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END-STAGE RENAL DISEASE

Medicare Payments for All ESRD Services, Including Injectable Drugs, Should Be Bundled

Statement of David M. Walker
Comptroller General of the United States



Mr. Chairman and Members of the Committee:

I am pleased to be here to discuss highlights from 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*.¹ The report examines Medicare payments for certain drugs provided to patients with end-stage renal disease (ESRD), a condition of permanent kidney failure.²

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. 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

¹GAO, *End-Stage Renal Disease: Bundling Medicare's Payment for Drugs with Payment for All Services Would Promote Efficiency and Clinical Flexibility*, [GAO-07-77](#) (Washington, D.C.: Nov. 13, 2006).

²These 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.

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 accounted for about \$2.9 billion. Medicare's payment for these separately billable drugs is the focus of my remarks today. My remarks are based on the information included in our aforementioned report.

Background

Since the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) was passed,³ how separately billable drugs are paid for has changed—from payment based on each drug's average wholesale price (AWP),⁴ to payment based on each drug's average acquisition cost, to payment based on the manufacturer's average sales price (ASP) for each drug. Specifically, beginning in 2006, payment for each drug is set at ASP + 6 percent.

In recent years, CMS has been exploring, as required by the Congress, the creation of a bundled payment for all ESRD services, including the drugs that facilities currently bill for separately. In response to a mandate that CMS study the feasibility of creating a bundled payment,⁵ 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 that CMS report on the design of a bundled prospective payment system for ESRD services, including a case-mix adjustment methodology, and conduct a 3-year demonstration to test the design of a bundled ESRD payment system.⁶

³Pub. L. No. 108-173, 117 Stat. 2066.

⁴Epogen, one of the separately billable drugs, was not paid under the AWP method. The method Medicare used to pay for Epogen was an amount set in statute for a single year—\$10.00 per 1,000 units in 1994. CMS continued to pay this rate at its discretion until 2005.

⁵Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub L. No. 106-554, app. F, § 422(b),(c), 114 Stat. 2763A-463, 2763A-516-517.

⁶Pub. L. No. 108-173, § 623(e),(f), 117 Stat. 2066, 2315-2317.

New Payment Provisions Reduced Subsidy from Separately Billable Drugs but Did Not Eliminate Incentives to Overuse These Drugs

The effect of several legislative and regulatory changes since 2003 has been to raise the composite rate for dialysis services while reducing Medicare's pre-2005 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, based on the ASP for each drug, Medicare's payment rates have varied from quarter to quarter but have remained relatively consistent with the lower 2005 payment rates.

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. Introduced in 1989, Epogen—the brand name for epoetin alpha—was an expensive breakthrough drug used to treat anemia in patients with ESRD. Most ESRD patients receive injections of Epogen at nearly every dialysis treatment. Preliminary data for 2006 suggest that Epogen use, which grew rapidly in the years before the MMA provisions took effect, continues to grow, 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,⁷ 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 services than necessary.

In the MMA, 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. Any payment changes based on CMS's report or demonstration would require legislation.⁸ Both the report, due in October 2005, and demonstration, mandated to start in 2006, are delayed, and CMS officials could not tell us when the report or results from the demonstration would be available.

⁷In the case of the composite rate, one dialysis session constitutes an episode of care. Unlike the current composite rate payment 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.

⁸The MMA specified that drugs billed separately at the time the legislation was enacted continue to be billed separately and not bundled in the composite rate. MMA sec. 623 (d)(1), § 1881 (b)(13)(B), 117 Stat. 2314-15 (to be codified at 42 U.S.C. § 1395rr(b)(13)(B)).

In light of these circumstances, we have 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 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.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions you or the other Committee Members may have.

Contacts and Acknowledgments

For further information regarding this testimony, please contact A. Bruce Steinwald (202) 512-7101 or steinwalda@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Phyllis Thorburn, Assistant Director; Jessica Farb; and Hannah Fein made key contributions to this statement.

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