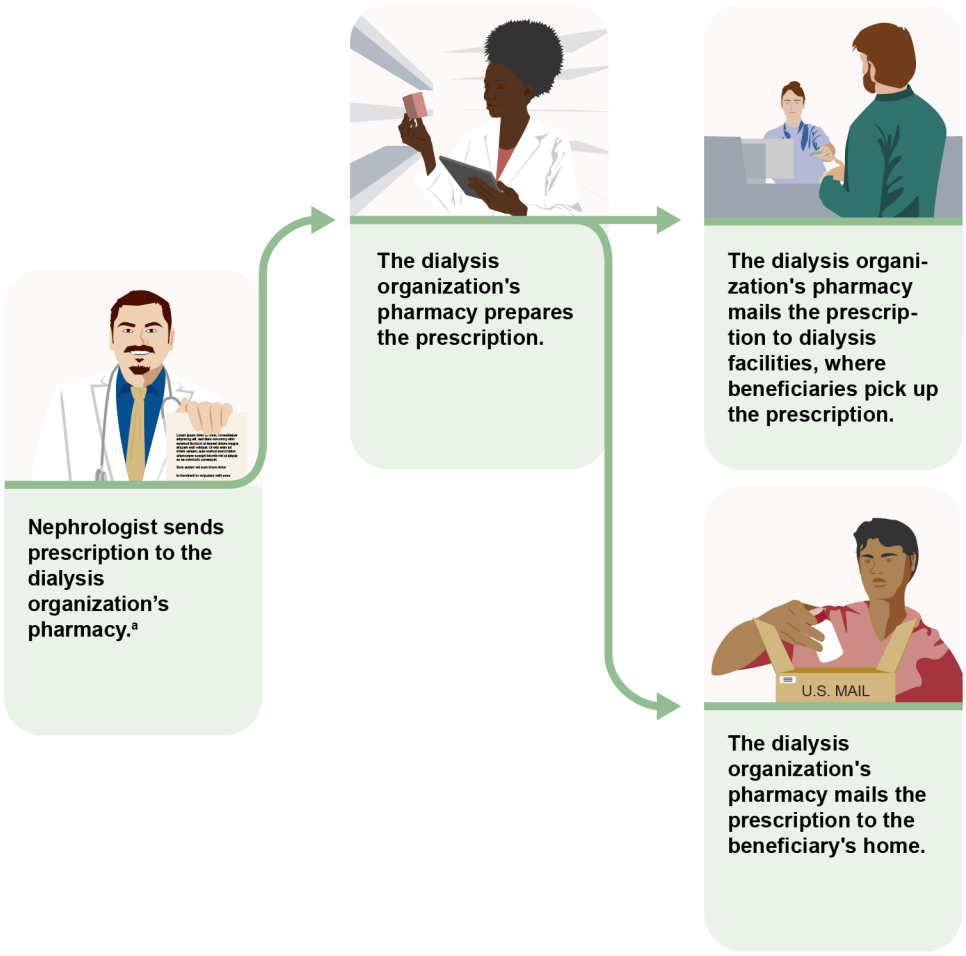
Representatives from all dialysis organizations we interviewed told us they currently dispense certain oral drugs to beneficiaries. These representatives also told us they anticipate that dispensing phosphate binders will require them to expand their existing capacity. According to the representatives, in comparison to other oral drugs that dialysis organizations currently dispense, dispensing phosphate binders will involve a higher volume of prescriptions and greater dispensing complexity.

Dialysis Organizations Say They Currently Have Capacity to Dispense Certain Oral Drugs to Medicare Beneficiaries

Representatives from all dialysis organizations we interviewed told us they currently dispense oral drugs included in the bundled payment to some Medicare beneficiaries, such as oral calcimimetics and oral vitamin D. While all representatives indicated they have the capacity to dispense oral drugs, the organizations use different processes for doing so. According to these representatives, the process they use to dispense oral drugs generally involves three steps (see fig.4).

[37]87 Fed. Reg. at 67,180.

Figure 4: Process Generally Used by Dialysis Organizations to Dispense Oral Drugs Included in Bundled Payment to Medicare Beneficiaries



Source: GAO analysis of interviews with dialysis organizations; GAO (illustrations). | GAO-24-106288

[a]Dialysis organizations can either operate their own pharmacy or contract with a pharmacy to prepare prescriptions for beneficiaries. We refer to both of these as "the dialysis organization's pharmacy."

Generally, dialysis organizations use the following steps to dispense oral drugs to beneficiaries:

- **Step one: nephrologist sends prescription to the dialysis organization's pharmacy.** All dialysis organization representatives we interviewed told us nephrologists send an electronic or written prescription for an oral drug to a pharmacy that the dialysis

organization either operates or contracts with, which we refer to as the "dialysis organization's pharmacy."

- **Step two: dialysis organization's pharmacy prepares the prescription.** Representatives of three of the five large dialysis organizations we interviewed told us they operate their own pharmacies. According to these representatives, operating their own pharmacy offered advantages such as managing costs and maintaining greater control of and more complete information on their patients' prescriptions. In addition, these representatives said they had already established their own pharmacies prior to the inclusion of oral calcimimetics in the bundled payment. Therefore, they were able to leverage their existing infrastructure to dispense oral drugs to beneficiaries once included in the bundle, according to these dialysis organization representatives. Representatives of the other two large dialysis organizations said they contracted with a pharmacy to dispense oral drugs, and small dialysis organizations representatives said they typically contracted with pharmacies as well. According to representatives of these dialysis organizations, they contract with a pharmacy because it can be difficult for a dialysis organization to operate a pharmacy—for instance, it can be challenging to navigate state pharmacy laws.
- **Step three: dialysis organization's pharmacy mails the prescription.** Representatives of four large dialysis organizations we interviewed told us their pharmacies mail oral drugs both to their dialysis facilities and to beneficiaries' homes.[38] When the oral drugs are mailed to dialysis facilities, the drugs are stored in their facilities and beneficiaries pick up the prescription when they receive treatment. Representatives of the other large dialysis organization told us their pharmacy only mails oral drugs to beneficiaries' homes. Representatives of small dialysis organizations we spoke with said they may use either of these strategies.

Dialysis organization representatives we interviewed told us multiple factors determine whether they mail oral drugs to beneficiaries' homes or to dialysis facilities for subsequent distribution to beneficiaries. According to representatives of all dialysis organizations we interviewed, dialysis organizations must comply with state pharmacy laws. Some of these representatives said that state laws may require that a dialysis

[38]Some dialysis organizations we interviewed also told us that for some patients receiving in-center dialysis, they administer oral calcimimetics—one of the oral drugs they are currently responsible for providing in the bundled payment—to beneficiaries three times per week when they receive dialysis treatment rather than dispensing a prescription.

organization's pharmacy mail drugs directly to beneficiaries' homes. Dialysis organization representatives noted that they also consider other factors, such as shipping costs or the need for storage, in determining whether to mail drugs directly to beneficiaries or to dialysis facilities. Representatives of one large dialysis organization told us their organization mails drugs directly to beneficiaries instead of storing and managing the distribution of these drugs to beneficiaries.

Dialysis Organizations Anticipate That Dispensing a High Volume of Phosphate Binders Will Require Expanding Existing Capacity

Representatives from all dialysis organizations we interviewed told us that dispensing phosphate binders will require them to expand their existing capacity to dispense oral drugs. They anticipate needing to expand capacity because dispensing phosphate binders involves a higher volume of prescriptions and greater complexity compared to other oral drugs, such as oral calcimimetics. For example, small dialysis organization representatives told us they expect the number of oral drug prescriptions they dispense will more than quadruple when phosphate binders are included in the bundle. Phosphate binders differ from the oral calcimimetics that dialysis organizations currently dispense in the following ways.

- **High volume of phosphate binders.** Phosphate binders are prescribed to a higher percentage of Medicare beneficiaries with ESRD. Medicare data show that in the last quarter of 2020, 62 percent of beneficiaries with ESRD utilized phosphate binders while 23 percent utilized oral calcimimetics.[39] In addition, beneficiaries who are prescribed phosphate binders typically take them with every meal and snack compared to calcimimetics, which are taken once daily.
- **Complexity of dispensing phosphate binders.** Phosphate binders are available in a variety of types, such as calcium-based or non-calcium-based, and beneficiaries may be prescribed multiple types of phosphate binders at one time. In addition, beneficiary prescriptions may change to ensure effective treatment of phosphorus levels and to

[39]Utilization data for each prescription is among Medicare fee-for-service beneficiaries enrolled in Part D and defined by the receipt of at least one dispensed prescription during the last quarter of 2020. United States Renal Data System, *2022 USRDS Annual Data Report.*

mitigate any side effects.[40] In contrast, there is only one type of oral calcimimetic.[41]

Dialysis organization representatives we interviewed described a number of adjustments that they anticipate needing to make in order to dispense phosphate binders.[42]

- **Updating information technology systems.** All dialysis organization representatives we spoke to told us that dispensing phosphate binders would require them to make changes to their systems such as their electronic medical record and billing systems. For example, representatives of one large dialysis organization said they will need to program their system to send phosphate binder prescriptions to their pharmacy and flag prescriptions that are likely to cause negative side effects for a particular beneficiary. Representatives of three large dialysis organizations we spoke to estimated it could take from 3 months to over a year to implement changes to their information technology systems.
- **Hiring additional staff.** Representatives of four of the five large dialysis organizations, as well as the small dialysis organizations interviewed, said they may need to hire additional staff—such as registered nurses, pharmacists, or clinical and administrative staff—to help manage the volume of phosphate binder prescriptions. For example, representatives of one large dialysis organization said they may hire additional staff to process additional prescription refills and manage beneficiary adherence. Representatives of another large

[40]One study found that 23 percent of patients taking phosphate binders changed the type of phosphate binder they were taking during a one-year period. Todd Berner et al., "Real-World Phosphate Binder Use Among Dialysis-Dependent Patients with CKD," *Nephron, (*2023): 6. https://doi.org/10.1159/000530230.

[41]There is one type of oral calcimimetics, which is available both as branded and generic. In addition, there is an injectable type of calcimimetics.

[42]Dialysis organization representatives we interviewed also indicated ongoing trends that, while not specific to phosphate binders, would pose challenges as they make the adjustments necessary to dispense phosphate binders. For example, representatives from all dialysis organizations we interviewed noted that an increasing share of dialysis organizations' patients are enrolling in Medicare Advantage plans. This dynamic increases work for dialysis organizations that have to manage contracts with multiple Medicare Advantage plans. The Medicare Payment Advisory Commission has reported that due to a statutory change allowing beneficiaries with ESRD to enroll in Medicare Advantage plans, enrollment of beneficiaries with ESRD in Medicare Advantage plans increased from 27 percent in December 2020 to over 40 percent in December 2021, while the share in fee-for-service decreased. Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: March 2023).

dialysis organization anticipate increasing staffing in their pharmacy as well as in its dialysis facilities. Representatives of three large dialysis organizations and of the small dialysis organizations we interviewed expect hiring additional staff to be challenging given that dialysis organizations currently experience difficulties maintaining sufficient staffing levels.

- **Establishing storage space.** Additional storage may be needed to accommodate the high volume of phosphate binders, according to representatives of four large dialysis organizations and the small dialysis organizations we interviewed. For example, representatives of one large dialysis organization told us they anticipate needing additional large filing cabinets to store these drugs and that they will have to comply with state requirements for storing these drugs in a secure location at their dialysis facilities.
- **Developing and implementing guidance for managing medications.** All dialysis organization representatives told us they have or are considering developing and implementing guidance to assist nephrologists in prescribing phosphate binders. Representatives of two large dialysis organizations noted that, while the guidance is intended to assist nephrologists, nephrologists would continue to maintain authority over prescribing. This guidance could, for example, help nephrologists identify opportunities to prescribe less expensive types of phosphate binders while maintaining beneficiary access to all types of phosphate binders, according to representatives of one of these dialysis organizations. These representatives of two large dialysis organizations also said they had developed and implemented similar guidance for other drugs in the bundled payment, such as calcimimetics.

All dialysis organization representatives we interviewed expressed concerns that CMS's plans to modify the bundled payment based on average sales price may not fully account for the costs associated with acquiring, shipping, and dispensing phosphate binders. The small dialysis organization representatives we interviewed told us they may not be able to negotiate competitive prices for phosphate binders with drug manufacturers because they lack the purchasing power of larger dialysis organizations. In addition, all dialysis organization representatives we interviewed expressed concerns that they risk financial losses when a beneficiary's prescription changes. Specifically, they noted that the dialysis organization would lose money if, when a beneficiary's prescription changes, the dialysis organization provides a new prescription before the beneficiary finishes the medications already dispensed.

CMS officials acknowledged that dialysis organizations would need to make operational adjustments to develop the capacity to dispense phosphate binders and also acknowledged dialysis organizations' concerns about payment adequacy. CMS officials expect that it will ultimately be feasible for dialysis organizations to develop the capacity necessary to dispense phosphate binders. CMS also expects dialysis organizations to determine the most appropriate way to dispense phosphate binders to ensure patients receive their required medications while mitigating their risk for drug costs, according to CMS guidance to dialysis organizations.[43] CMS officials stated that, as they finalize the process for modifying the bundled payment to include phosphate binders, they would assess the adequacy of the bundled payment as we previously recommended. They also said they would examine any concerns raised by the public through the rulemaking process to ensure that beneficiaries continue to have access to the medications they need.

CMS Plans to Monitor Utilization and Health Outcomes as Phosphate Binders Are Included in the Bundled Payment

CMS plans to monitor beneficiary utilization of phosphate binders and related health outcomes as it includes these drugs in the bundled payment, according to agency officials. Including phosphate binders in the bundled payment may result in changes in utilization as dialysis facilities adjust to this payment change. Therefore, CMS's monitoring plans are intended to identify any adverse effects on health outcomes of changes in utilization that may occur once these drugs are included in the bundled payment. CMS also plans to explore new quality measures that could further support its monitoring efforts.

Monitoring utilization and health outcomes. CMS plans to monitor beneficiary utilization of phosphate binders as well as beneficiary health outcomes that might be related to phosphate binder treatment as it includes these drugs in the bundled payment, according to agency officials. CMS officials also stated that the agency has begun its monitoring of phosphate binder utilization to establish a baseline period prior to the policy change. CMS plans to continue its monitoring on a monthly basis and plans to compare trends to the baseline period once the policy change is implemented, according to agency officials. In addition, CMS plans to monitor across beneficiary characteristics including race/ethnicity and dual eligibility status—those beneficiaries eligible for both Medicare and Medicaid.

[43]Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Implementation of the Transitional Add-on Payment,* MM10065 (Baltimore, MD: 2018).

Centers for Medicare & Medicaid Services (CMS) Monitoring of Calcimimetics in the Bundled Payment

CMS began monitoring utilization of calcimimetics and related health outcomes when these drugs were included in the bundled payment in 2018, according to agency officials. CMS officials noted that the agency continues this monitoring on an ongoing basis. Through this monitoring, CMS observed that utilization of calcimimetics increased overall and did not observe any sustained adverse health outcomes related to changes in utilization of calcimimetics.

In particular, CMS observed the following changes in the utilization of calcimimetics.

- During the transition period when Medicare coverage of calcimimetics shifted from Part D to Part B, utilization increased significantly, particularly among beneficiaries without Part D prescription drug coverage.
- Subsequently, when the bundled payment was modified to include calcimimetics, utilization (1) decreased relative to the transition period, and (2) shifted toward the less expensive oral calcimimetics from the more expensive injectable calcimimetics. These changes in utilization are consistent with the incentives of the bundled payment to provide these drugs more efficiently.

Source: Centers for Medicare & Medicaid Services (CMS). | GAO-24-106288

According to CMS officials, the agency's plans include monitoring trends in the following:

- Phosphate binder utilization by phosphate binder type, brand or generic drug use, and dialysis organization size.
- Beneficiary phosphorous and calcium levels. Changes in these clinical indicators may be associated with changes in phosphate binder utilization. For example, a beneficiary with high phosphorous levels may benefit from phosphate binder treatment to lower their phosphorous levels.
- Beneficiary health outcomes that may be associated with changes in phosphate binder utilization. For instance, CMS plans to monitor changes in adverse cardiovascular events—myocardial infarction and heart failure. CMS also plans to monitor changes in other adverse events that may be associated with changes in phosphate binder utilization, including: hospitalizations, fractures, strokes, parathyroidectomies—a procedure to remove one or more of the parathyroid glands—and calciphylaxis—a rare condition in which calcium accumulates in blood vessels.

Based on the experience incorporating calcimimetics into the bundled payment, agency officials expect overall phosphate binder utilization will increase and do not expect health outcomes to change noticeably when the agency includes phosphate binders in the bundled payment. Specifically, CMS expects that adding phosphate binders to the bundled payment may increase utilization among beneficiaries without Part D prescription drug coverage.

CMS officials also expect the type of phosphate binders prescribed may shift away from expensive options (like branded drugs) to less expensive options (like generic drugs) after the transition period ends. For example, CMS officials noted the potential that prescribing patterns may shift toward calcium-based phosphate binders. While calcium-based phosphate binders are inexpensive, clinical treatment guidelines recommend limiting the use of calcium-based phosphate binders to avoid excessive exposure to calcium.[44] As a result, if utilization of calcium-based phosphate binders increases, officials may expect to see an increase in beneficiaries' calcium levels through their monitoring efforts. However, as noted above, agency officials do not expect health outcomes

[44]Kidney Disease: Improving Global Outcomes, "2017 Clinical Practice Guideline Update."

to change noticeably when phosphate binders are included in the bundled payment.

Developing new quality measures. New quality measures related to treatment of mineral and bone disorder could enhance CMS's monitoring efforts when phosphate binders are included in the bundled payment and could also be used in CMS's Quality Incentive Program.[45] New measures could enhance CMS's monitoring efforts given the drawbacks of the existing mineral and bone disorder measures. According to officials, CMS plans to begin work with a contractor to develop new measures after August 2023. As part of the measure development process, CMS plans to hold a technical expert panel, comprised of experts with relevant knowledge and experience, to provide input on potential quality measures. CMS officials expect that measure development and implementation will be a multi-year process.

Although CMS plans to explore new quality measures related to mineral and bone disorder treatment, the persistent shortcomings in clinical evidence in this area will likely continue to pose challenges. CMS officials and the nephrologists we interviewed reported that there is general agreement that elevated phosphorous levels should be lowered, but there remains no consensus on what the target phosphorous levels should be. This lack of evidence has impeded the development of measures in the past. For instance, in 2011, CMS's quality measure contractor did not recommend outcome measures related to a target range for patients' phosphorous levels due, in part, to a lack of clinical evidence. Furthermore, CMS and nephrologists we interviewed noted that the complex interactions between phosphorous levels and other factors—such as beneficiary nutrition, dialysis treatments, and comorbidities—further complicate how to measure quality of phosphate binder treatment. For example, a beneficiary's phosphorus levels fluctuate in response to various factors other than phosphate binder utilization, such as timing of their last dialysis treatment or their recent diet, according to these nephrologists.

Agency Comments

We provided a draft of this report to the Department of Health and Human Services for comment. The agency provided technical comments, which we incorporated as appropriate.

[45]CMS is required to include a measure related to mineral and bone disorder and oral-only drugs in the Quality Incentive Program. Currently CMS meets this requirement with a measure of high calcium—called hypercalcemia.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report will be available at no charge on GAO's website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at gordonlv@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix I.

Leslie V. Gordon
Director, Health Care

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Appendix I: GAO Contact and Staff Acknowledgments

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Acknowledgments

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