

THE KIDNEY CARE COUNCIL

BASIC POLICY PARAMETERS OF A BUNDLED PAYMENT SYSTEM CRITICAL DESIGN FEATURES FOR CREATING A VIABLE BUNDLE

Overview

At present, Medicare pays suppliers of dialysis services using a bundled approach. Routine costs for supplies, equipment, space and other overhead, personnel, some laboratory tests and some drugs that are necessary for conducting the procedure are paid by a per-treatment prospective payment referred to as the “composite rate.” This rate varies to reflect the acuity (or “case mix”) of individual patients and is also adjusted geographically consistent with Medicare methodology for other providers. In 2007, the base composite rate for free-standing facilities was approximately \$133.¹ The average drug add-on payment was approximately \$20. Under current law, certain drugs and clinical laboratory tests are excluded from the composite rate and paid separately. Payments do not vary at present to reflect the quality of care delivered.

The Centers for Medicare & Medicaid Services (CMS), the Medicare Payment Advisory Commission, the Government Accountability Office (GAO), and some in Congress have noted that an expanded payment bundle would improve efficiency and clinical flexibility. The Medicare Modernization Act of 2003 (MMA) requires CMS to design a modified system that would no longer pay for each injectable end stage renal disease (ESRD) drug under a separate rate but would bundle payment for these drugs together with other ESRD items and services under a single rate. The MMA also mandated a demonstration testing the feasibility of such a system. Both CMS’s design report and the demonstration are delayed.

In light of Congress’ interest in establishing a bundled payment system for all ESRD services, and the uncertain timeline necessary for CMS to test bundling, the Kidney Care Council (KCC) submits the following key policy parameters it believes are essential for any new bundled payment system. These general points are not specified in detail but are offered as guideposts for legislative decision making.

Policy Parameters

I. BUNDLE PURPOSE, APPLICATION AND KEY COMPONENTS

A. Purpose.

A viable bundling policy should assure continued improvement in the quality of patient care delivery, foster continued improvement in clinical outcomes, better control overall Medicare costs, and ensure patient access to this life-saving therapy. Expanding the payment bundle may help create a more rational and consistent payment structure and

¹ Hospital-based facilities are paid an average of about \$4 more than free-standing facilities.

afford physicians and facility managers strong incentives to improve quality and efficiency.

B. Application.

The payment bundle should apply to a single unit of service, defined as one treatment, regardless of where that treatment is provided. The hospital rate differential – currently about \$4 more per treatment than the in-center rate – should be eliminated, and payments should be site neutral, consistent with Medicare Payment Advisory Commission (MedPAC) recommendations. The unit of service, across all settings, should be by treatment to ensure that all beneficiaries receive adequate access to dialysis services and that potential changes to clinical standards and/or the adoption of more frequent dialysis treatments are not obstructed by a monthly or weekly payment policy.

C. Special Provision for Erythropoietin Stimulating Agents (ESAs).

The GAO noted in a November 2006 report to Congress on dialysis bundling that, in the context of Average Sales Prices (ASP)-based payment methodology for ESRD drugs, the moderating influence of competition is absent from the marketplace for single source pharmaceutical products critical to the management of dialysis patients.² This lack of competition could have a considerable impact on the seller's pricing practices that could disadvantage providers subjected to a fixed bundled rate.

- ESAs are a necessary part of the standard of care for dialysis therapy provided to ESRD patients.
- ESAs represent a very high proportion, 25%, of Medicare's costs for patients on dialysis.
- ESAs are manufactured by a single source seller. This seller has increased the price of this drug over the years.
- With a fixed payment bundle, providers would be uniquely vulnerable to these price increases.

The success of any policy that expands the composite rate bundle will depend critically on provisions to protect providers from increases in the price of ESAs that are not adequately addressed by annual Medicare payment increases. Examples of protective measures that would shelter providers from incremental or dramatic single source pharmaceutical price increases might include changes to drug reimbursement methodology for ESRD-related drugs, including:

- Adding ESAs into the payment bundle, but providing an "opt-in" mechanism that allows providers to choose whether or not to participate;
- Excluding ESAs from the payment bundle and establishing a statutory rate for the drug. If this option is chosen, any differential in drug price up to

² Government Accountability Office, Report to the Chairman, Committee on Ways and Means, House of Representatives, *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 (November 2006).

but not exceeding 6 percent must be moved into the composite rate to prevent disruption in patient access to dialysis services; or

- Adding ESAs into the payment bundle and establishing a single statutory per-case rate for the drug.

D. Additional Components.

The expanded payment bundle should include those services now included in the bundle plus those drugs and services that are commonly provided to ESRD patients during the provision of dialysis care. Additional elements should include:

- The annually-adjusted drug add-on amount.

Other items and services of an expanded bundle may include:

- Specified drugs that are routinely administered in the dialysis unit, including vitamin D analogs (IV), iron (IV) and others (antibiotics). Erythropoietin presents distinct issues and requires protective measures, as outlined above.

E. Exceptions.

As at present, physicians' services should be paid separately, not as part of the expanded bundle. The expanded bundle should also exclude, blood products, non-ordinary course high cost drugs, nutritional supplements, access monitoring care services and new technologies as they arise (see below).

The expanded bundle should exclude additional laboratory tests beyond those currently included in the bundle. The current composite rate includes those tests that are routinely used on a monthly basis. This well-established set of tests provides the basic and fundamental information needed for the monthly management of patients on dialysis. Other tests are used on a much less frequent or much less routine basis and do not appear to be suitable candidates for inclusion in the composite rate, which is the rate for a bundle of services provided daily. In 2005, the Advisory Board on the Demonstration of Payment System for ESRD Services noted: "A broader bundling requirement under which all or most laboratory tests would be bundled would create significant administrative responsibilities for the dialysis facility, would require complex exceptions for tests that cannot be delayed or obtained through the facility, and would have potentially adverse effects on quality of care." In addition, "Medicare would need to establish rules defining the obligation of dialysis facilities to supply laboratory testing data and/or to perform or pay for tests ordered by physicians and other practitioners not affiliated with the facility." Consequently, no changes in this set of tests included in the composite rate should be made at this time.

II. CRITICAL DESIGN FEATURES

A. Risk Adjustment.

The revised payment system (the expanded bundle) must include a risk adjustment mechanism or mechanisms with a high degree of validity and reproducible predictors of resource consumption for drug utilization within the expanded bundle.

B. Outliers.

Dialysis facilities need resources to accommodate unusually high-cost patients, with exceptional ESA utilization. The revised payment system should include an appropriate outlier mechanism to account for the one percent of patients whose care requires extraordinarily high resources.

C. New Drugs and Technology Pass-Through Policy.

The revised payment system should include a mechanism, similar to the “transitional pass-through payment” provision in the outpatient prospective payment system that exempts new technologies from the payment bundle for a reasonable period of time by allowing costs to be “passed through” and paid separately for two to three years. New drugs should be paid at ASP+6 percent and other new technology should be paid to reflect incremental cost for the pass-through period.

D. Budget Neutrality.

The revised payment system should be budget neutral in the first year of its implementation. It should be designed to result in the same aggregate amount of expenditures for such services as would be made if the revised payment system was not implemented. In addition, the revised payment system should include a two-year look back mechanism that requires adjustment of baseline spending in out-years to compensate for any variation between estimated and actual spending in the first year. The baseline must include assumption of a permanent annual update.

E. Permanent Annual Update.

Reflecting recent MedPAC recommendations for positive updates to the composite rate, the revised payment system must include a permanent mechanism that generates a predictable, annual payment update for providers using the CMS-developed ESRD market basket adjustment.

G. Inspector General Studies on Utilization Patterns.

To reduce risk that the initial payment bundle is set using inappropriate utilization levels, the policy should include a requirement that the Office of Inspector General (OIG) analyze utilization values with the most recent data available in the six-month period

before implementation. Section 623(c) of the MMA, which mandated OIG studies on ESRD drugs, may be an appropriate model.

H. Quality Monitoring.

CMS should be directed to collaborate with the provider community to identify and track metrics that accurately measure care, quality and clinical performance under the revised payment system.

Facilities, providers, and physicians should report quality data, based upon clinical quality of life measures developed in consultation with the kidney care community and receive quality bonus payments based upon the attainment of benchmarks and maintenance of outcomes. Bonus payments could be drawn from a portion of an annual update, which would link the annual update to clinical performance consistent with section 203 of The Kidney Care Quality and Education Act (KCQEA – H.R. 1193 – J. Lewis/Camp; S. 691 – Conrad).

I. 12-Month Extension of Medicare Secondary Payer Period.

To offset any net cost resulting from the above policy changes, Congress should extend the Medicare Secondary Payer (MSP) period. The KCQEA proposes an extension of 12 months, from the current 30-month period to 42 months. In its 2007 Budget Options Book, the Congressional Budget Office (CBO) proposes an extension to 60 months and scored this change as saving \$3.07 billion over 10 years.

Congress has extended the MSP period three times in the past (to 12 months in 1981, to 18 months in 1990, and to 30 months in 1997). During the same period of time, patient access to disease management services has increased, and further private payer investment in patient health and well-being is anticipated if Congress acts to extend the current MSP period.

J. Cost Reporting Reform.

With a revised payment system, CMS should collect the appropriate financial information which would allow accurate monitoring of program margins, calculation of the annual market basket and potentially expanding the payment bundle over time. The current cost report template was last revised in the 1980s and has not kept pace with the changes in the program. The cost report form should be revised to capture detailed cost data reflecting the full and reasonable costs of services related to the care of covered beneficiaries.