

Table of Contents Page Number Guide

Provision (Page Number)

I. Background (14)

- A. Overview of the Proposed ESRD PPS (14)
- B. Legislative History and Statutory Authority for the ESRD Prospective Payment System (15)
- C. Existing Basic Case-Mix Adjustments (30)

II. Summary of the Proposed Provisions and Responses to Comments on the Proposed Rule (34)

- A. The Proposed ESRD PPS Bundle (40)
 - 1. Composite Rate Services (40)
 - 2. ESAs and Their Oral Forms (42)
 - 3. Other Drugs and Biologicals and Their Oral Forms (48)
 - a. Oral-Only ESRD-Related Drugs (50)
 - b. Other Drugs and Biologicals (83)
 - 4. Diagnostic Laboratory Tests and Other Items and Services (127)
 - 5. Physicians' Services (138)
 - 6. Other Services (139)
 - 7. Home Dialysis Patients (Method I and II) and Self Dialysis Training (145)
 - a. Payment for Home Dialysis (Method I and Method II) (145)
 - i. Method I— The Composite Rate (154)
 - ii. Method II—Dealing Directly with Suppliers (157)
 - b. Self-Dialysis Training (178)
- B. Unit of Payment (189)
- C. Data Sources (194)
 - 1. Patient Claims Data (199)
 - 2. Medicare Cost Reports (202)

Provision (Page Number)

3. Patient Claim and Cost Report Summary Data 2006–2008 (202)
4. Data for the Case-Mix Analyses, 2006–2008 (210)
5. Prescription Drug Event Data, CY 2007, CY 2008, Jan–Sept 2009 (211)
- D. Analytical Approach (213)
- E. Development of ESRD PPS Base Rate (214)
 1. Calculation of the CY 2007 Unadjusted Rate Per Treatment (223)
 - a. Composite Rate Services (225)
 - b. Part B Drugs and Biologicals (226)
 - c. Laboratory Tests (226)
 - d. Durable Medical Equipment (DME) and Supplies (227)
 - e. Dialysis Support Services (227)
 - f. Supplies and Other Services Billed by Dialysis Facilities (227)
 - g. Former Part D Drugs (228)
 - h. Total Medicare Hemodialysis (HD)-Equivalent Sessions (236)
 - i. Average MAP Per Treatment (237)
 2. Determining the Update Factors for the Budget-Neutrality Calculation (239)
 - a. Composite Rate Services (239)
 - b. Self-Dialysis Support Services For Method II Patients (243)
 - c. Part B Drugs And Biologicals (243)
 - d. Laboratory Tests (246)
 - e. DME Supplies and Equipment (246)
 - f. Supplies and Other Services (247)
 - g. Former Part D Drugs (247)
 3. Standardization Adjustment (250)
 4. Calculation of the Budget-Neutrality Adjustments (253)

Provision (Page Number)

- a. Outlier Adjustment (253)
- b. 98 percent Budget-Neutrality Adjustment (254)
- 5. Calculation of the Transition Budget-Neutrality Adjustment (257)
- F. Regression Model Used to Develop Final Payment Adjustment Factors (266)
 - 1. Regression Analysis (266)
 - a. Dependent Variables (267)
 - i. Average Cost Per Treatment for Composite Rate Services (267)
 - ii. Average Medicare Allowable Payment (MAP) for Separately Billable Services (270)
 - b. Independent Variables (276)
 - i. Control Variables (277)
 - ii. Case-Mix Adjustment Variables (278)
 - 2. Choosing Between a Separately Billable Model Based on Patient-Year or Patient-Month Data (282)
 - 3. Patient-Level Adjustments (288)
 - a. Patient Age (294)
 - b. Patient Sex (298)
 - c. Body Surface Area and Body Mass Index (301)
 - d. Onset of Dialysis (New Patient Adjustment) (305)
 - e. Co-morbidities (327)
 - f. ICD-9-CM Coding (404)
 - g. Race/Ethnicity (409)
 - h. Modality (446)
 - 4. Proposed Facility-Level Adjustments (449)
 - a. Wage Index (449)
 - b. Low-Volume Adjustment (460)

Provision (Page Number)

- i. Defining a Low-Volume facility (460)
- ii. Defining the Percent of Increase (489)
- c. Alaska/Hawaii Facilities (492)
- d. Rural (494)
- e. Site Neutral ESRD PPS Rate (501)
- 5. Determination of ESRD PPS Payment Adjusters (502)
- G. Pediatric Patients (507)
 - 1. The Revised Payment Methodology for the Pediatric Payment Adjustments (524)
 - 2. Composite Rate Payments for Pediatric Patients (524)
 - 3. Separately Billable Services (526)
 - 4. No Caps Applied to the Separately Billable MAP per Treatment (528)
 - 5. A Combined Composite Rate and Separately Billable Payment Model for Pediatric Patients (531)
 - 6. Adult Payment Adjustments That Do Not Apply to Pediatric Patients (534)
- H. Outlier Policy (538)
 - 1. Eligibility for Outlier Payment (539)
 - a. ESRD Outlier Services (542)
 - b. Predicted ESRD Outlier Services MAP Amounts (561)
 - c. Estimating the Imputed ESRD Outlier Services MAP Amounts (569)
 - i. Data Used to Estimate Imputed ESRD Outlier Services MAP Amounts (570)
 - ii. Determining Imputed Per Treatment ESRD Outlier Services MAP Amount (580)
 - d. Outlier Percentage and Fixed Dollar Loss Amounts (581)
 - 2. Outlier Payments (589)
 - 3. Hypothetical Outlier Payment Examples (592)

Provision (Page Number)

4. Application of Outlier Policy During the Transition and in Relation to the ESA Monitoring Policy, Other Claims Processing Tools, and Other CMS Policies (596)
 - I. Comprehensive Payment Model Examples (607)
 - J. ESRD Bundled Market Basket (634)
 - K. Implementation (681)
 1. Transition Period (681)
 - a. New ESRD Facilities (694)
 - b. Limitation on Beneficiary Charges under the ESRD PPS and Beneficiary Deductible and Co-insurance Obligations (695)
 2. Claims Processing (715)
 - a. Consolidated Billing Rules and Edits (716)
 - i. Laboratory Tests (719)
 - ii. Drugs and Biologicals (726)
 - iii. Home Dialysis (745)
 - b. Expansion of the Data Elements Reported on Claims (746)
 3. Miscellaneous Comments (748)
 4. Comments Regarding Monitoring (764)
 5. Comments Beyond the Scope of this Final Rule (770)
 - L. Evaluation of Existing ESRD Policies and Other Issues (772)
 1. Exceptions Under the Case-Mix Adjusted Composite Payment System (773)
 2. Erythropoiesis Stimulating Agent (ESA) Claims Monitoring Policy (779)
 3. ESRD Facility Network Deduction (779)
 4. Bad Debt (780)
 5. Limitation on Review (789)
 6. 50 Percent Rule Utilized in Laboratory Payments (791)

Provision (Page Number)

- 7. Medicare as a Secondary Payer (793)
- 8. Conforming Regulation Changes (795)
- M. Anemia Management and Dialysis Adequacy Measures (797)
 - 1. Anemia Management Measures: Hemoglobin Less Than 10g/dL and Hemoglobin Greater Than 12g/dL (806)
 - 2. Hemodialysis Adequacy Measure: Urea Reduction Ratio (URR) (815)
 - 3. Additional Comments (823)

III. Collection of Information Requirements (843)

- A. ICRs Regarding a Low-volume adjustment (§413.232(f)) (844)
- B. ICRs Regarding Transition Period (§413.239) (846)

IV. Regulatory Impact Analysis (851)

- A. Overall Impact (851)
- B. Anticipated Effects (857)
 - 1. Effects on ESRD facilities (857)
 - 2. Effects on Other Providers (864)
 - 3. Effects on the Medicare and Medicaid programs (865)
 - 4. Effects on Medicare Beneficiaries (865)
- C. Alternatives Considered (866)
- D. Accounting Statement and Table (867)
- E. Conclusion (877)

Regulations Text

APPENDIX (912)