

## High-Level Summary:

### End-Stage Renal Disease Prospective Payment System, Proposed Rule CMS-1418-P, On Display 09-15-09

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On Tuesday, September 15, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule to implement a bundled prospective payment system (PPS) for Medicare outpatient End-Stage Renal Disease (ESRD) services. The proposed ESRD PPS would replace the current payment system beginning January 1, 2011, in compliance with the statutory requirement of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. Comments on the proposed rule are due on December 16, 2009.

The following is a summary of the proposed rule, CMS-1418-P, prepared by Avalere Health, LLC and Baxter Healthcare Corporation. The page numbers from the proposed rule document are provided for your reference.

#### Renal Dialysis Services Included and Excluded from the ESRD PPS

- In accordance with Section 1881(b)(14)(B) of MIPPA, CMS considers all items and services currently in the composite rate to be renal dialysis services and included in the ESRD PPS [\(page 39\)](#)
- CMS proposes that, as directed in MIPPA, erythropoiesis-stimulating agents (ESA) in oral and injectable form be included in the ESRD PPS [\(page 41\)](#)
- CMS interprets Section 1881(b)(14)(B)(iii) of MIPPA, “Other Drugs and Biologicals and their Oral Equivalents,” as requiring the inclusion of all ESRD drugs and biologicals formerly separately-payable under Medicare Part B and Part D regardless of route of administration [\(page 42\)](#)
- The agency interprets MIPPA as specifically excluding vaccines from the payment bundle, and therefore, proposes vaccines be excluded from the proposed ESRD PPS [\(page 45\)](#)
- As directed by MIPPA, CMS proposes to include in the ESRD PPS laboratory tests that are either:
  - » Separately-billable by ESRD facilities; or
  - » Ordered by a physician who receives monthly capitation payments (MCP) and performed by independent laboratories
- CMS believes section 1881(b)(14)(A)(i) of MIPPA, “Physicians’ Services,” governs payment to ESRD facilities, and therefore does not propose to significantly modify payment to physicians’ services in this proposal [\(page 57\)](#)

#### Appropriate Unit of Payment for Renal Dialysis Services

- CMS proposes to establish an ESRD PPS that relies on a per treatment unit of payment [\(page 60\)](#)
- The agency proposes to continue the present per treatment payment method because of the administrative complexity associated with other payment units and the belief that other units of payment may incent skipping of dialysis treatments [\(page 61\)](#)
- CMS proposes to continue paying for up to three treatments per week, unless medical necessity is justified for more than three weekly treatments [\(page 60\)](#)

#### Payment for Home Dialysis

- CMS proposes to include payment for all home dialysis services, excluding physicians’ services, under the proposed ESRD PPS, including home dialysis supplies, equipment, and home support services [\(page 48\)](#)

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- CMS proposes to include the costs of home dialysis services furnished to both Method I and Method II payment beneficiaries, along with self-dialysis training services, in the proposed ESRD PPS ([page 49](#))
- CMS proposes to discontinue Method II, thus sending all reimbursement through a facility ([page 53](#))

#### **Data Sources for the ESRD PPS**

- CMS identifies multiple data sources used to quantify cost and payment information when constructing the payment bundle ([page 67](#))
  - » These include dialysis cost reports, outpatient institutional claims, and Part D stand-alone prescription drugs plan claims
- CMS proposes a plan to evaluate available claims from Medicare ESRD beneficiaries for CYs 2007, 2008, and 2009 to identify the year with lowest average payment amount per treatment to comply with MIPPA requirements for “lowest per patient” utilization and budget neutrality ([page 70](#))
- CMS calculates payments for Medicare Part D drugs from CY 2007 claims submitted by Part D prescription drug plans ([page 76](#))

#### **CMS’ Analytic Approach to the ESRD PPS**

- CMS proposes using a case-mix model developed by the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) and plans on using the two-equation model outlined in the Secretary’s report to Congress submitted in February 2008 ([page 81, 83](#))
- The two-equation model uses two separate regressions: ([page 82](#))
  - » The first regression accounts for variation in composite rate costs at the facility level, and uses information from the cost reports
  - » The second regression accounts for variation in separately-billable payments at the patient level, and uses information from the outpatient claims
  - » CMS combines the two sets of weights from each regression to form one set of adjustors, weighted by the relationship between composite rate costs and separately-billable costs

#### **Cost Regression Approach**

- CMS uses data for separately-billable services for CYs 2004 through 2006 for outpatient dialysis services where Medicare was the primary payer ([page 123](#))
- CMS calculates the Medicare Allowable Payment (MAP) by inflating services that have a 20 percent patient coinsurance by a factor of 1.25 ([page 124](#))
- CMS proposes using seven control variables in its cost regression analysis: renal dialysis facility type, facility size, type of ownership, whether the ESRD facility received a composite rate payment exception between November 1993 and July 2001, adequacy of dialysis, rural versus urban location, and calendar year ([page 128, 129](#))
- CMS proposes the following patient-level adjustments: patient age, patient sex, body surface area and body mass index, onset of dialysis (i.e., a “new patient” adjustment), and co-morbidities ([pages 133-158](#))
- CMS examines including race/ethnicity as an adjustor, but is concerned about the reliability of this indicator ([page 193](#))
- CMS is not proposing to develop an ESRD PPS that uses type of dialysis modality as a payment variable ([page 197](#))

#### **Development of the ESRD PPS Base Rate**

- The unadjusted per treatment base rate for CY 2011 is \$261.58. In estimating this amount, CMS updates the unadjusted per treatment amount for CY 2007 to reflect CY 2011 prices for each component of the bundle ([page 103](#))

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- The CY 2011 proposed base rate per treatment including an outlier adjustment and budget neutrality is \$198.64 ([page 107](#))
  - » CMS notes that this amount reflects the 98 percent budget neutrality, outlier, and other adjustments, and that this amount would be adjusted based on specific case-level and facility-level characteristics
- In addition, to address the overall effect of dialysis facilities decision of whether to be paid under the transition or under the ESRD PPS, CMS proposes to adjust all payments to ESRD facilities during the transition, whether blended, or 100 percent ESRD PPS, downward by 3 percent ([page 120](#))
  - » CMS' analysis suggests that 36 percent of ESRD facilities will choose payment at 100 percent of the new ESRD PPS and 64 percent will choose the blended rate ([page 119](#))

#### **Provisions Related to Facility-Level Adjustments**

- CMS proposes to adjust payments using an ESRD wage index to account for differences in geographical variation ([page 198](#))
- CMS proposes to pay low-volume facilities a 20.2 percent increase to the base rate for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014 ([page 228](#))
  - » CMS proposes to define low-volume facilities as those that over a three-year period had 1) not opened, closed, or received a new provider number due to a change in ownership, and 2) remained small (less than 3,000 treatments per year) in each of the 3 years before the payment year ([page 222](#))
- CMS is not proposing to adjust payments based on rural location
  - » CMS believes the use of a low-volume adjustment would reduce the need for a rural adjustment ([page 231-233](#))
- The site neutral payment provisions under the current ESRD payment system will automatically be incorporated under the ESRD PPS and used to establish a single base rate that will apply to ESRD facilities (i.e., payments will not differ between hospital-based and free-standing dialysis facilities) ([page 233](#))

#### **Provisions Related to Pediatric Patients**

- CMS proposes a range of 0.963 to 1.215 as the patient-specific case-mix adjustment factors for pediatric patients under the ESRD PPS, with an average pediatric patient-specific payment adjustment multiplier of 1.067 ([page 260](#))
- As proposed, pediatric facilities would receive a payment adjustment based upon dialysis modality, which differs from the approach with adults ([page 252](#))

#### **Outlier Payments**

- As required in MIPPA, CMS proposes to include a payment adjustment for high-cost outliers due to unusual variations in the type or amount of medically necessary care ([page 262](#))
- CMS proposes to set aside 1 percent of aggregate ESRD PPS payments for payment of outlier cases ([page 287](#))
- The outlier payment is proposed at 80 percent of the amount by which the facility's imputed costs exceed the outlier threshold ([page 263](#))
- CMS proposes to limit outlier services to items and services that are currently separately-billable under Part B and drugs that are currently separately-billable under Part D ([page 265](#))
  - » CMS proposes to exclude Automated Multi-Channel Chemistry (AMCC) laboratory tests to which the 50 percent rule apply from the definition of outlier services, thus negating the need to apply the 50 percent rule under the proposed ESRD PPS ([page 268](#))
- CMS proposes an annual monitoring process to identify patterns of increased utilization of and payment for outlier services ([page 289](#))

### **ESRD Bundled Market Basket**

- Beginning in CY 2012, the ESRD bundled payment amount must receive an annual increase by an ESRD market basket minus 1 percent, to reflect the changes in prices of an appropriate mix of goods and services [\(page 310\)](#)
- CMS currently estimates the CY 2011 ESRD market basket will be 2.5 percent, and will average 2.7 percent over the next 10 years [\(page 98, 339\)](#)

### **Transition Period Implementation**

- As directed by MIPPA, CMS proposes to phase-in (transition) from the current case-mix adjusted composite payment system in equal increments [\(page 343\)](#)
  - » CMS proposes to transition to the ESRD PPS by making payments based on: [\(page 345\)](#)
    - CY 2011: 75 percent of the payment rate under the current case-mix adjusted composite payment system and 25 percent of the payment rate under the ESRD PPS
    - CY 2012: 50 percent of the case-mix adjusted composite payment system and 50 percent of the ESRD PPS payment rate
    - CY 2013: 25 percent of the case-mix adjusted composite payment system and 75 percent of the ESRD PPS payment rate
    - 100 percent of the payment amount under the ESRD PPS on or after January 1, 2014
- For renal dialysis services, including home dialysis services, provided during the transition period, CMS proposes ESRD facilities receive a blended payment for each dialysis treatment consisting of the payment amount under the current case-mix adjusted composite system and the payment amount under the ESRD PPS [\(page 344\)](#)
  - » The agency proposes that during the transition, the portion of the blended rate based on the current composite payment system be comprised of the composite rate, the drug add-on amount, and the payment amounts for separately-paid items and services furnished to dialysis patients under Part B by Medicare to entities other than the ESRD facility [\(page 346\)](#)
- To account for ESRD drugs and biologics currently paid under Part D, during the transition, CMS proposes a \$14 adjustment to the portion of the blended rate related to the current case-mix adjusted payment system [\(page 346\)](#)

### **Election for Exclusion from Transition Period**

- Though MIPPA specifies facilities seeking exclusion from the transition make their election prior to January 1, 2011, CMS proposes ESRD facilities notify CMS no later than 60 days prior to implementation of the ESRD PPS [\(page 349\)](#)
- CMS believes that only ESRD facilities providing renal dialysis services to Medicare beneficiaries before implementation of the ESRD PPS should have the option to choose if their payment is under the transition or the ESRD PPS [\(page 351\)](#)

### **Limitation on Beneficiary Charges**

- CMS proposes that ESRD facilities receiving an ESRD PPS payment may only charge the Medicare beneficiary for the applicable deductible and 20 percent coinsurance amount [\(page 354\)](#)
- Since Medicare currently generally pays facilities monthly, CMS proposes to continue to pay ESRD facilities monthly [\(page 354\)](#)

### **Operational Issues with Payment for Self Administered Drugs and Biologicals**

- Since CMS is proposing to include renal dialysis service drugs formerly covered under Part D in the proposed ESRD PPS, it also proposes that ESRD facilities be required to furnish these and any other ESRD-related drugs to beneficiaries either directly or under arrangement [\(page 361\)](#)
- CMS expects ESRD facilities would coordinate provisions of renal dialysis service drugs on behalf of traveling patients and is considering the incorporation of an ESRD indicator on the Part D eligibility

information that would prevent Part D drug payments for bundled ESRD drugs and biologicals at the pharmacy ([page 363](#))

### Existing ESRD Policies

- CMS reviewed existing ESRD policies to determine their applicability to the proposed ESRD PPS and proposes to: ([page 365](#))
  - » Eliminate the exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix), and pediatric facilities that exist under the composite payment system; and
  - » Maintain the current ESA monitoring policy (EMP), bad dept policy, reporting requirements for circumstances whereby Medicare is the secondary payer (MSP), and the 50-cent deduction to fund the ESRD Networks

### Provisions Related to Quality Incentives in the ESRD Program

- In the proposed rule, CMS describes the potential components of the MIPPA-mandated Quality Incentive Program (QIP), but intends to issue a subsequent proposed rule that details proposals for the QIP ([page 377](#))
  - » However, CMS is specifically proposing quality measures in this rule
- CMS proposes using three existing Dialysis Facility Compare measures that focus on anemia management and hemodialysis adequacy, including: ([page 388](#))
  - » Anemia management: Percentage of patients at a provider/facility whose hemoglobin levels were less than 10 g/dl ([page 389](#))
  - » Anemia management: Percentage of patients at a provider/facility whose hemoglobin levels were greater than 12 g/dl ([page 389](#))
  - » Hemodialysis adequacy: Percentage of hemodialysis patients at a provider/facility whose urea reduction ratio (URR) is 65 percent or greater ([page 391](#))
- Notably, the anemia management measures track the percentage of patients at a facility whose anemia was not controlled at both the high and low ends of the FDA-recommended hemoglobin levels, which are different from those currently required in the EMP ([page 397](#))
- For the initial measurement year, provider/facility performance will be compared to either its own performance or the national average (whichever is lower) during a prior year ([page 397](#))
  - » CMS will finalize measurement and comparison years in subsequent rulemaking
- Because CMS is required to implement the payment reduction starting January 1, 2012, it must start the reporting period prior to that date. CMS suggests the reporting period be all or portions of 2010 ([page 398](#))
- Payment reductions up to 2 percent will apply to services furnished on or after January 1, 2012 ([page 386](#))
  - » CMS proposes a sliding scale to determine payment reductions so that providers/facilities with the lowest score will receive the largest payment reductions ([page 401](#))

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Contact your local Baxter Account Executive if you have any additional questions or comments.