



THE KIDNEY CARE COUNCIL

HHS REPORT TO CONGRESS:

“A Design for a Bundled End Stage Renal Disease Prospective Payment System”

A RESPONSE FROM THE NATION’S LEADING PROVIDERS OF DIALYSIS CARE

The Kidney Care Council (KCC) supports many of the findings of the Department of Health and Human Services (HHS) in its Report to Congress, “A Design for a Bundled End Stage Renal Disease Prospective Payment System”, transmitted in February 2008. The Report presents a thoughtful, practical design for a modernized, comprehensive, case-mix adjusted prospective payment system (PPS) that Medicare could use to pay prospectively for dialysis services with appropriate updates to reflect technological change, changes in productivity, and inflation. We believe the time is ripe for this reform and urge Congress to enact needed changes in the Medicare law as soon as possible.

The KCC in particular applauds the work of HHS and other policymakers in Congress and the Executive Branch who for years have sought a more accurate, refined and fair payment system for dialysis services. We believe the Report presents a viable path by which to expand the current bundle of services for patients with end stage renal disease (ESRD).

In some instances, the Report leaves open important details about the basic design features of an expanded bundle and other elements that need to be resolved for a new payment system to be fully successful. In other instances, the Report presents multiple options for consideration. The following pages set forth the KCC’s response to the Report, making recommendations where options are presented and offering suggestions for further refinement before Congress legislates.¹ We think Congress should enact appropriate reforms in payment for treatment of ESRD quickly in order to secure the advantages of these reforms without delay. We look forward to working with Congress and the Executive Branch in achieving a successful policy design.

I. DESIGNING A COMPREHENSIVE PROSPECTIVE PAYMENT SYSTEM FOR THE MEDICARE ESRD PROGRAM

A. Purpose.

The KCC shares HHS’ view that important objectives of a viable ESRD payment reform, including expanding the current bundle, are to design an adequate dialysis payment system that encourages and rewards clinical excellence in a way that saves

¹ In general, this discussion follows the outline of the KCC’s initial bundling recommendations shared with Congress and the policy community in 2007. See http://www.kidneycarecouncil.org/files/white_paper/the_first.swf

taxpayers money when total cost is considered. A comprehensive ESRD prospective payment system, which would also include new risk-adjustors and an annual update mechanism, could also foster continued improvement in clinical outcomes.

B. Scope of Services.

The Report presents two versions of an expanded bundle. The KCC supports a modified version of the “alternate” bundle with appropriate modifications. An expanded 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 payment and may include routine ESRD-related laboratory tests and specified drugs that are routinely administered in the dialysis unit, including vitamin D analogs (IV), iron (IV) and others (antibiotics).

The Report also discusses very briefly a possible further expansion of the bundle to include physicians’ services, blood products, non-ordinary course high-cost drugs, nutritional supplements, access monitoring care services, and new technologies as they arise. The KCC believes that, while inclusion of such services might hold some promise in the future, adding them would make the reform more risky. Adding such services to the bundle could present significant operational difficulties and may be of questionable value. Accordingly, we believe extensive analysis of the operational implications and possible impacts of such an expansion is necessary before this option could be considered ready for enactment. Thus, for the time being, Medicare should continue to pay for these items and services separately.

C. Unit of Payment.

The difficulties of implementing a new payment system are multifaceted and we agree with the conclusion of HHS that further analysis would need to be conducted before a per-month approach could be implemented. Therefore the KCC prefers that the unit of payment for a comprehensive ESRD PPS be a single unit of service defined as one treatment regardless of where that treatment is provided, and that the complexity of changing the unit of payment not be considered at this time. In particular the KCC is concerned that a per-month approach, which HHS acknowledges would require further study before implementation, might present operational difficulties in determining months in which patients received dialysis in multiple facilities, as may occur when patients travel, and who bears responsibility for making prorated facility payments in months that include inpatient stays.

D. Base Payment.

An essential feature of a comprehensive ESRD PPS is the establishment of a base payment rate. The Report sets forth a base rate that represents an estimate of the Medicare Allowable Payment (MAP) for combined composite rate and separately billable outpatient dialysis services of \$234.66 in 2006 dollars, a figure that appears to understate or ignore annual growth in the drug add-on amount, resulting in a lower overall payment

level.² As the Report recognizes, this amount is nearly five percent lower than the actual amount HHS estimates would be paid under the current methodology, which is \$245.18 per treatment based upon composite cost averaged in 2002-2004. Considering the normal increase in nursing labor costs and other inflationary pressures, it is likely that the MAP is even more than five percent short of actual cost. The base rate should be set at a level that at least covers the cost of providing services to beneficiaries and should be updated for changes in the drug add-on payment as well as interim updates to the composite rate. The Report relies on 2006 reimbursement data that fails to accurately capture the current cost per treatment. As Congress works to establish base payment rates, the KCC urges Congress to set the bundle's initial payment structure based on the most current available data at the time the expanded bundle is initiated, and to include appropriate adjustments to insure that the new bundle is budget neutral to the old.

E. Payment Adjustments.

1) Case-Mix Adjustment.

The KCC agrees that any comprehensive ESRD PPS must be appropriately case-mixed. The Report indicates that relevant case-mix adjustment factors include: age, gender, body surface area, underweight, duration of RTT, alcohol/drug dependence, cardiac arrest, pericarditis, HIV/AIDS, hepatitis B, specific infections (septicemia, bacterial pneumonia, etc.), gastro-intestinal bleeding, sickle cell anemia, cancer, myelodysplastic syndrome, and monoclonal gammopathy since 1999. The analysis presented in the Report indicates that these are the most appropriate predictors available for clinical resource use; however, the Report acknowledges that it fell short of fully explaining variation in pharmaceutical utilization. We recommend that the Centers for Medicare & Medicaid Services (CMS) work closely with the kidney care community to ensure that any case-mix adjustors are fully considered and take into account appropriate clinical data and experience before they are implemented in the payment system. In addition, adjustors for use of clinical resources and for use of pharmaceuticals in particular may require further modification and refinement as the new system matures.

2) Outlier Payment.

The KCC believes that outlier adjustments to account for patients whose care requires extraordinarily high resources should be included in a comprehensive ESRD PPS. Yet, we agree with HHS that additional information and analysis may be required before specific thresholds are established.

3) Other Adjustments.

The Report predicts that as a result of the new system, changes in average payments to rural facilities would be reduced by -0.7 percent, and suggests that special

² Composite rate services average MAP (\$151.48) + Separately billable services average MAP (\$83.18) = \$234.66. The Medicare Modernization Act of 2003 requires CMS, beginning in 2006, to annually increase the add-on payment based on the estimated growth in drug spending from the previous year. The 2007 add-on payment of 14.9 percent of the composite rate includes an update of 0.5 percent. The 2008 add-on payment of 15.5 percent also includes an update of 0.5 percent. *See* Medicare Payment Advisory Commission, Report to Congress: Medicare Payment Policy (March 2008) at 127.

adjustments for rural areas may not be warranted. The KCC believes that the statute should permit such an adjustment in the initial implementation, or in the future as the new policy's impact on rural facilities and on access to services in rural areas is studied and more fully understood. However, the KCC believes other adjustments, like those the Report suggests could be made on the basis of chain or ownership size, may not be appropriate and are without precedent elsewhere in Medicare payment policy. Additionally, the Medicare Payment Advisory Commission (MedPAC), in recommendations and commentary to Congress, consistently supports principles of payment neutrality.³

F. Permanent Annual Update.

The KCC believes that any transition to a comprehensive PPS and an expanded bundling methodology must be accompanied by a permanent, automatic annual market basket update mechanism that adequately recognizes the inflationary cost increases providers experience. To achieve its intended purposes and facilitate access to high quality care, the expanded bundle must be supported by proper funding in the base rate and a stable automatic mechanism for providing annual updates. The Report discusses in detail how one might be constructed based largely on the updates used for other Medicare prospective payment systems where adjustments are included for productivity, efficiency, case-mix and other discretionary adjustment factors. The market basket used by MedPAC to recommend an update for dialysis facilities is one approach, but that measure is itself limited and ultimately not adequate because it excludes pharmaceuticals. Therefore, the KCC strongly urges policymakers to include a comprehensive update mechanism in whatever reform efforts they undertake for the ESRD program.

G. Revision of the System Over Time.

A new system will need to be revised from time to time to reflect possible changes in the underlying prevalence and severity of disease in the patient population, progress in medical technology, changes in the quality of care in response to incentives, and improvements in data available resulting from the introduction of the comprehensive ESRD PPS itself. The parameters of any new system to be implemented will be, of necessity, estimated based on data from the old system. As the new system comes into effect, it will itself change the landscape of care delivered and thus affect how well the reformed system actually works. To ensure that the new system continues to achieve its goals in a post-implementation world, it will need to be revisited in light of implementation experience and data derived from a period when the new system is actually in use. Furthermore, in ensuing years periodic adjustments will be needed to ensure the new system does not become significantly outmoded. The KCC believes that the enabling legislation should include provisions requiring the Secretary to adjust the system, including re-estimating its parameters – particularly the case-mix adjustment factors and the outlier parameters – on a periodic basis. Such revisions should be accomplished not more frequently than annually and no less often than every five years.

³ See *id* at 225. “That similar patients are treated in different settings also raises questions about parity across providers. The Commission has long held that payment for the same set of services should be the same regardless of where the services are provided.”

II. OTHER ISSUES

A. Implementation.

The KCC concurs with Acting CMS Administrator Kerry Weems and others that implementation of the new system should begin as early as possible, in 2010 or 2011, when CMS is prepared to fully launch the new system in an orderly fashion, and that a demonstration project or other validation study is not necessary for the new prospective payment system to succeed. The KCC urges adoption of a policy requiring CMS to work with the provider community to determine a reasonable transition methodology.

B. Budget Neutrality.

The KCC believes that the revised payment system should be budget neutral to the existing system at 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. Additionally, the KCC believes that the perennial problem of lack of concurrence between estimates and actual experience should be addressed with a statutory mechanism that adjusts baseline spending in out years to compensate for any variation between estimated and actual spending in the first year. Further, as discussed above, Congress should provide for future updates through adoption of a permanent annual update mechanism. These updates, of course, would not be budget neutral to the existing system, since it lacks an update mechanism.

C. Site-Neutral: Hospital Based versus Independent Facilities.

The KCC agrees with HHS that the hospital rate differential – currently about \$4.00 more per treatment than the in-center rate – should be eliminated, and payments should be site-neutral, a view consistent with 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.

D. More Frequent Dialysis.

The KCC supports HHS' efforts to examine treatment modality options for patients. We also recognize that a comprehensive PPS will require rethinking the current payment methodology for more frequent dialysis or other modalities.

E. Part B and Part D Drugs.

The Report notes that the broader bundle could include payment for an ESRD drug regardless of its form, and that the bundle could be adjusted accordingly to avoid ambiguity among providers and Part D plan sponsors in categorizing drugs as Part B versus Part D and reduce any overpayment risk that may result. Today, drugs delivered in the dialysis setting do not extend beyond those delivered intravenously. Facilities are not at present prepared to deliver oral medications since they are neither the patient's prescribing physician nor its pharmacist. From an operational perspective, the KCC

believes adding Part D drugs to the bundle could be difficult to implement without further attention to and refinement of the clinical and licensure issues that prevent oral drug administration in the dialysis setting today.

F. New Drugs and Technology Pass-Through Policy.

The Report does not explicitly discuss a special payment policy for new drugs and technology. The KCC believes the revised payment system should include a mechanism similar to the “transitional pass-through payment” provision in Medicare’s outpatient prospective payment system that pays new technologies outside the otherwise applicable payment method for two to three years. During the pass-through period, new drugs should be paid at average sales price plus six percent (ASP+6) and other new technology should be paid to reflect incremental cost to facilities. The KCC believes the pass-through method is an important and well-developed means by which Medicare’s prospective payment systems facilitate access of beneficiaries to new technologies. Immediate packaging of new drugs and technologies into an expanded bundle would present significant clinical and financial management challenges, while diffusion of these technologies, with their promise of improvements in efficiency and quality of care, would be significantly aided by two to three years of pass-through treatment. Removal of new technology status should be tied to periodic revision of the system as described in Section I.G. If these technologies are handled in this fashion, the clinical and economic effects of their use can be appropriately reflected in the routine payment structure once new technology status expires.

G. Inspector General Studies on Utilization Patterns.

As discussed above in the “Base Payment” section, the KCC believes setting initial payment levels based on aged utilization data, particularly on use of drugs, from a prior year may introduce significant inaccuracies. The KCC supports a requirement that the Office of Inspector General (OIG) analyze utilization of services with the most recent data available in the six-month period before implementation. Section 623(c) of the Medicare Modernization Act of 2003, which mandated OIG studies on ESRD drugs, may be an appropriate model.

H. Quality Monitoring and Performance-Based Bonus Payments.

The KCC supports the dialysis-specific quality tools that CMS has implemented to date: Dialysis Facility Compare, 13 ESRD Clinical Performance Measures (CPMs) derived from the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NQF K/DOQI) guidelines, and data collection efforts. The KCC is also pleased that CMS will transition its reporting to the electronic CROWNWeb system, and the proposed ESRD Conditions for Coverage rule would require facilities to adopt a quality program and require electronic reporting on all patients. Additionally, this effort should require that standard definitions and measurements be applied to the data being submitted for comparative purposes. Facilities, providers, and physicians should all report quality data based upon clinical quality-of-life measures developed in consultation with the kidney care community. Accordingly, the KCC strongly supports the work of the Kidney Care Quality Alliance and the measure development undertaken by facilities and the broader provider community.

The KCC also believes that quality related payments should be awarded based upon attaining specific benchmarks and demonstrating improvement in quality, as defined by ESRD-specific quality measures. The payments could be funded by using a portion of an annual update which would link the annual update to clinical performance. Such a policy is consistent with Section 203 of The Kidney Care Quality and Education Act (KCQEA – H.R. 1193 – J. Lewis/Camp; S. 691 – Conrad).

I. Cost Reporting Reform.

While the Report does not address long-overdue modernizations in facility cost reporting, the KCC believes attention to changes in this area is essential. With a revised payment system, CMS should collect the appropriate financial information that would allow accurate monitoring of program margins and use in calculation of the annual inflation updates and wage-index adjustments. Such information may also be used over time in considering possible changes in the expanded bundle and in the adjustment factors. 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 provision of dialysis care.