



Highlights of [GAO-07-77](#), a report to the Chairman, Committee on Ways and Means, House of Representatives

Why GAO Did This Study

Medicare covers dialysis—a process that removes excess fluids and toxins from the bloodstream—for most individuals with end-stage renal disease (ESRD), a condition of permanent kidney failure. CMS pays for certain dialysis services under a type of bundled rate, called a composite rate, and, for certain dialysis-related drugs, pays a separate rate per dose each time the drug is administered. These drugs are referred to as “separately billable” and are paid at 6 percent above manufacturers’ average sales price (ASP). Recently, the Congress required CMS to explore the creation of a bundled payment for all ESRD services, including separately billable drugs. GAO was asked to examine (1) recent changes in payments for ESRD services, (2) the ASP payment method of setting rates for separately billable ESRD drugs, and (3) CMS efforts to develop a bundled payment method that includes all ESRD drugs. GAO obtained information for this study from CMS, the U.S. Renal Data System, ESRD experts, and previously issued GAO reports.

What GAO Recommends

The Congress should consider establishing a bundled payment system for all ESRD services, including drugs, as soon as possible. CMS generally agreed with GAO’s view, but said it needed to finalize, among other things, the development of a sound case-mix adjuster before bundling payment for all ESRD services.

www.gao.gov/cgi-bin/getrpt?GAO-07-77.

To view the full product, including the scope and methodology, click on the link above. For more information, contact A. Bruce Steinwald at (202) 512-7101 or steinwalda@gao.gov.

END-STAGE RENAL DISEASE

Bundling Medicare’s Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility

What GAO Found

The effect of several legislative and regulatory changes since 2003 has been to raise the composite rate while reducing Medicare’s pre-2005 generous payments for separately billable ESRD drugs. In 2005, when the first legislative change was implemented, Medicare expenditures for certain separately billable drugs dropped 11.8 percent. In 2006, Medicare regulation changed the payment for these drugs to a method based on ASP. Since then, Medicare’s payment rates have varied from quarter to quarter but have remained relatively consistent with the lower 2005 payment rates. Medicare’s cost containment efforts have targeted the most expensive of the separately billable drugs—Epogen®—for which program spending totaled \$2 billion in 2005. Epogen is used to treat anemia in ESRD patients; most patients receive this drug at nearly every dialysis session. Recent data indicate that Epogen use per patient continues to rise, although more slowly than in previous years.

Several unknowns about the composition of ASP and the lack of empirical evidence for the percentage level added to ASP make it difficult for CMS to determine whether the ASP-based payment rates are no greater than necessary to achieve appropriate beneficiary access. Paying for Epogen under the ASP method is of particular concern. The ASP method relies on market forces to moderate manufacturers’ prices; but Epogen is the product of a single manufacturer and has no competitor products in the ESRD market. Without competition, the power of market forces to moderate price is absent. For rarely used products, the lack of price competition may be financially insignificant, but for Epogen, which is pervasively and frequently used, the lack of price competition could be having a considerable effect on Medicare spending.

In 2003, the Congress required CMS to issue a report and conduct a demonstration of a system that would bundle payment for ESRD services, including drugs that are currently billed separately, under a single rate. The bundled payment approach, used to pay for most Medicare services, encourages providers to operate efficiently, as they retain the difference if Medicare’s payment exceeds the costs they incur to provide the services. GAO and others have found that a bundled rate for all ESRD services would have advantages for achieving efficiency and clinical flexibility in treating ESRD patients. CMS’s demonstration testing the feasibility of a bundled rate, mandated to start in January 2006, is delayed, as is the completion of the agency’s mandated report to the Congress on bundling. The report was due in October 2005; as of November 2006, CMS officials could not tell us when the report would be available.