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New PPS for End Stage Renal Dialysis Facilities Effective January 1, 2011

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CMS issued a final rule on July 23, 2010 that creates a new bundled prospective payment system (PPS) for facilities that furnish renal dialysis services and home dialysis to Medicare beneficiaries with End-Stage Renal Disease (ESRD). This new rule replaces the current system, which pays facilities a composite rate for a defined set of items and services, while paying separately for drugs, laboratory tests, or other services that are not included in the composite rate. Under the new ESRD PPS, CMS will make a single bundled payment to the dialysis facility for each dialysis treatment that will cover all renal dialysis services and home dialysis. The new bundled payment system will be effective for dialysis treatments furnished to beneficiaries on or after Jan. 1, 2011.

Currently, Medicare pays ESRD facilities a composite rate for furnishing outpatient maintenance dialysis in the facility or in the beneficiary's home. The composite rate payment covers dialysis treatment costs and certain routinely furnished ESRD-related drugs, laboratory tests, and supplies. The composite rate is adjusted by a drug add-on payment that accounts for changes in the drug pricing methodology that occurred in 2005, and by basic case-mix adjustment factors including age and body size. A special adjustment is applied for services to pediatric patients. In addition, the composite rate is adjusted for geographic differences in costs using a wage index. For 2010, the unadjusted composite rate is $135.15 and the drug add-on payment is $20.33.

The composite rate does not include a number of other ESRD-related items and services, particularly injectable drugs, such as erythropoietin (EPO) to treat ESRD-associated anemia, iron sucrose, vitamin D, and non-routine laboratory tests. These items and services are currently paid separately under Medicare.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended the Social Security Act to require CMS to develop a new, fully bundled

prospective payment system for renal dialysis services to replace the existing composite rate payment methodology. MIPPA also mandated that the estimated total amount of payments for renal dialysis services for 2011 be 98 percent of the estimated total amount of payments that would have been made in 2011 if the ESRD PPS had not been implemented. The law further required CMS to phase in the new bundled payment system over a four-year period. However, facilities will be given the opportunity to choose to be paid entirely under the new payment system beginning on January 1, 2011.

Summary of Final Rule For ESRD Prospective Payment System

According to a fact sheet issued by CMS, the new ESRD PPS rule:

- Creates a home or self-care dialysis training payment adjustment specifically directed to patients trained by facilities certified to provide home dialysis training.
- Finalizes payment adjustments for dialysis treatments furnished to adults for patient age, body surface area, and body mass index, onset of dialysis, and certain co-morbidities, but does not finalize adjustments for the patient's sex or the patient's race or ethnicity.
- Finalizes a payment adjustment for dialysis treatments furnished to pediatric patients, based on patient age and dialysis modality, but not co-morbidities.
- Finalizes a definition for renal dialysis services that includes ESRD-related oral-only drugs, but postpones payment for such drugs under the ESRD PPS until Jan. 1, 2014.

ESRD Base Rate and Bundle of Services

The final budget-neutral standardized base rate per dialysis treatment for 2011 is $229.63. The amount represents the single Medicare payment for all services in the bundle prior to adjustments for case-mix and the wage index, including the former composite rate services and services that were previously separately billable, such as non-routine laboratory services and all ESRD-related Part B drugs and their equivalent forms covered under Part D.

Patient-Level Adjustments

MIPPA requires that the bundled payment system "include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors." In the final rule, CMS finalizes case-mix payment adjusters for age, body surface area (BSA), and body mass index (BMI). In the final rule, CMS also adopts a "new patient adjustment" that recognizes that patients have higher costs in their first four months of maintenance dialysis. In addition, the final rule creates a payment adjustment for treatment of pediatric patients, based on two age categories and the patient's dialysis modality. Finally, in the final rule CMS finalizes six co-morbidities categories (three acute and three chronic) for the co-morbidity case-mix adjustment.

At this time, CMS is not finalizing case-mix payment adjustment factors for patient sex or race/ethnicity. CMS plans to continue studying the issue to ensure that all beneficiaries with ESRD have access to quality care, and in the meantime, plans to implement an active monitoring program to respond to concerns about disparities in access to care.

Facility-Level Adjustments

MIPPA requires an adjustment of at least 10 percent for low-volume facilities until Jan. 1, 2014, and gives the Secretary discretion to adopt additional facility-level adjustments. The final rule defines low-volume facilities as those facilities that: (1) furnished fewer than 4,000 treatments in each of the three years preceding the payment year; and (2) have not opened, closed, nor received a new provider number due to a change in ownership during the three years preceding the payment year. The low-volume facility adjustment is not applied to pediatric claims.

CMS is finalizing a wage index using the core-based statistical area (CBSA) definitions developed by the Office of Management and Budget. The wage index values will be based on the most current hospital wage data, prior to application of the rural floor and occupational mix adjustments, and geographic reclassifications.

Training Adjustment

The final rule provides a payment adjustment for dialysis training treatments for home or self dialysis for both hemodialysis and peritoneal dialysis modalities. The ESRD training add-on adjustment will target payments for training to those ESRD facilities that actually conduct training treatments rather than including such training in the base rate for all facilities. A home dialysis training adjustment of $33.38 will be added on to the per treatment ESRD PPS payment each time training is conducted. The training adjustment will be adjusted by the geographical wage index based on the location of the ESRD facility. The home or self-dialysis training adjustment is not available, however, during the four-month new patient adjustment for the onset of dialysis.

Outlier Policy

MIPPA requires outlier payments be paid to ESRD facilities that treat high-cost patients — patients who use more than the predicted amount of services, including variation in the amount of erythropoietin stimulating agents (ESAs) used to manage dialysis-related anemia. CMS is finalizing the outlier percentage as 1.0 percent. As noted previously, since outlier payments increase total spending, and since the system is required to be budget-neutral, CMS is reducing the standardized base rate payment amount for all dialysis treatments by 1.0 percent, to fund the 1.0 percent outlier policy under the new ESRD PPS. CMS is setting the fixed dollar loss amount at $155.44 for adult and $195.02 for pediatric dialysis patients. Once the fixed dollar loss amount is met, CMS will pay 80 percent of the ESRD facility's outlier service costs. CMS projects that approximately 4.7 percent of adult and 2.2 percent of pediatric patient months would qualify for outlier payments.

Annual Payment Rate Updates

The ESRD PPS base rate will be updated annually by an ESRD market basket index reduced by a productivity adjustment.

Beneficiary Coinsurance

Under the ESRD PPS, the beneficiary coinsurance amount will be 20 percent of the ESRD PPS bundled payment amount, including applicable case-mix and facility-level adjustments and outlier payments. For those beneficiaries served by facilities that are going through the four-year transition period, the coinsurance would be 20 percent of the blended payment amount. Although clinical laboratory services are not currently subject to coinsurance, laboratory services that are bundled would be subject to the 20 percent coinsurance obligation as part of the bundled set of renal dialysis services under the ESRD PPS. Similarly, drugs being bundled that are currently payable under Medicare's prescription drug program and subject to a separate coinsurance structure, would be subject to the 20 percent coinsurance as part of the set of bundled renal dialysis services under the ESRD PPS.

Transition Period

As required by the law, the final rule provides a four-year phase-in (transition) of the payments under the ESRD PPS, with the phase-in occurring in equal increments until CY 2014 when payments would be based entirely on the ESRD PPS. For CY 2011, transition payments consist of 75 percent based on the payment rate under the current basic case-mix adjusted composite payment system and 25 percent based on the ESRD PPS payment amount. Dialysis facilities will have opportunity for a one-time election to be excluded from the transition and paid entirely under the new ESRD PPS. The rule requires that this election be made by Nov. 1, 2010.

Ober|Kaler's Comments

While the new ESRD PPS rates and methodology are intended to be "budget neutral," providers are reminded that Congress directed CMS to estimate 2011 ESRD payments at 98% of what would have been paid out under the current system. Providers are urged to carefully review their current costs of providing a single dialysis treatment, breaking out the costs that presently are paid as add-ons (particularly injectable drugs and EPO), in order to see how they will fare under the new FY 2011 PPS payment of $229.63 unadjusted base rate. Those providers whose current costs are significantly below this base rate should consider filing the one-time election to be excluded from the 4 year transition period and go

immediately to full payment under the new PPS system. This election must be filed before November 1, 2010.