

XIII. Proposed Implementation for the ESRD PPS

A. Transition Period

Section 1881(b)(14) of the Act replaces the current basic case-mix adjusted composite payment system with a case-mix adjusted bundled prospective payment system, or the ESRD PPS, for Medicare outpatient ESRD facilities beginning January 1, 2011. Section 1881(b)(14)(E)(i) of the Act requires the Secretary to provide "a four-year phase-in" of the payments under the ESRD PPS for renal dialysis services furnished on or after January 1, 2011. Although the statute uses the term "phase-in", other Medicare payment systems use the term "transition" to describe the timeframe during which payments are based on a blend of the payment rates under the prior payment system and the new payment system. For purposes of this ESRD PPS proposed rule, we will use the term "transition" to describe this timeframe. Section 1881(b)(14)(E)(i) of the Act further requires that the transition occur "in equal increments," with payments under the ESRD PPS "fully implemented for renal dialysis services furnished on or after January 1, 2014." In addition, section 1881(b)(14)(E)(ii) of the Act permits an ESRD facility to make a one-time election to be excluded from the transition from the current basic case-mix adjusted composite payment

system, with its payment amount for renal dialysis services based entirely on the payment amount under the ESRD PPS. This election must be made prior to January 1, 2011. In addition, section 1881(b)(14)(E)(iii) of the Act requires that we make an adjustment during the transition so that payments during the transition equal the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. The transition budget-neutrality adjustment is discussed further in section VII.E.

In accordance with section 1881(b)(14)(E) of the Act, we propose to implement the transition from the current basic case-mix adjusted composite payment system in equal increments, with renal dialysis services and home dialysis furnished on or after January 1, 2014, paid entirely based on the payment amount under the ESRD PPS. Specifically, we propose that for renal dialysis services and home dialysis services provided during the transition period beginning January 1, 2011 and ending December 31, 2013, ESRD facilities receive a blended payment for each dialysis treatment consisting of the payment amount under the basic-case mix adjusted composite system and the payment amount under the ESRD PPS. Therefore, because ESRD facilities would receive an all-inclusive payment during the

transition for all renal dialysis services and home dialysis items and services, other entities, such as Method II DME suppliers, laboratories, and Part D plans would no longer bill Medicare beginning January 1, 2011. To the extent these entities furnish items or services to ESRD patients, the entities would need to seek payments from the patient's ESRD facility. Further discussion on Method II DME suppliers, laboratories, and Part D plans can be found below.

For CY 2011, we are proposing to make payments based on 75 percent of the payment rate under the basic case-mix adjusted composite payment system and 25 percent of the payment rate under the ESRD PPS. For CY 2012 we are proposing to make payment based on 50 percent of the payment rate under the basic case-mix adjusted composite payment system and 50 percent of the payment rate under the ESRD PPS. For CY 2013 we are proposing to make payment based on 25 percent of the payment rate under the basic case-mix adjusted composite payment system and 75 percent of the payment rate under the ESRD PPS. For renal dialysis services furnished on or after January 1, 2014, we propose that payment to ESRD facilities be based on 100 percent of the payment amount under the ESRD PPS.

In particular, we propose that the portion of the blended rate based on the payment amount with regard to the basic case-mix adjusted composite payment system would be comprised of the composite payment rate (which is adjusted by the basic case-mix and a wage index), the drug add-on amount, and payment amounts for items and services furnished to dialysis patients that are currently separately paid under Part B by Medicare to entities other than the ESRD facility. In addition to the above components of the basic case-mix adjusted payment system, as part of the transitional budget neutrality adjustment (describe in section VII.E.), we are also proposing to include a 14 dollar adjustment to the portion of the blended rate related to the basic case-mix adjusted payment system during the transition. The 14 dollar adjustment to the portion of the blended payment amount related to the basic case-mix adjusted payment system accounts for the ESRD related drugs and biological that are currently separately paid under Part D and are being proposed to be included in the ESRD PPS base rate.

For the years during which the phase-in (transition) is applicable, section 1881(b)(14)(F)(ii) of the Act requires the Secretary to annually increase the portion of the proposed ESRD PPS that is based on the composite rate

that would otherwise apply if the ESRD PPS had not been enacted. In particular, section 1881(b)(14)(F)(ii)(II) of the Act requires the composite rate portion of the blended payment to be updated annually by the ESRDB market basket minus 1.0 percentage point. Our interpretation of section 1881(b)(14)(F)(ii) of the Act is that the ESRDB market basket minus 1.0 percentage point would be applied only to the composite payment rate portion of the blended payment amount for each year of the transition (which includes CY 2011). A full description of the ESRDB market basket is presented in section XII.

Therefore, for each year of the transition, we are proposing that the composite payment rate portion of the blended amount would be updated by a case-mix adjustment, the drug add-on adjustment, the current wage index, the ESRDB market basket minus 1.0 percentage point, and an adjustment to account for former ESRD-related Part D drugs to maintain transitional budget neutrality. Payments for items and services furnished to dialysis patients that are paid separately under Part B with regard to the current composite payment rate methodology, that is, ESRD-related laboratory tests, ESRD-related drugs, and ESRD-related supplies, blood, and blood products would no longer be paid separately. Instead, those items and services would be

priced to reflect how they are currently paid, for example, using a fee schedule or ASP amount.

We note that there are ESRD facilities that have existing exception amounts that are used for payment in lieu of the composite rate, drug add-on payment, and basic case-mix adjustments (further discussion of exceptions under the basic case-mix adjustment composite payment system can be found in section I.B.3). Any existing exception amount would not be updated by the ESRDB market basket throughout the transition.

The portion of the blended rate based on the payment amount under the ESRD PPS includes the base rate and all applicable patient-level and facility-level adjustments, as would be determined under proposed §413.231 and §413.235. As set forth in proposed §413.237, we propose that the ESRD PPS portion of the blended rate would also include outlier payments.

As specified in proposed §413.178, bad debt is paid separately from the ESRD PPS and any payment for bad debt would occur at the time a FI/MAC reviews an ESRD facility's cost report and makes a final determination on if there are any overpayments/underpayments due to the ESRD facility/Medicare. For more information regarding bad debt payments see section XIV.D.

As previously noted, section 1881(b)(14)(E)(ii) of the Act gives an ESRD facility the option to make a one-time election to be excluded from the four-year transition from the current basic case-mix adjusted composite payment system in the form and manner specified by the Secretary. Once made, this election may not be rescinded. ESRD facilities may choose to be paid the blended rate under the transition period in order to give them time to determine the impact of the ESRD PPS on their operations and to adjust their operations accordingly. We believe ESRD facilities will choose to be excluded from the transition if they conclude that they would benefit financially from the payment amount under the ESRD PPS.

Section 1881(b)(14)(E)(ii) of the Act requires that ESRD facilities wishing to be excluded from the transition make their election prior to January 1, 2011, in the form and manner specified by the Secretary. We are proposing that ESRD facilities notify CMS of their election choice in a manner established by their respective FI/MAC no later than November 1, 2010 regardless of any postmarks or anticipated delivery dates. A timeframe of 60 days before implementation is consistent with the timeframe that a FI/MAC is given to incorporate any updates to rates. We are also proposing that those ESRD facilities that become

certified for Medicare participation and begin to provide renal dialysis services between November 1, 2010 and December 31, 2010 would notify their FI/MAC of their election choice at the time of enrollment. Once an ESRD facility notifies their respective FI/MAC of their election choice, on or before November 1, 2010 (or at the time of enrollment for newly certified ESRD facilities that begin to provide renal dialysis services between November 1, 2010 and December 31, 2010), the ESRD facility's election cannot be rescinded. We note that section 1881(b)(14)(E)(ii) of the Act provides that all ESRD facilities wishing to be excluded from the transition must make an election to be excluded from the transition. We therefore are further proposing that those ESRD facilities that fail to affirmatively make an election by November 1, 2010, would be paid based on the blended amount under the transition. Elections submitted by ESRD facilities that wish to be excluded from the transition that are received, postmarked, or delivered by other means after November 1, 2010 would not be accepted. All ESRD facilities wishing to be excluded from the transition should submit their election choice by the proposed deadline if they wish to be excluded from the transition and paid entirely based on the payment amount under the ESRD PPS for renal dialysis services

furnished on or after January 1, 2011. Instruction as to how the FIs/MACs would implement the proposed ESRD PPS would be provided in future guidance. If the FIs/MACs express concern about the November 1, 2010 date, we would revisit the deadline in the ESRD PPS final rule. The proposed transition period policy is set forth in proposed §413.239.

We are requesting public comment regarding our proposed blended payment rates and our proposed process for making the election to be excluded from the transition period.

1. New ESRD Facilities

Although the first sentence of section 1881(b)(14)(E)(i) of the Act permits "a provider of services or renal dialysis facility" to make a one-time election to be excluded from the transition, the second sentence provides that this election must be made prior to January 1, 2011. Reading these two sentences together, we believe that only ESRD facilities providing renal dialysis services to Medicare beneficiaries before January 1, 2011, should have the option to choose whether to be paid under the transition or under the ESRD PPS. We further note that the transition period provided for under section 1881(b)(14)(E)(i) of the Act is intended to provide

existing ESRD facilities time to adjust from payments based on the current basic case-mix adjusted composite payment methodology to bundled payments under the ESRD PPS. New ESRD facilities that begin providing renal dialysis services and home dialysis to Medicare beneficiaries on or after January 1, 2011, would not have received payment under the current basic case-mix adjusted composite payment system; therefore, we do not believe new ESRD facilities require a transition period in order to make adjustments to their operating procedures. Accordingly, we propose that ESRD facilities that are certified for Medicare participation and begin providing renal dialysis services and home dialysis on or after January 1, 2011, not have the option to choose whether to be paid a blended rate under the transition or the payment amount under the ESRD PPS. Rather, we propose that new ESRD facilities be paid based on 100 percent of the payment amount under the ESRD PPS.

As set forth in §413.171 of this proposed rule, we are proposing to define a new ESRD facility as an ESRD facility that is certified for Medicare participation on or after January 1, 2011.

2. Limitation on Beneficiary Charges under the Proposed ESRD PPS and Beneficiary Deductible and Coinsurance Obligations

Section 1833 of the Act governs payments of benefits for Part B services and the cost sharing amounts for services that are considered medical and other health services. In general, many Part B services are subject to a payment structure that requires beneficiaries to be responsible for a 20 percent coinsurance after the deductible (and Medicare pays 80 percent). With respect to dialysis services furnished by ESRD facilities to individuals with ESRD, under section 1881(b)(2)(a) of the Act, payment amounts are 80 percent (and 20 percent by the individual).

In this rule, we have proposed the items and services that would be considered renal dialysis services included in the ESRD PPS payment such as the composite rate related services, certain separately billable drugs, former Part D drugs used in the treatment of ESRD, laboratory testing, etc. We understand that certain items and services such as laboratory tests and Part D drugs have different beneficiary coinsurance structures. However, these items and services would be considered renal dialysis services after the ESRD PPS is implemented when furnished by an ESRD dialysis facility to an ESRD beneficiary. Therefore, a

20 percent beneficiary coinsurance would be applicable to the ESRD PPS payment for these services including any

adjustments to the ESRD PPS payment such as adjustments for case-mix, geographic wage index, outlier, etc.

Thus, we are proposing that an ESRD facility receiving an ESRD PPS payment may charge the Medicare beneficiary or other person only for the applicable deductible and coinsurance amounts as specified in §413.176. The beneficiary coinsurance amount for the ESRD PPS base rate is 20 percent of the total ESRD PPS payment (including payments made under the transition). We note that the amount of coinsurance is based on the proposed ESRD PPS payment for renal dialysis services and home dialysis in

42 CFR Part 413. In general, facilities are paid monthly by Medicare for the ESRD services they furnished to a beneficiary even though payment is on a per treatment basis. We are proposing to continue this practice to pay ESRD facilities monthly for services furnished to a beneficiary beginning January 1, 2011. During the transition period before January 1, 2014, ESRD facilities that do not elect to go 100 percent into the ESRD PPS in 2011 would receive a blended payment amount of the prospective payment system in effect prior to January 1, 2011, and the ESRD PPS payment amount for services furnished to a beneficiary. ESRD Facilities would receive a monthly payment that is a blended payment amount for

services furnished to a beneficiary. The services included in this blended monthly payment amount would be subject to a 20 percent beneficiary coinsurance.

Additionally, in accordance with section 1881(b)(1) of the Act and consistent with other established prospective payment systems policies, we are proposing in §413.172(b) that an ESRD facility may not charge a beneficiary for any service for which payment is made by Medicare. This policy would apply, even if the ESRD facility's costs of furnishing services to that beneficiary are greater than the amount the ESRD facility would be paid under the proposed ESRD PPS.

B. Claims Processing

As indicated above, section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made for renal dialysis services and other items and services related to home dialysis. For example, those services would include supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, and support services.

Implementation of the proposed ESRD PPS will require a significant amount of changes to the way we process claims. Some of the changes could entail consolidated billing rules

and edits and the data elements reported on claims, as discussed below.

1. Consolidated Billing

Since the ESRD PPS payment model represents an all-inclusive payment for renal dialysis services and home dialysis items and services, the ESRD facility itself is responsible for virtually all of the services mentioned above that its patients receive. It is important that billing and payment for these services, which could be provided by other entities, such as laboratories, is made only to the ESRD facility so that duplicate payment is not made by Medicare. Therefore, as stated previously in section XIII.B, suppliers, laboratories, and Part D plans would not be permitted to bill Medicare for renal dialysis services and home dialysis items and services that they furnish to ESRD beneficiaries. The consolidated billing approach essentially confers to the ESRD facility itself the Medicare billing responsibility for all of the renal dialysis services that its patients receive.

a. Laboratory Tests

ESRD patients generally have many co-morbid conditions and are treated by other specialists for those conditions. As such, many of the same laboratory tests ordered by a physician to monitor a patient's ESRD, could also be

ordered by other physician specialists treating the ESRD patient for other medical conditions. Therefore, it is difficult to differentiate between an ESRD related laboratory test and a test ordered for another condition. While the ideal scenario would be to require that payment for all potential ESRD related laboratory tests be made only to the ESRD facility, ESRD facilities may not be able to control the ordering of tests by physicians not treating the patient's renal disease. A consolidated billing approach could identify the source of a given laboratory test to allow separate payment when the test was not ordered in connection with the patient's ESRD condition. In order to ensure proper payment in all settings, we are exploring the use of modifiers to identify those services furnished to ESRD beneficiaries, which are excluded from the proposed ESRD PPS.

b. Drugs and Biologicals

Certain drugs and biologicals routinely furnished to ESRD beneficiaries that are paid under the Medicare ESRD benefit are included in the current basic case-mix adjusted composite rate. Other ESRD-related injectable drugs are separately paid under Medicare Part B. However, as mentioned above, section 1881(b)(14)(B) of the Act requires the inclusion of all drugs and biologicals used for the

treatment of ESRD, including drugs and biologicals that were formerly covered under Medicare Part D. Therefore, we would include these drugs as part of the consolidated billing mechanism discussed above. As a result of including these former Part D ESRD drugs and biologicals in the proposed ESRD PPS, we are proposing that ESRD facilities would be required to furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement. Such arrangements would prevent potential Medicare overpayments made under both Parts B and D. Further discussion regarding payment for former Part D drugs and biologicals can be found in section III.C.

c. Home dialysis

Section 1881(b)(14)(A)(i) of the Act requires the costs of home dialysis supplies and services furnished under Method I and Method II, regardless of home treatment modality, be included in the proposed ESRD PPS. Thus, we are proposing that the Method II home dialysis approach in its present form would no longer exist under the proposed ESRD PPS effective January 1, 2011. This proposal does not eliminate Method I in its present form. Therefore, a supplier could only furnish, under arrangement with the ESRD facility, home dialysis equipment and supplies to a

Medicare home dialysis beneficiary, and the supplier would have to look to the ESRD facility for payment. We believe that this approach is simpler and would reduce the administrative burden of maintaining two payment methods for home dialysis patients, as we believe that section 1881(b)(14)(A)(i) of the Act requires that all Medicare home dialysis supplies and services be paid under the proposed ESRD PPS and such payment be made to the ESRD facility. Further discussion of this proposal and information on home dialysis can be found in section III.E.

2. Expansion of the data elements reported on claims

Under the current basic case-mix composite adjusted payment system, ESRD facilities are paid a composite rate for each dialysis treatment performed. Currently the composite rate includes a number of items and services beyond the dialysis treatment itself. The services that are billed on the claim do not provide any detail of the composite rate items and services that are furnished to the patient beyond the treatment itself. Examples of additional types of items and services that are included in the composite rate but are not captured on the claims and that we believe would be helpful in our ability to predict composite rate costs are: time on machine, nutritional services, social work services, and nursing services. We

are not proposing additional reporting requirements at this time, but we believe that collecting additional data at patient-level is necessary for refinements to the proposed case-mix adjustments of the proposed ESRD PPS payment model.

In the future, we may implement new reporting requirements where data elements, such as time on machine, nutritional services, social work services, and nursing services, would be relevant for case-mix refinements. We are requesting public comment regarding these data elements and other claim-based information that would identify patients who are high cost. Identifying other factors that explain costs could assist us in developing future patient-level adjusters that would further refine the model that we used to develop the proposed ESRD PPS. Detailed instruction as to how claims would be processed under the proposed ESRD PPS will be provided in future guidance.

C. Operational Issues Surrounding Payment for Self Administered ESRD-Related Drugs and Biologicals

As we discussed in section III. of this proposed rule, section 1881(b)(14)(B) of the Act defines renal dialysis services to include, among other things, certain drugs and biologicals, including drugs and biologicals that were separately payable under Parts B and D. Under the current

ESRD basic case-mix adjusted composite payment system, ESRD facilities generally do not furnish oral drugs and biologicals to their ESRD patients. ESRD patients currently acquire these drugs and biologicals either through Medicare Part D, private insurance, or independently.

As described in section III. of this proposed rule, we are proposing to include renal dialysis service drugs formerly covered under Part D under the proposed ESRD PPS. As a result, we are further proposing that ESRD facilities would be required to furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement. Regardless of the mechanism by which these drugs would be furnished (directly or under arrangement), as ESRD facilities assume responsibility for the provision of these drugs that were formerly furnished by the Part D plans, we believe that some of the Part D provisions set forth in the 42 CFR Part 423, would become relevant for ESRD facilities. We are particularly interested in assuring beneficiary access to these drugs. As such, we request public comment on the extent to which Part D access requirements including, but not limited to, pharmacy networks and formularies may be relevant in the

context of ESRD facilities' provision of renal dialysis service drugs.

In addition, consistent with the patients' rights processes set forth in §494.70(a) and the condition: governance processes set forth in §494.180(e) of the conditions for coverage for ESRD facilities, we would expect that the ESRD facilities would update their grievance processes to account for all self-administered ESRD-related drugs. Patients would continue to have access to both internal and external grievance processes including the ESRD Network and the State survey agency.

In the case of any ESRD facility that would seek to furnish drugs directly by dispensing on-site, we would expect that such facility comply with state pharmacy licensure requirements. As an alternative, we believe that many ESRD facilities would forego the process of becoming licensed as a pharmacy and instead, furnish renal dialysis service drugs formerly covered under Part D under arrangement with a licensed pharmacy. Under this scenario, the patient's MCP physician would prescribe the drugs or biologicals. The patient would obtain these drugs from a retail or mail order pharmacy with which the ESRD facility has contracted. We would expect that the ESRD facility would provide their patients with a listing of pharmacies

with which it would have arrangements with to dispense the renal dialysis service drugs.

As indicated in proposed §413.241 of this proposed rule, we would further expect that the ESRD facilities would establish arrangements with pharmacies in a manner that would facilitate beneficiary access to renal dialysis service drugs. That is to say, at a minimum, we would expect that the arrangement would take into account variables like the terrain, whether the patient's home is located in an urban or rural area, the availability of transportation, the usual distances traveled by patients in the area to obtain health care services, and the pharmacy's capability to provide all classes of renal dialysis service drugs to patients in a timely manner.

In addition, we would expect that ESRD facilities would coordinate the provision of renal dialysis service drugs on behalf of traveling patients to facilitate ongoing compliance with the plan of care during periods of travel.

To prevent duplicate payment under both Part D and Part B for bundled drugs and biologicals formerly covered under Part D, we are 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. For example, similar to

the Part D requirements in §423.120(c), ESRD facilities could issue a card or other type of technology that its enrollees may use to access renal dialysis service drugs through pharmacies with which they have established arrangements.

The pharmacy would bill the ESRD facility for all renal dialysis service drugs and biologicals included in the proposed ESRD PPS that were dispensed, but would not be permitted to bill the patient for the usual Part B coinsurance amount, nor treat these drugs in accordance with the Part D rules. As discussed in section XIII.A.2. of this proposed rule, the ESRD facility would collect applicable beneficiary coinsurance that is based on the proposed ESRD PPS per treatment payment amount.

As discussed in section VII. of this proposed rule, the cost of the drugs and biologicals currently separately payable under Part D that we propose to be designated as Part B renal dialysis services for purposes of the proposed ESRD PPS, would be reflected in the ESRD PPS portion of the blended payment. In addition, the mechanism by which we propose to address payment for these drugs during the transition as an adjustment to the blended payment related to basic case-mix adjusted composite payment system is discussed in section VII.D.b. of this proposed rule.

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