

XIV. Evaluation of Existing ESRD Policies and Other Issues

We reviewed existing ESRD policies to determine their applicability to the proposed ESRD PPS. We propose to eliminate the exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities that exist under the case-mix adjusted composite payment system. We would maintain the current erythropoiesis stimulating agent monitoring policy, bad debt policy, reporting requirements for circumstances whereby Medicare is the secondary payer (MSP), and the 50-cent deduction to fund the ESRD Networks. We also propose to set forth in §413.195 the limitation on review with regard to the ESRD PPS. In addition, we are considering the extent to which the laboratory services 50 percent rule would continue to apply under the proposed ESRD PPS.

A. Exceptions Under the Case-Mix Adjusted Composite Payment System

Section 1881(b)(7) of the Act and §413.182 generally address exceptions to the composite payment rates. Section 422(a)(2) of BIPA prohibited the granting of new exceptions to the composite payment rates after December 31, 2000, but

did allow the continuation of the existing exceptions as long as the exception rate exceeded the applicable composite payment rate. Section 623(b) of the MMA amended section 422(a)(2) of BIPA to restore composite rate exceptions for pediatric facilities that did not have an exception rate in effect as of October 1, 2002. Section 422(a)(2)(D) of BIPA defined a pediatric facility as a renal dialysis facility at least 50 percent of whose patients are under 18 years of age.

In the calendar year (CY) 2005 Physician Fee Schedule (PFS) proposed rule (69 FR 47535), we explained that section 422(a)(2)(C) of BIPA provided that any ESRD composite rate exception in effect on December 31, 2000, would continue as long as the exception rate exceeds the applicable composite payment rate. We further explained that when computing an exception amount, the facility's patient population and the higher costs relating to case-mix are taken into consideration. We indicated that we were proposing to allow each dialysis facility the option of continuing to be paid at its exception rate or at the basic case-mix adjusted composite rate. On April 1, 2004, we opened the exception window for pediatric facilities and noted that the window would close in September 27, 2004.

In the CY 2005 PFS final rule with comment period (69 FR 66332), we stated that the exception process was opened each time there is a legislative change in the composite payment rate or when we open the exception window. We indicated our intent to open the pediatric exception windows on an annual basis. We also noted that we would provide for the continuation of the home training exception to allow for facilities with home training exceptions to retain their current training exception rates as well as take advantage of the case-mix adjusted rates for non-training dialysis.

While section 153 of the MIPPA does not directly address exceptions, we believe that the ESRD PPS under section 1881(b)(14) of the Act, creates an ESRD bundled prospective payment in lieu of payment under previous ESRD payment systems and given that the ESRD PPS no longer directly addresses changes in the ESRD composite rate, we believe that the exceptions currently in place would no longer apply. We also believe that we have addressed the higher costs relating to case-mix through the patient characteristic adjustments and outlier payments that are discussed in detail in sections VIII.B and X.A. Therefore, we are proposing the elimination of the isolated essential

facility, self dialysis training costs, atypical service intensity (patient mix) and pediatric facility exceptions effective for ESRD renal dialysis services furnished on or after January 1, 2014 (at the conclusion of the phase-in). In other words, any existing exceptions would terminate effective for ESRD treatment on or after January 1, 2014. Additionally, no further exception windows would be open effective for ESRD treatment furnished on or after January 1, 2011, the effective date of the ESRD PPS. In the event that an ESRD facility elects to receive full payment under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011, any existing exceptions would no longer be recognized. In the event that an ESRD facility elects to receive payment under the transition period, any existing exceptions would be recognized for purpose of the basic case-mix adjusted composite payment system portion of the blended payment through the transition. We propose to include the periods of exceptions and the elimination of the exceptions to the composite payment rates in §413.180 of the regulations. With respect to appeals under §413.194(b) we point out that such appeals apply only to exceptions to the composite rate granted before January 1, 2011.

B. Erythropoiesis Stimulating Agent (ESA) Monitoring Policy

In 2003, we solicited input from the ESRD community, in order to develop an erythropoiesis stimulating agent (ESA) Monitoring Policy. After input from the community, we implemented, through administrative issuance, the first iteration of the monitoring policy effective for services provided on or after April 1, 2006. On July 20, 2007, we issued through administrative issuance, a revised policy effective for services furnished on or after January 1, 2008. We are currently evaluating the extent to which we could continue the ESA Monitoring Policy for renal dialysis services furnished on or after January 1, 2011. Specifically, at the current time it is not known how the reduction in payment that is currently applied to the separately billed ESAs would be applied under the proposed ESRD PPS. As discussed in section X.A, we are also continuing to evaluate how to establish eligibility for outlier payments in instances where the ESA Monitoring Policy is implicated. We request public comments on this issue to inform our evaluation.

C. ESRD Facility Network Deduction

Pursuant to section 1881(b)(7) of the Act, to fund the ESRD Networks, 50 cents is deducted from the amount of each

payment for each treatment (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis). The reduction amount applies to all treatment modalities. The methodology for calculating the reduction is described in the Medicare Claims Processing Manual, Pub. 100-04, Ch. 8, section 110. We would continue this deduction with the ESRD PPS effective for services provided on or after January 1, 2011, with a 50 cent reduction per treatment from the payment made to ESRD facilities under the ESRD PPS for facilities that elect to receive payment under the ESRD PPS (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis). For facilities that elect to receive ESRD payment during the transition, we would apply the reduction methodology as described above to the blended payment amount during the transition.

D. Bad Debt

Section 413.89 of the regulations and Chapter 3 of the Provider Reimbursement Manual, Part 1 (PRM) (CMS Pub. 15-1) set forth the general requirements and policies for payment of bad debts attributable to unpaid Medicare deductibles and coinsurance amounts. Additional requirements for ESRD facilities are set forth at §413.178.

Under the basic case-mix adjusted payment system, Medicare pays ESRD facilities 80 percent of a prospectively set composite rate for outpatient dialysis services. The Medicare beneficiary is responsible for the remaining 20 percent as coinsurance, as well as any applicable deductible amounts as set forth in §413.176 of the regulations. If the ESRD facility makes reasonable collection efforts, as described in the Section 310 of the PRM, but is unable to collect the deductible or coinsurance amounts for items or services associated with the composite rate, we consider the uncollected amount to be a "bad debt" if the facility meets the requirements at §413.178 and §413.89 of the regulations and Chapter 3 of this proposed rule.

At the end of the ESRD facility cost reporting period, Medicare recognizes a facility's Medicare bad debts. However, §413.178(a) requires CMS to reimburse ESRD facilities for its allowable bad debt up to the facility's costs as determined under Medicare principles.

In developing the proposed changes to the ESRD payment system described in this proposed rule, section 153(a)(4) of MIPPA states, as a Rule of Construction, that, "nothing in this subsection or the amendments made by this

subsection shall be construed as authorizing or requiring the Secretary of Health and Human Services to make payments under the payment system implemented under paragraph (14) (A) (i) of section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)), as added by paragraph (1), for any unrecovered amount for any bad debt attributable to deductible and coinsurance on items and services not included in the basic case-mix adjusted composite rate under paragraph (12) of such section as in effect before the date of the enactment of this Act."

Therefore, under the proposed ESRD PPS, bad debt payments will continue to be made for the unpaid Medicare deductibles and coinsurance amounts for only those items and services associated with the basic case-mix adjusted composite rate. However, since the proposed single ESRD payment rate is for items and services included in the composite rate and for drugs and laboratory tests, we are proposing to use only the composite rate portion of the proposed single ESRD payment rate to determine bad debt payments. We are proposing that bad debt payments for ESRD facilities would continue to be capped as required under §413.178(a). The Medicare cost report and instructions in the PRM, Part 2 (CMS Pub. 15-2) may be revised to report the case mix adjusted composite rate payment and associated

cost data necessary to compute the ESRD facility bad debt payments.

In addition, we are proposing to make a conforming change to regulation text at §413.178(d) regarding ESRD bad debt payment made under the proposed ESRD payment system described in this proposed rule. We are also including a cross-reference to §413.178 in §413.89(h) and (i).

E. Limitation on Review

In addition to requiring the establishment of the ESRD PPS, section 153(b) of MIPPA amends section 1881(b) of the Act to provide for a limitation on review. Specifically, section 1881(b)(14)(G) of the Act provides the following: "There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act or otherwise of the determination of payment amounts under [section 1881(b)(14)(A)], the establishment of an appropriate unit of payment under [section 1881(b)(14)(C)], the identification of of renal dialysis services included in the bundled payment, the adjustments under [section 1881(B)(14)(D)], the application of the phase-in under [section 1881(b)(14)(E)], and the establishment of the market basket percentage increase factors under [section

1881(b)(14)(F)].” We propose to codify this limitation on review in §413.195 of the regulations.

F. 50 Percent Rule Utilized in Laboratory Payments

As specified in CMS Pub 100-04, Chapter 16, Sect. 40.6, for a particular date of service to a beneficiary, if 50 percent or more of the covered laboratory tests within an Automated Multi-Channel Chemistry (AMCC) test are included under the composite rate payment, then all submitted tests are included within the composite payment and no separate payment in addition to the composite rate is made for any of the separately billable tests. If less than 50 percent of the covered laboratory tests within the AMCC are composite rate tests, then all AMCC tests submitted are separately payable. When ordering ESRD-related AMCC tests, ESRD facilities identify, for a particular date of service, each test that is included in the composite rate and each test that is not included. A “non-composite rate test” is defined as “any test separately payable outside the composite rate or beyond the normal frequency covered under the composite rate that is reasonable and necessary.”

During the transition period, the 50 percent rule would continue to apply to the basic case mix adjusted composite payment system portion of the blended payment.

Under the proposed consolidated billing provisions discussed further in section XIII B. of this proposed rule, the ESRD facility itself would assume the Medicare billing responsibility for all of the renal dialysis services that its patients receive, including laboratory tests. As a result, the ESRD facilities would apply the 50 percent rule billing procedures including application of the relevant modifiers.

As described in section X of this proposed rule, under the proposed ESRD PPS, Medicare would not make separate payment for laboratory tests, rendering the 50 percent rule irrelevant for payment purposes. The 50 percent rule's relevance would be limited to its use in determining eligibility for outlier payment.

In addition, preliminary analyses reveal a small impact upon removing from eligibility for outlier services the AMCC tests to which the 50 percent rule applies. As a result, we are considering excluding AAMC tests to which the 50 percent rule applies from the definition of outlier services, thus negating the need to apply the 50 percent rule under the proposed ESRD PPS. We plan to continue to evaluate the impact of this approach and include further discussion in the final rule. We request public comments on whether or not to include the AMCC tests to which the 50

percent rule applies within the definition of outlier services and retain the 50 percent rule under the proposed ESRD PPS.

G. Medicare as a Secondary Payer

Medicare may be a secondary payer (MSP) when the primary payer is a group health plan for ESRD items and services furnished to Medicare beneficiaries during the 30-month Medicare coordination of benefit period. At this time, we are unable to identify the systems operations and billing procedures impact of this relationship under the current basic case-mix adjusted composite payment system, and we are exploring how it will be utilized and managed under the proposed ESRD prospective payment system. We believe that while there may need to be system changes in order to process MSP claims under the Proposed ESRD prospective payment system, there should be no impact on ESRD providers and on primary payers. We will issue through administrative issuance, any changes in the manner of reporting information, should that be required. We are soliciting public comment on the operational issues of MSP under the proposed ESRD payment system.

XV. Quality Incentives in the End-Stage Renal Disease

(ESRD) Program

A. Introduction