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END-STAGE RENAL DISEASE

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

GAO Highlights

Accountability • Integrity • Reliability

Highlights of GAO-11-365, a report to congressional committees

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.

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.