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END-STAGE RENAL DISEASE

Medicare Should Pay a Bundled Rate for All ESRD Items and Services

Statement for the Record of A. Bruce Steinwald
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Mr. Chairman and Members of the Subcommittee:

I am pleased to provide, as requested, a statement for the record on Medicare payments for certain drugs provided to patients with end-stage renal disease (ESRD), a condition of permanent kidney failure.¹ Through Medicare's ESRD benefit, patients receive a treatment known as dialysis, which removes excess fluids and toxins from the bloodstream. Patients also receive items and services related to their dialysis treatments, including drugs to treat conditions resulting from the loss of kidney function, such as anemia and low blood calcium. Detailed information on the prudence of bundling payments for all ESRD items and services and a recommendation to establish a bundled payment system as soon as possible are included in our report entitled *End-Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All ESRD Services Would Promote Efficiency and Clinical Flexibility*.² This report, along with a testimony statement, was released at a December 6, 2006, hearing of the full Committee on Ways and Means.³ Today's statement highlights the information in that report and refers to information other witnesses presented at the hearing. The work we performed for the report was conducted in accordance with generally accepted government auditing standards.

¹These drugs are covered under Medicare Part B, the part of Medicare that covers a broad range of medical services, including physician, laboratory, and hospital outpatient services and durable medical equipment. Part B-covered drugs are typically administered by a physician or other medical professional rather than by patients themselves. In contrast, drugs covered under the new prescription drug benefit, known as Part D, are generally self-administered by patients.

²GAO, *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).

³GAO, *End-Stage Renal Disease: Medicare Payments for All ESRD Services, Including Injectable Drugs, Should Be Bundled*, [GAO-07-266T](#) (Washington, D.C.: Dec. 6, 2006).

Revised Medicare Payment Provisions Do Not Eliminate Incentives to Overuse Certain Drugs Billed for Separately

The way Medicare currently pays for injectable drugs provided to patients during dialysis treatments helps explain the potential for these drugs to be overused. The Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare program, divides ESRD items and services into two groups for payment purposes. In the first group are dialysis and associated routine services—such as nursing, supplies, equipment, and certain laboratory tests. These items and services are paid for under a composite rate—that is, one rate for a defined set of services. Paying under a composite rate is a common form of Medicare payment, also known as bundling. In the second group are primarily injectable drugs and certain laboratory tests that were either not routine or not available in 1983 when Medicare implemented the ESRD composite rate. These items and services are paid for separately on a per-service basis and are referred to as “separately billable.”

Over time, Medicare’s composite rate, which was not automatically adjusted for inflation, covered progressively less of the costs to provide routine dialysis services, while program payments for the separately billable drugs generally exceeded providers’ costs to obtain these drugs. As a result, dialysis facilities relied on Medicare’s generous payments for separately billable drugs to subsidize the composite rate payments that had remained nearly flat for two decades. In addition, the use of the separately billable drugs by facilities became routine, and program payments for these drugs grew substantially. In 2005, program spending for the separately billable drugs totaled about \$2.9 billion.

The effect of several legislative and regulatory changes since the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)⁴ has been to raise the composite rate for dialysis services while reducing Medicare’s generous payments for separately billable ESRD drugs. Under the first legislative change in 2005, Medicare expenditures for certain of these drugs dropped 11.8 percent. Under the current payment method—which for each drug equals the manufacturer’s average sales price (ASP) plus 6 percent—Medicare’s payment rates have varied from quarter to quarter but have remained relatively consistent with the lower 2005 payment rates.

⁴Pub. L. No. 108-173, 117 Stat. 2066.

The ASP-based rates are an improvement over the pre-MMA method, as ASP is based on actual transactions. However, certain unknowns about the composition of ASP and the ASP-based payment formula make it difficult for CMS to determine whether the ASP-based payment rates are no greater than necessary to achieve appropriate beneficiary access. For one thing, CMS has no procedures for validating the accuracy of a manufacturer's ASP, which is computed by the manufacturer. For another, CMS has no empirical justification for the 6 percent add-on to ASP. Regardless of how payment for these drugs is calculated, as long as facilities receive a separate payment for each administration of each drug and the payment exceeds the cost of acquiring the drug, an incentive remains to use more of these drugs than necessary.

The ASP payment method is of particular concern with respect to Epogen®, which in 2005 accounted for \$2 billion in Medicare payments and is Medicare's highest Part B expenditure drug.⁵ Most ESRD patients receive injections of Epogen at nearly every dialysis treatment, and whether Epogen is being overused has been called into question by some experts. At the December 2006 hearing of the full Committee, expert witnesses discussed their study results regarding Epogen use. One study found that kidney disease patients who were given high levels of Epogen experienced a higher risk of cardiovascular events and mortality than those who received lower levels of the drug.⁶ Another study found that Medicare spent at least a third more on Epogen—amounting to hundreds of millions of dollars—than it would have if the levels of Epogen administered were in line with practice guidelines recommended by the National Kidney Foundation.⁷

⁵Introduced in 1989, Epogen—the brand name for epoetin alpha—was an expensive breakthrough drug used to treat anemia in patients with ESRD. In treating anemia—a condition in which not enough red blood cells carry oxygen throughout the body—Epogen is used to achieve a certain level of hemoglobin, the part of the red blood cell that carries oxygen. The National Kidney Foundation develops guidelines on the optimal hemoglobin range.

⁶See Ajay Singh et al., "Correction of Anemia with Epoetin Alfa in Chronic Kidney Disease," *The New England Journal of Medicine*, vol. 355, no. 20 (Nov. 16, 2006).

⁷See Laura Pizzi et al., "Economic Implications of Non-Adherence to Treatment Recommendations for Hemodialysis Patients with Anemia," *Dialysis and Transplantation*, vol. 35, no. 11 (November 2006).

Our own study found that Epogen use, which grew rapidly in the years before the MMA provisions took effect, continued to grow through the first half of 2006, although at a slower rate than previously. Epogen is the only product available in the domestic ESRD market for anemia management. However, the ASP method relies on market forces to achieve a favorable rate for Medicare. When a product is available through only one manufacturer, Medicare's ASP rate lacks the moderating influence of competition. The lack of price competition may be financially insignificant for noncompetitive products that are rarely used, but for Epogen, which is pervasively and frequently used, the lack of price competition could be having a considerable adverse effect on Medicare spending.

Bundled Payment System for ESRD Services, Including Injectable Drugs, Would Promote Efficiency and Clinical Flexibility

Medicare's approach to paying for most services provided by health care facilities is to pay for a group—or bundle—of services using a prospectively set rate. For example, under prospective payment systems, Medicare makes bundled payments for services provided by acute care hospitals, skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities. In creating one payment bundle for a group of associated items and services provided during an episode of care, Medicare encourages providers to operate efficiently, as providers retain the difference if Medicare's payment exceeds the costs they incur to provide the services. Medicare's composite rate for routine dialysis and related services was introduced in 1983 and was the program's first bundled rate.

Experts contend that a bundled payment for all dialysis-related services would have two principal advantages. First, it would encourage facilities to provide services efficiently; in particular, under a fixed, bundled rate for a defined episode of care,⁸ facilities would no longer have an incentive to provide more ESRD drugs than clinically necessary. Second, bundled payments would afford clinicians more flexibility in decision making because incentives to prescribe a particular drug or treatment are reduced. For example, providers might be more willing to explore alternative methods of treatment and modes of drug delivery if there were no financial benefit to providing more drugs and services than necessary.

⁸In the case of the composite rate, one dialysis session constitutes an episode of care. Unlike this method, a newly designed payment bundle could define the episode of care more broadly. For example, the new payment bundle could cover dialysis and related items and services for 1 month.

In response to a congressional mandate that CMS study the feasibility of creating a bundled payment,⁹ the agency issued a study in 2003 concluding that developing a bundled ESRD payment rate was feasible and that further study of case-mix adjustment—that is, a mechanism to account for differences in patients’ use of resources—was needed. In the MMA, the Congress required CMS to issue a report and conduct a 3-year demonstration of a system that would bundle payment for ESRD services, including drugs that are currently billed separately, under a single rate.¹⁰ Both the CMS report, due in October 2005, and the demonstration, mandated to start in January 2006, are delayed.

Any payment changes based on CMS’s report or demonstration would require legislation, because the MMA specified that drugs billed separately in 2003 would continue to be billed separately and not bundled in the composite rate.¹¹ In light of the uncertain time frame for CMS’s test of bundling and the need for explicit legislation, in our report we asked the Congress to consider establishing a bundled payment for all ESRD services as soon as possible. In our view, Medicare could realize greater system efficiency if all ESRD drugs and services were bundled under a single payment. A bundled payment would encourage facilities to use drugs more prudently, as they would have no financial incentive to use more than necessary and could retain the difference between Medicare’s payment and their costs. To account for facilities’ increased or decreased costs over time, a periodic reexamination of the bundled rate may be necessary. This would ensure that facilities would be paid appropriately and that Medicare could realize the benefit of any cost reductions.

Contacts and Acknowledgments

For more information regarding this statement, please contact A. Bruce Steinwald at (202) 512-7114 or steinwalda@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Phyllis Thorburn, Assistant Director; Jessica Farb; and Hannah Fein made key contributions to this statement.

⁹Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub L. No. 106-554, app. F, § 422(b) and (c), 114 Stat. 2763A-463, 2763A-515—2763A-517.

¹⁰Pub. L. No. 108-173, § 623(e)–(f), 117 Stat. 2066, 2315-17.

¹¹MMA § 623(d)(1), § 1881(b)(13)(B), 117 Stat. 2314-15 (to be codified at 42 U.S.C. § 1395rr(b)(13)(B)).

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