Open Door Forum
End Stage Renal Disease Prospective Payment System (ESRD PPS) Proposed Rule

October 15, 2009 – 3:30-5:00 P. M. EDT
Agenda

- Background
- Features of proposed ESRD PPS:
  - Payment bundle, unit of payment, data sources, base rate, market basket, patient-level adjustments, modality, pediatric adjustments, facility-level adjustments, and outliers
- Impact analysis
- Review of existing policies
- Implementation issues
- Areas of interest for the final rule
- Quality Incentive Program (QIP)
- Q/A session
Background*

- 1972- Congress authorized the Medicare ESRD benefit
- 1983- HCFA implemented the composite payment system
  - Separately billable items and services currently paid outside composite payment system
- 2003-2008- Secretary issued Reports to Congress describing an expanded bundle of services
- 2005- CMS implemented basic case-mix adjustments
- 2008- Medicare Improvements for Patients and Providers Act (MIPPA) enacted

* 74 FR 49923
The Proposed Payment Bundle**

1. Composite rate services;
2. ESAs (and their oral forms) used to treat ESRD;
3. Other drugs and biologicals used to treat ESRD (including oral forms) and for which separate payment was made under Title XVIII of the Act; and
4. Lab tests and other items and services used to treat ESRD*

CMS proposed a per treatment unit of payment**

*§1881(b)(14)(B)(i-iv) of the Act
**74 FR 49931
Data Sources – Case-Mix Analysis*

- Composite rate services
  - Medicare cost reports from hospital-based ESRD outpatient dialysis providers and independent ESRD facilities for CYs 2004 – 2006
- Separately billable services
  - Outpatient institutional claims and carrier claims for CYs 2004 – 2006
- Drugs currently covered under Part D
  - Part D claims for CY 2007

* 74 FR 49934
Data Sources - Case-Mix Analysis (cont.)

- Patient Characteristics
  - Form 2728 - Medicare Evidence Report
  - REMIS - Renal Management Information System
  - EDB – Enrollment Database
  - SIMS - ESRD Standard Information Management System

- Facility Characteristics
  - SIMS
  - Cost Reports
  - OSCAR – Online State Certification & Reporting System
Unadjusted Base Rate*

- Based on average 2007 Medicare claims payments including:
  - Composite rate services;
  - Support services for Method II patients;
  - Dialysis training services
  - Part B drugs/biologicals;
  - Lab tests;
  - DME equipment/supplies;
  - Supplies/other services; and
  - Current Part D drugs

* 74 FR 49939
Update Factors and Adjustments to Base Rate*

- Update factors applied to components of base rate to yield projected 2011 unadjusted per treatment base rate -> $261.58
- Standardization adjustment of 0.7827 -> $204.74
- Outlier adjustment of 1 % -> $202.69
- Budget neutrality adjustment of 2 % -> $198.64

* 74 FR 49942
2-Part Transition Budget Neutrality Adjustment*

1. To ensure payments would equal what would have been made in the absence of a transition
   - Recomputed each year of transition
   - 3% in 2011
   - Would apply to payments under the current system and the proposed ESRD PPS

2. Part D drug payment adjustment to basic case-mix adjusted composite payment system portion of blended payment

* 74 FR 49944
ESRD Bundled Market Basket*

- **MIPPA (section 153(b))**
  - Effective 2012
  - Annual increase minus 1.0 percentage point
  - Factor reflect changes in goods and services prices
  - Update composite portion during phase-in

- **ESRDB**
  - All-inclusive input price index
  - Price index (cost categories), their weights & price proxy

* 74 FR 49997
Patient-Level Adjustments

- Resource use varies by patient $\rightarrow$ costs to provide dialysis

- Patient-specific case-mix adjustment factors from 2 equations
  - Composite rate
  - Separately billable services

- Multiple regression $\rightarrow$ case-mix adjusted payments/treatment
  - age
  - BSA
  - Low BMI
  - Sex
  - Co-morbidity categories
  - Renal dialysis onset
Patient-Level Adjustments (cont.)*

- **Patient Age**
  - Reference Group – 45 to 59 years
  - 18-44 years = 19.4% more costly
  - > 80 years = 7.6% more costly

- **Patient Sex**
  - Females 13.2% more costly than males

- **Body Size**
  - BSA = 3.4% cost/0.1m² increase from 1.87
  - BMI = < 18.5kg/m²; 1.020 increase from 1.112

* 74 FR 49949
Patient-Level Adjustments (cont.)

- **Onset of dialysis (in-facility & home)**
  - Higher costs in first 4 months on dialysis (onset)
    - Stabilization need
    - Administrative & labor costs
    - Initial home training
  - Adjustment for period of time of dialysis under the ESRD benefit

- **Co-morbidities**
  - Used multiple claim types (SNF, HH, Hospice, etc)
  - 11 categories (substance dependence; cardiac arrest; pericarditis; HIV/AIDS; hepatitis B; infections; GI bleed; hemolytic/sickle cell anemia; cancer; myelodysplastic syndrome & monoclonal gammopathy)
Patient-Level Adjustments (cont.)

- Race/Ethnicity
  - Data Source: REMIS (from form 2728) & EDB (from SSA and RRB)
  - Concerns:
    - 2 versions of form 2728; completed by facility/physician
    - Limited data from RRB
    - Large number of “unknowns” or defaults
    - Enumeration process
    - Ill-defined terms

- Modality
  - No distinction between HD and PD in adults
Pediatric Dialysis*

- Current Payment = 1.62 adjustment factor
- Proposed ESRD PPS = 8 categories
  - Age ( < 13 years & 13-17)
  - Modality (PD and HD)
  - Co-morbidity (none or 1 or more)

* 74 FR 49981
Facility-Level Adjustments – Wage Index*

- Current method and source of wage index values
  - Based on hospital wage data
  - OMB’s CBSA-based geographic area designations
  - Labor-related share – 53.711
  - Wage index budget neutrality factor

- Proposed changes
  - Would no longer have a wage index floor under the ESRD PPS
  - Wage index value for rural Puerto Rico
  - Labor-related share from the proposed ESRD PPS – 38.160

* 74 FR 49968
Facility-Level Adjustments – Low-Volume*

- MIPPA
  - Section 1881(b)(14)(D)(iii) requires a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services; and
  - such payment adjustment shall not be less than 10 percent

* 74 FR 49969
Facility-Level Adjustments – Low-Volume (cont.)

- Facility-Level characteristics
  - Size
    - Number of treatments
  - Ownership Type
    - LDO, Independent, Regional, & Unknown
  - Location
    - Urban/Rural status
Facility-Level Adjustments – Low-Volume (cont.)

- Low-Volume Definition
  - Furnished less than 3,000 treatments in each of the 3 years preceding the payment year; and
  - Has not opened, closed, or received a new provider number due to a change in ownership during the 3 years preceding the payment year

- Additional Criteria
  - Geographic proximity for commonly owned facilities

- Payment Adjustment
  - 20.2%
Facility-Level Adjustments – Low-Volume (cont.)

- Other issues
  - Training only facilities
  - Regional Office involvement
    - Survey and certification monitoring
Facility-Level Adjustments – Other*

- Alaska and Hawaii Facilities
  - Did not propose COLA Adjustment

- Rural Facilities
  - Did not propose a separate adjustment

* 74 FR 49978
Outlier Policy*

- Would protect facilities from losses linked to unusually high costs
- Patient-level eligibility
- Payments would be added to per-treatment payment amount
- Outlier services defined as separately billable services including ESRD-related Part D drugs

* 74 FR 49987
Outlier Policy (cont.)

- Outlier eligibility
  - Compare predicted and imputed payment amounts
  - Predicted amounts = outlier services payment adjusters times the average outlier services payment amount ($64.54)
  - Imputed amounts = outlier services on monthly claim divided by treatments
  - Imputed payment amounts > predicted outlier services payment amount + outlier threshold (fixed dollar loss amount) would generate outlier payment
    - Adult fixed dollar loss amount - $134.96
    - Pediatric fixed dollar loss amount - $174.31
Outlier Policy (cont.)

- Outlier Payment
  - Imputed payments amounts > predicted outlier services payment amount + outlier threshold (fixed dollar loss amount) would generate outlier payment
  - Payment would be made at 80% (loss sharing percentage) of this excess amount
  - Proposed loss sharing percentage and fixed dollar loss amounts result in 1% overall reduction to the base rate
Impact Analysis*

- Show how ESRD facilities are affected by the proposed ESRD PPS
- Compared estimated payments in CY 2011 under proposed ESRD PPS to estimated payments under the current payment system
- Estimated payments in CY 2011 under proposed ESRD PPS
  - Opt in for transition
  - Opt out of transition
- Assume 36% excluded from transition

* 74 FR 50017
Existing ESRD Policies & Other Issues*

- Exceptions – Eliminate
- ESA Claims Monitoring Policy – Continue
- Network Deduction – Continue
  - 50 cents
  - Medicare Claims Processing Manual, Pub 104, chapter 8, section 110
- Bad Debt – Continue
  - Composite rate portion
  - Cap (§ 413.178(a))

* 74 FR 49997
Existing ESRD Policies & Other Issues (cont.)

- Limitation on Review
  - Payment determination
  - Unit of payment
  - Renal dialysis services
  - Adjustments
  - Transition
  - Market basket increase factor

- 50 % Rule (Laboratory Payments)
  - Medicare Claims Processing Manual, Pub 100.04, chapter 16, §40.6
  - 50% or > covered lab tests (AMCC) → no separate payment
  - Considering exclusion from outlier eligibility

- MSP – No change
Implementation*

- MIPPA
  - 4 year transition period
    - Blended payment
  - One-time election
    - Cannot be rescinded
    - FI/MAC involvement
    - New facilities
  - Payments made during the transition are to be budget neutral

* 74 FR 50003
Implementation (cont.)

- **Blended Payment**
  - All-inclusive payment
    - All renal dialysis services and home dialysis items and services
    - Items and services that are currently separately payable
      - Method II DME suppliers
      - Laboratories
      - Part D plans
Implementation (cont.)

- Blended Payment
  - Basic case-mix adjusted composite payment system portion
    - Composite rate; (adjusted by the case-mix and wage index)
    - Drug Add-on amount;
    - Payment amounts for items and services that are currently separately paid under Part B;
    - ESRD drugs and biologicals that are currently separately paid under Part D; and
    - ESRDB market basket minus 1 percentage point
Implementation (cont.)

- Blended Payment
  - ESRD PPS portion
    - Base rate;
    - Applicable patient-level and facility-level adjustments; and
    - Outlier payments
- The beneficiary coinsurance amount would be 20% of the total ESRD PPS payment or 20% of the blended payment amount for those facilities that decide to transition
Implementation (cont.)

- Claims Processing
  - Consolidated Billing Approach
    - Laboratory Tests
    - Drugs and biologicals that were formerly covered under Part D
      - ESRD facility responsibility
  - Home dialysis
    - All home dialysis would be furnished under Method I
    - Method II would be eliminated
Further Analysis

- Update of data sources
- Evaluation of comments
- Other issues
  - Retiree Drug Subsidy payments
  - 50 percent rule and ESA claims monitoring policy as related to the outlier policy
Generally speaking, MIPPA, 153 (c):
- Requires Centers for Medicare & Medicaid Services (CMS) to create a Quality Incentive Program (QIP) to promote improved End-Stage Renal Disease (ESRD) patient outcomes.
- As part of the End-Stage Renal Disease Prospective Payment system (ESRD PPS), which takes into account all services related to ESRD care and "bundles" them into one payment, the QIP helps to ensure the quality of services delivered under the "bundled payment".
What does the QIP do?

- Connects Medicare payment rate to provider/facility performance based on specific measures
- Providers/facilities that do not meet or exceed the specified performance standards, will receive a payment reduction of up to 2.0%
- Payment reductions will apply with respect to the year involved and will not be taken into account when computing future payment rates
Goals of the QIP

- CMS expects to:
  - Improve quality and safety for beneficiaries;
  - Promote efficiency;
  - Minimize risks of unintended consequences related to a bundled payment system;
  - Encourage meaningful use of health information technology; and
  - Improve transparency for beneficiaries and other stakeholders
QIP Proposed Measures

- CMS proposes to use three claims based measures that focus on the management of anemia and the adequacy of dialysis treatment

- Rationale for the measures:
  - They fulfill the statutory requirement
  - The measures have been in use for several years by facilities
  - CMS has data available to develop and test the various models
  - Providers and stakeholders are familiar with the measures
  - Time limitations on the development of new measures for the first reporting year
Claims Based Measures

- CMS expects to use three claims-based measures for 2012
- Two measures are for anemia management (Percent of patients whose Hgb levels are less than 10g/dL and Percent of patients whose Hgb levels are greater than 12g/dL)
- One is for hemodialysis adequacy (Achieved Urea Reduction Ratio greater than 65 percent)
- Data for these measures derived from ESRD claims and have been utilized for public reporting since the release of Dialysis Facility Compare (DFC) January 2001
Next Steps

- CMS will continue development of a Quality Incentive Program
- CMS will release the details of that program in future rulemaking
- The public may submit comments on the QIP conceptual model via instructions found in the ESRD PPS NPRM
Questions?
Wrap Up

- Public comments welcome
- The proposed rule is available at: http://www.cms.hhs.gov/ESRDPayment/
- Click “End-Stage Renal Disease (ESRD) Payment Regulations and Notices”
- Select the link to the proposed rule