

**July 30, 2010**

## **Summary of Final ESRD Bundling Rule**

Fundamentally changing how Medicare pays for dialysis services for patients with end-stage renal disease (ESRD), the Centers for Medicare and Medicaid Services (CMS) released the Final ESRD Prospective Payment System (PPS) Rule on Monday, July 26, 2010. Under the new “bundled” payment system, effective January 1, 2011, Medicare will provide a single payment that covers all renal dialysis services—including drugs and diagnostic laboratory tests—to dialysis facilities for each dialysis treatment. This replaces the current system, under which Medicare pays facilities a composite rate for most items and services, while paying separately for certain drugs, laboratory tests, and other services.

The ASN Public Policy Board, ESRD Task Force, and policy staff analyzed and commented extensively upon the ESRD PPS Proposed Rule in 2009. Notably, the final rule addressed many of the concerns ASN conveyed to CMS during the comment period. Creating separate payments for home dialysis training, preserving physician flexibility in ordering lab tests and medications, monitoring the bundle's influence on patient care and access, and evaluating the effect of new copayments on patients are among the many revisions CMS made to its proposals following ASN's comments. ASN would like to thank the members of the Policy Board and ESRD Task force for their contributions on behalf of the society.

Currently, these ASN groups are conducting an in-depth review of the final rule—which is not open for public comment. This summary presents an overview of several of the most significant provisions in the Rule, and over the coming weeks and months ASN will continue working to help members understand how medical practice and patient care will be affected by these changes. The society will also be working closely with CMS as a liaison between the Agency and the nephrology community.

### **Scope of the Bundle: Oral-Only Drugs**

CMS finalizes its proposal to make a single bundled payment to dialysis facilities for each dialysis treatment that covers all dialysis-related drugs, diagnostic laboratory tests, equipment, supplies and staff time. For 2011, CMS sets the standardized base rate of the bundle at \$229.63, which will be multiplied by patient and facility-level payment adjusters. As CMS originally proposed in 2009, the bundle will include erythropoiesis-stimulating agents (ESAs) and “oral-only ESRD-related drugs and biologicals”

However, CMS will not add oral-only medications to the bundle until January 1, 2014. Patients will continue to have access to these products under Medicare Part D until that date. Importantly, this delay period will enable CMS to address many of the concerns raised by ASN in its comment on the Proposed Rule about ESRD facilities' ability to furnish drugs formerly covered under Part D, as well as the Agency's ability to identify and remediate any negative changes in availability or quality of patient care. Among other things, the delay will specifically allow:

- CMS time to conduct additional analysis regarding the ability of ESRD facilities to provide oral-only ESRD drugs.
- ESRD facilities time to develop the arrangements or infrastructure necessary to provide oral-only drugs and negotiate prices with drug companies.
- CMS time for additional analysis of ESRD facilities' ability to provide oral-only ESRD drugs.

- CMS time to evaluate the need for additional clinical indicators applicable to the monitoring of certain patient conditions treated with oral-only drugs, such as bone loss and mineral metabolism associated with the provision of calcimimetics and phosphate binders. This could assist in determining the impact of the fully bundled payment system, and any unintentional consequences that might ensue, on quality of care.

### **Scope of the Bundle: Oral Drugs with an Injectable Equivalent**

In the final rule, CMS will include oral drugs with an injectable equivalent will be included in the bundle beginning January 1, 2011. CMS classifies these products into five ESRD drug categories based on the mechanism of action, and envisions that these categories will provide flexibility to incorporate new products into the bundle as they become available in the future. The final rule also delineates several drug categories that are expressly excluded from the base rate, which CMS will continue to bill separately. These include drugs and biological classified as immunosuppressant drugs, vaccines, and chemotherapeutic drugs. The final rule, which is accessible on ASN's website, contains a complete list of these drugs.

Responding directly to ASN's comment that many nephrologists serve as primary care providers for their patients and in this capacity sometimes need to prescribe non-ESRD-related drugs, CMS ruled that nephrologists may continue to order such products in the new payment environment. The agency created a new modifier on the claim form for this purpose. CMS also identifies a small number of products that are sometimes ESRD-related but are also often prescribed for other reasons. Facilities will be eligible to receive separate payment for these products, using the same new modifier to indicate the drug was not administered for ESRD care.

### **Diagnostic Laboratory Tests**

Similarly, the Agency addressed ASN's concerns that nephrologists continue to be able to order laboratory values that are not related to renal dialysis services. Allowing MCP nephrologists to order laboratory values that are not related to renal dialysis services minimizes patient discomfort, protects vascular access, and enables nephrologists to serve as primary care providers. CMS adopts the society's recommendation to identify non-ESRD-related lab tests by using another separate modifier that allows for a separate payment for those tests. As such, CMS compiled a list of 53 lab tests used to diagnose or monitor ESRD-related conditions. Only tests included on this list will be paid under the bundle. CMS notes that the list was compiled based on tests most frequently identified by commenters as ESRD-related, input from physicians at the University of Michigan Kidney Epidemiology and Cost Center, and a medical review by CMS physicians and other staff.

### **Patient-Level Adjustors**

In the final rule, CMS adopts four patient-level case-mix payment adjustors—for age, body mass index, body surface area, and new patients—as well as six co-morbidity categories (listed below) for the co-morbidity case-mix adjustment.

- Pericarditis (acute)
- Bacterial Pneumonia (acute)
- Gastrointestinal Tract Bleeding with Hemorrhage (acute)
- Hemolytic Anemia with Sickle Cell Anemia (chronic)
- Myelodysplastic Syndrome (chronic)
- Monoclonal Gammopathy (chronic)

CMS originally proposed to include an adjustor for patient sex and for race/ethnicity, but at this time is not finalizing its proposals for these characteristics. ASN had expressed concern that the data employed to determine patient-level case-mix adjustors may not be complete or capture the most costly variables in

patient care. Stating in the final rule that it is updating processes for collecting and validating patient-level data, CMS will continue studying patient sex and for race/ethnicity. The agency also intends to perform additional studies to determine whether there are underlying clinical or biological factors contributing to the increased cost of providing care to certain groups.

Importantly, as it weighs decisions on the patient sex and race/ethnicity adjustors, CMS states it will continue to monitor for evidence of decreased access to renal dialysis services—a key activity ASN emphasized the Agency must conduct in the new payment environment.

### **Co-Payments**

Under the new ESRD PPS, the beneficiary's coinsurance amount will be 20 percent of the ESRD PPS bundled payment amount, including applicable case-mix and facility-level adjustments and outlier payments. Patients accessing care at facilities undergoing the four-year transition period will pay coinsurance on 20 percent of the blended payment amount (described elsewhere).

Under the existing payment system, patients are not responsible to pay coinsurance, on laboratory services, but will become subject to the 20 percent coinsurance obligation when the services are bundled into the set of renal dialysis services on January 1, 2011. Similarly, drugs being bundled that are currently payable under Medicare Part D—and currently subject to a separate coinsurance structure—will be subject to the 20 percent coinsurance part of the set of bundled renal dialysis services.

Importantly, however, oral-only ESRD drugs will not immediately be among the products patients are responsible to pay coinsurance for, as CMS will continue to pay these drugs under Part B until January 1, 2014 when CMS adds them to the bundle. ASN voiced concerns about the new financial burden created for patients by adding drugs that were formerly payable under Part D to the bundle. In response, CMS stated in the final rule that it plans to collect data on the oral-only ESRD drugs to assess the impact on beneficiaries and facilities. The agency will address the implementation of oral-only drugs in a future notice of proposed rulemaking.

Notably, the new base rate reflects the average cost for furnishing dialysis services to patients. For this reason, CMS explains, if patients today use less than the average of separately billable items and services (that is, items and services that were separately paid under the current basic case-mix adjusted composite payment system), they can expect an increase in their co-insurance obligation. However, if patients currently use more than the average of separately billable items and services, they should pay less in co-insurance under the new bundled payment system. The amount of the difference in co-insurance under the current payment system and the new bundled payment system for an individual patient is directly related to how their use of separately billable services compares to the average amount.

### **Home Dialysis**

As encouraged by ASN and others, CMS adopts a payment adjustor for home dialysis training for both hemodialysis and peritoneal dialysis (PD) modalities. The agency will provide this add-on adjustment to facilities each time they conduct home dialysis training, rather than accounting for the cost of home training in the base rate applied to all facilities, as CMS originally proposed. However, facilities are not eligible to receive the home dialysis training add-on during the first four months after initiating dialysis while the new-patient adjustor is in effect.

### **Transition Period**

The final rule includes a four-year phase-in (transition) of bundled payments, with the phase-in occurring in equal increments until 2014, when 100 percent of ESRD services will be covered under the bundle. In 2011, 75 percent of the transition will be based on the payment rate under the current basic case-mix adjusted composite payment system and 25 percent based on the new bundled ESRD PPS payment amount. In 2012, the balance will be 50-50, and in 2013, 25 percent of the transition will be based on the

payment rate under the current basic case-mix adjusted composite payment system and 75 percent based on the new bundled ESRD PPS payment amount. Dialysis facilities have until November 1, 2010 to make a one-time selection to be excluded from the transition and paid entirely under the new fully-bundled system as of January 1, 2011.

### **Physician Services**

CMS states in the final rule that it does not, at this time, intend to modify payment for physicians' services. The agency is limiting the scope of this rulemaking to payment for dialysis services, and notes that any changes whatsoever in payment for physician services would be addressed in future rulemaking.

For more information on the ESRD final rule, and the Quality Improvement Program (QIP) Proposed Rule, please visit [http://asn-online.org/policy\\_and\\_public\\_affairs/esrd-bundling.aspx](http://asn-online.org/policy_and_public_affairs/esrd-bundling.aspx).