

implement effective January 1, 2011, in compliance with the statutory requirements of MIPPA.

II. Overview of the Proposed ESRD PPS

This proposed rule would implement a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis patients beginning January 1, 2011, in accordance with the statutory provisions set forth in section 153(b) of MIPPA. We propose to implement this new system as described in proposed §413.172 and §413.215. The proposed ESRD PPS would replace the current basic case-mix adjusted composite payment system and methodologies for the reimbursement of separately billable outpatient ESRD services. Specifically, we propose that the ESRD PPS would combine payments for composite rate and separately billable services into a single base rate of \$198.64 developed from CY 2007 claims data. Under the proposed rule, the base rate would be subsequently adjusted using patient-specific case-mix adjustment factors developed from separate equations for composite rate and separately billable services. The case-mix adjusters would include variables for age, body surface area (BSA), low body mass index (BMI), gender, eleven co-morbidity categories, and the onset of renal dialysis. These proposed adjustment factors were developed using standard techniques of multiple

regression to yield case-mix adjusted payments per treatment. The per treatment payment amounts would also be adjusted to reflect urban and rural differences in area wage levels using an area wage index developed from Core Based Statistical Areas (CBSAs definitions). The proposed rule also provides that ESRD facilities treating patients with unusually high resource requirements as measured through their utilization of identified services beyond a specified threshold would be entitled to outlier payments, that is, additional payments beyond the otherwise applicable case-mix adjusted bundled prospective payment amount. The proposed ESRD PPS also provides for special adjustments for pediatric patients and for facilities treating a low volume of ESRD patients, as well as a 4-year transition (phase-in) period under which facilities would receive a blend of payments under the prior case-mix adjusted composite payment system and the new ESRD PPS.

III. The Proposed ESRD PPS Bundle

Section 1881(b)(14)(A)(i) of the Act, as added by section 153(b) of MIPPA, specifies that the ESRD PPS must represent a single payment to ESRD facilities for "renal dialysis services" in lieu of any other payment, and home dialysis supplies, equipment, and support services furnished pursuant to section 1881(b)(4) of the Act.

Section 1881(b)(14)(B) of the Act, which identifies the renal dialysis services that are to be included in the ESRD PPS payment bundle, provides the following:

...the term "renal dialysis services" includes—

(i) items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease;

(iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before application of this [new ESRD PPS]) made separately under this title, and any oral equivalent form of such drug or biological; and

(iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

The methodology, which we subsequently describe, for the development of the proposed ESRD PPS, generally identifies the renal dialysis services that we propose to include in the proposed payment bundle in accordance with our interpretation of the statute. We also discuss in more detail below the definition for renal dialysis services under section 1881(b)(14)(B) of the Act.

A. Composite Rate Services

Section 1881(b)(14)(B)(i) of the Act requires that the ESRD PPS payment bundle include composite rate services.

As we indicated previously, the current case-mix adjusted composite payment system represents a limited PPS for a

bundle of outpatient renal dialysis services that includes maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies, and staff time. It applies to Medicare beneficiaries receiving dialysis in ESRD facilities and to patients who have elected Method I home dialysis. (Under Method I, the ESRD facility with which the home patient is associated assumes responsibility for furnishing all home dialysis equipment, supplies, and home support services included in the provision of composite rate services. (See section 2740 of CMS Pub. 15-1.)) The ESRD facility receives reimbursement under the current case-mix adjusted composite payment system. For all other ESRD outpatient services not included in the composite payment rate under the current system, such items and services are billed separately in accordance with Medicare fee schedules and other payment methodologies under Part B and Part D. We propose to include in the proposed ESRD PPS those items and services included in the composite rate for renal dialysis services as of December 31, 2010, including self-dialysis training services, such as labor, supplies, and equipment (for greater detail, see discussion on self-dialysis training sessions in section E.2). Therefore, these costs for such

composite rate services would be included in our computation of the proposed ESRD PPS base rate as explained in section VII. of this proposed rule. This not only would include payments for the costs of services directly related to dialysis, including payments for the costs of self-dialysis training sessions, but also payments authorized in accordance with the composite payment rate exception provisions set forth in 42 CFR §413.180 through §413.186. The costs for composite rate services are also included in our development of the composite rate regression model used to create the two equation patient specific case-mix adjusters that would be applied to the base rate. Composite rate services are defined in proposed §413.171.

B. ESAs and Their Oral Forms

Section 1881(b)(14)(B)(ii) of the Act requires that ESAs and any oral form of such agents that are furnished to individuals for the treatment of ESRD be included in the ESRD PPS payment bundle. Epoetin alfa (EPO, for example, Epogen®) and darbepoetin (ARANESP®) are injectable ESAs, which are currently separately billable outside of the case-mix adjusted composite payment system. Payments for EPO® and ARANESP® would be included in the calculation of the proposed ESRD PPS base rate. These agents would also be included in the separately billable regression model

used to create the two equation patient specific case-mix adjusters for the proposed ESRD PPS. We are currently unaware of any other injectable ESAs or oral forms of such ESAs used for the treatment of ESRD. However, should such agents become available subsequent to the implementation of the ESRD PPS on January 1, 2011, these agents would be considered renal dialysis services and subject to payment under the ESRD PPS. That is, consistent with the statute, we propose that no additional payment would be provided for such agents outside of the bundle of renal dialysis services included in the ESRD PPS. The inclusion of ESA's and their oral forms as renal dialysis services in the ESRD PPS payment bundle is set forth in proposed Medicare regulation 413.171.

C. Other Drugs and Biologicals and their Oral Equivalentents

Section 1881(b)(14)(B)(iii) of the Act specifies that other drugs and biologicals that were furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, prior to the implementation of the ESRD PPS, and their oral equivalent forms, must be included in the ESRD PPS payment bundle. Given the reference to "this title," we interpret clause (iii) as requiring the inclusion in the ESRD PPS payment bundle all drugs and biologicals that were separately

billable prior to the implementation of MIPPA under title XVIII of the Act. Therefore, we believe the ESRD PPS payment bundle would include all drugs and biologicals formerly separately payable under Medicare Part B and Part D. We recognize that an alternative reading of the last part of clause (iii) with respect to the phrase "and any oral equivalent form of such drug or biological" could be interpreted to limit the scope of the drugs and biologicals included in the bundle to only oral versions of injectables (or other non-oral routes of administration). However, we believe that this reading of the statute is unduly constrained. Therefore, our view is that the intent of clause (iii) is to include all drugs and biologicals formerly payable under either Medicare Part B or Part D used to treat ESRD, regardless of the route of administration.

We believe that the exclusion of oral drugs and biologicals for which there is no injectable equivalent (or other non-oral form of administration) from the ESRD PPS would defeat one of the very purposes of the new system—the inclusion of all renal dialysis services furnished to ESRD patients in a comprehensive payment bundle to which a reasonable payment amount can be attached empirically. In addition, the exclusion of oral drugs and biologicals for

which there is no injectable (or other non-oral) version does not make sense from a payment policy perspective. Such a policy would result in the gradual growth of excluded services from the ESRD PPS payment bundle, and the progressive erosion of the payment system, as new oral-only drugs and biologicals for the treatment of ESRD emerge. Moreover, we believe the inclusion of such drugs and biologicals is supportable under clause (iv). That is, we believe the language under clause (iv) addressing "other items and services not covered in clause (i)," provides sufficient authority to include all drugs and biologicals, including oral-only drugs and biologicals, used to treat ESRD in the ESRD PPS payment bundle. Therefore, we are proposing that drugs and biologicals used to treat ESRD that were separately payable prior to January 1, 2011, be included as part of the proposed ESRD PPS payment bundle. Accordingly, we propose to include such drugs and biologicals in the development of the proposed patient-specific case-mix adjusters and in the calculation of the proposed ESRD base rate to which the adjusters would be applied. We identified specific National Drug Codes (NDCs) for drugs and biologicals previously payable under part D that we propose to include in the payment bundle. However, we propose that the ESRD PPS will apply, regardless of the

emergence of new drugs or biologicals, or different NDCs for the classes of drugs and biologicals included in the ESRD PPS bundle. Finally, section 1881(b)(14)(B) of the Act specifically excludes vaccines from the payment bundle and, therefore, vaccines will not be included in the proposed ESRD PPS. We are seeking comments on our proposals above.

We have found that eleven drugs and biologicals accounted for 99.7 percent of the payments under Part B for all injectable drugs and biologicals that were furnished to outpatient ESRD patients in CY 2007. These drugs and biologicals are epoetin alfa (EPO®), darbepoetin alfa (ARANESP®), calcitriol, doxercalciferol, paracalcitol, iron sucrose, sodium ferric gluconate, levocarnitine, alteplase recombinant, vancomycin, and daptomycin. These drugs and biologicals, as well as the others comprising 0.3 percent of the total payments for drugs and biologicals under Part B in CY 2007, would be included in the proposed ESRD PPS payment bundle. Of the top eleven injectable drugs and biologicals, several have oral versions. For example, levocarnitine, and the vitamin D analogues calcitriol, doxercalciferol, and paricalcitol are also available in oral form. The oral versions of these drugs are currently covered under Medicare Part D. Other drugs used to treat

ESRD are available only in oral form and are currently payable under Part D. These include cinacalcet hydrochloride, lanthanum carbonate, calcium acetate, sevelamer hydrochloride, and sevelamer carbonate.

Consistent with our interpretation of section 1881(b)(14)(B)(iii) of the Act, we propose that payments for all drugs and biologicals furnished to ESRD patients and separately billable prior to January 1, 2011, would be included under the proposed ESRD PPS payment bundle as renal dialysis services. Under this proposal, separate billing for these services would be prohibited. The proposed ESRD PPS methodology, both with respect to the computation of the case-mix adjusters and the calculation of the proposed ESRD base rate to which the adjusters would be applied, includes payments for these services. The inclusion of other drugs and biologicals and their oral equivalents as renal dialysis services in the ESRD PPS payment bundle is set forth in proposed §413.171.

D. Diagnostic Laboratory Tests and Other Items and Services

Section 1881(b)(14)(B)(iv) of the Act requires that diagnostic laboratory tests not included under the composite payment rate (that is, currently separately billable laboratory tests) must be included as part of the

ESRD PPS payment bundle. We propose to define such laboratory tests as laboratory tests that are separately billed by ESRD facilities as of December 31, 2010, and laboratory tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients that are separately billed by independent laboratories. Because many of the same diagnostic laboratory tests can be performed for both ESRD and non-ESRD patients, we believe that this approach for including laboratory services appropriately captures tests for inclusion in the payment bundle. We propose that payments for these laboratory services would be included in the development of the proposed patient-specific case-mix adjusters and in the proposed ESRD base rate to which the adjusters would be applied.

Section 1881(b)(14)(B)(iv) of the Act also requires that the ESRD PPS payment bundle include "other items and services not described in clause (i)". We believe that this language can be reasonably interpreted to include other separately billable items and services used in the treatment of ESRD, such as supplies. Examples of such items and services would include, but not be limited to, items such as syringes, specialized tubing, as well as blood and blood products, which facilities may furnish

during the dialysis treatment. We also believe that the language also can be interpreted to include the cost of other self-dialysis training services in the ESRD PPS (for further detail on self-dialysis training, see section E.2. below). We propose that such items and services be included in the ESRD PPS bundle. The inclusion of diagnostic laboratory tests and other items and services as renal dialysis services in the ESRD PPS payment bundle is set forth in proposed §413.171.

E. Home Dialysis Patients (Method I and II) and Self
Dialysis Training

Section 1881(b)(4) of the Act authorizes the Secretary to make payment to providers of services and renal dialysis facilities, and to suppliers of home dialysis supplies and equipment, for the cost of home dialysis supplies and equipment and self-care home dialysis support services furnished to patients for self-care home dialysis. As a result of section 153(b) of MIPPA, as explained 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 under this title to an ESRD facility for renal dialysis services and for such services and items furnished pursuant to section 1881(b)(4) of the Act. As we explained above, we also believe that self dialysis training services

would be considered renal dialysis services as defined in section 1881(b)(14)(B) of the Act. As a result, we are proposing that the costs of home dialysis services furnished to both Method I and Method II home dialysis patients under the current basic case-mix adjusted payment system, as well as self-dialysis training services, must be combined into a single payment under the proposed ESRD PPS.

1. Payment for Home Dialysis

Currently, Hemodialysis, Continuous Cycling Peritoneal Dialysis (CCPD), Intermittent Peritoneal Dialysis (IPD) and Continuous Ambulatory Peritoneal Dialysis (CAPD) treatment modalities may be performed at home by appropriately trained patients. Medicare beneficiaries dialyzing at home must complete a Medicare Beneficiary Form (CMS-382) selecting between two methods of payment (Method I or Method II) as described below.

a. Method I - The Composite Rate

If a Medicare home dialysis patient chooses Method I, the ESRD facility with which the patient is associated must assume responsibility for providing all home dialysis equipment and supplies as well as providing home support services and receives the composite payment rate for such services. Support services needed to furnish home dialysis services include, but are not limited to: (1) periodic

monitoring of a patient's adaptation to home dialysis and performance of dialysis; (2) visits by trained technical personnel made in accordance with a plan prepared by a professional team; (3) unscheduled visits on an as needed basis; and (4) providing, installing, repairing, testing, and maintaining home dialysis equipment including appropriate water testing and treatment. For these services, the ESRD facility receives, in accordance with §414.330(a), the same Medicare dialysis payment rate as it would receive for an in-facility patient under the basic case-mix adjusted composite payment system. Under Method I, the ESRD facility bills the Medicare Administrative Contractor/Fiscal Intermediary (MAC/FI) and the beneficiary is responsible for paying the Medicare Part B deductible and the 20 percent coinsurance on the Medicare rate to the facility.

b. Method II - Dealing Directly with Suppliers

In accordance with regulations at §414.330(a)(2), a Medicare ESRD beneficiary can elect to obtain home dialysis equipment and supplies from a supplier, that is not a Medicare approved dialysis facility (Method II). If a beneficiary elects Method II, the beneficiary will deal directly with a single Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier to

secure the necessary supplies and equipment to dialyze at home. The selected DMEPOS supplier (not a dialysis facility) must accept assignment and bills the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). The beneficiary is financially responsible to the supplier for any unmet Medicare Part B deductible and for the 20 percent Medicare Part B coinsurance requirement. The amount of Medicare payment under Method II for home dialysis equipment and supplies may not exceed \$1,974.25 per month for CCPD and \$1,490.85 per month (57 FR 54186, published November 17, 1992) for all other modalities of home dialysis.

For each beneficiary it serves, the supplier is required to maintain a written agreement with an approved ESRD facility to provide backup and support services. An ESRD facility that has a written agreement to supply backup and support services bills the MAC/FI for services provided under the agreement. Under Method II, an ESRD facility may be paid up to \$121.15 (57 FR 54186, published November 17, 1992) per month for home dialysis support services, such as arranging for the provision of all ESRD related laboratory tests and billing for the laboratory tests that are included in the composite payment rate. An ESRD facility

may not be paid for home dialysis equipment or supplies under Method II.

Based on 2004-2006 data, only 3.1 percent of renal facilities report support service costs furnished to Medicare Method II home dialysis patients. The data also show that the number of Method II patients is small and has significantly declined over the study period (that is, 2004-2006) as shown below.

Patients	Year
5289	2004
4465	2005
2635	2006

We are proposing that payment for all home dialysis services excluding physicians' services (See section III.F. below regarding the exclusion of physicians' services) would be included in the bundled payment to the ESRD facility, under the proposed ESRD PPS.

In addition, as we indicated, section 1881(b)(14)(A)(i) of the Act requires that a single payment for renal dialysis services and items and services under section 1881(b)(4) be made to an ESRD facility. Therefore, since we are proposing that the costs of home dialysis services furnished under Method I and Method II

(see section V Data Sources), regardless of home treatment modality, would be included in the proposed ESRD PPS, we also are proposing that the Method II home dialysis approach in its present form would no longer exist under the proposed ESRD PPS. With regard to payment limits for home dialysis services, in accordance with 6203(b) of P.L. 101-239, we published a final rule on November 17, 1992 implementing (57 FR 54179), Medicare program payment changes for home dialysis. In section 413.330(c), we set payment limits on what Medicare would pay for home dialysis supplies, equipment, and home support services as explained above. Accordingly, effective January 1, 2011, we propose to revise §414.330 to reflect that payment as established in section 1881(b)(14) of the Act will be the basis for home dialysis supplies, equipment, and home support services and therefore, Medicare would pay for home dialysis equipment, supplies and support services only under the prospective payment rate established in proposed 413.210 and payment limits previously established for such would no longer apply. We also note, that this proposal would not eliminate Method I in its present form. Therefore, effective January 1, 2011, a supplier could only furnish, under an arrangement with the ESRD facility, home dialysis equipment and supplies to a Medicare home dialysis

beneficiary, and then the supplier would need to look to the ESRD facility for payment. We believe that this would reduce the administrative burden of maintaining two payment methods for home dialysis patients, since we believe that section 1881(b)(14)(A)(i) requires that all Medicare home dialysis patients would be paid under the ESRD PPS. We invite public comments on this proposal.

2. Self Dialysis Training

Currently, Medicare covers home hemodialysis training and two forms of PD training programs. Home dialysis and self-dialysis can only be performed after an ESRD patient has completed an appropriate course of training. The scope of training services that a certified facility provides to ESRD patients is described in §494.100(a). Medicare pays the ESRD facility its case-mix adjusted composite rate plus \$12 per training treatment for CAPD and \$20 per training treatment for CCPD. For hemodialysis training, Medicare pays the ESRD facility its case-mix adjusted composite rate plus \$20 per training treatment (Medicare Claims Processing Manual, Chapter 8, Outpatient ESRD Hospitals, Independent Facility, and Physician/Supplier Claims, Section 50.8, Training and Retraining). We point out that effective January 1, 2011, under the proposed ESRD PPS, ESRD facilities would no

longer receive an add-on of \$12 for CAPD and \$20 for hemodialysis and CCPD to the otherwise applicable payment amount per treatment for the costs of training. In addition, ESRD facility training expenses are included in the base period payment rate to which the combined rate and payment multiplier in the proposed two-equation model is applied.

As we indicated, section 1881(b)(14)(B) of the Act, as added by section 153(b) of MIPPA, specifies the renal dialysis services that must be included in the ESRD PPS. Since self-dialysis training is used to train patients for the treatment modality of home dialysis with little or no help, we believe that these services would be considered "renal dialysis services." As we indicated above, services related to self-training would meet the definition under clauses (i) and (iv) of section 1881(b)(14)(B) of the Act. As such, we propose to include the cost of self-dialysis training in the proposed ESRD PPS. We evaluated the current training cost reported by ESRD facilities (see section V Data Sources) to train ESRD patients for home dialysis. Training costs have been included in the composite rate payment adjusters in the proposed ESRD PPS. In section VIII.A. of this proposed rule, we point out that total composite rate costs included in the per treatment

calculation include costs incurred for training expenses, as well as all home dialysis costs. We used the ESRD facilities cost reports to identify provider costs for training rather than payments. Therefore, in this proposed rule we propose to include these costs in the composite rate portion of the two-equation ESRD PPS model described in section VI of this proposed rule. We believe that including training and home dialysis costs in the ESRD PPS would provide increased flexibility to dialysis centers for greater use of less costly PD and alternative treatment regimens such as nocturnal dialysis, home hemodialysis using compact portable dialysis machines, and shorter but more frequent dialysis sessions. For these reasons, we are proposing to include training and home dialysis costs in the proposed ESRD PPS, as set forth in proposed §413.217. Training costs were included in the calculation of the composite rate costs used to develop the regression-based adjustment factors for the composite rate portion of the two-equation model described in section VIII. In addition, the base rate to which the patient-specific case-mix adjustment factors are applied includes payments to ESRD facilities for training expenses. Because we are proposing that training costs under the ESRD PPS would be treated no differently than any other overhead expense, an explicit

adjustment to the bundled payment amount for HD and PD training expenditures would not be necessary. We are seeking comments on our proposal to include home dialysis training services in the proposed ESRD PPS.

F. Physicians' Services

Section 1881(b)(14)(A)(i), as added by MIPPA, states as follows in pertinent part:

"...the Secretary shall implement a payment system under which a single payment is made under this title to a provider of services or a renal dialysis facility for renal dialysis services (as defined in subparagraph (B)) in lieu of any other payment...and for such services and items furnished pursuant to [section 1881(b)(4)]."

We believe this provision generally governs payment to ESRD facilities. With regard to physicians' services related to renal dialysis, such services are addressed in section 1881(b)(3) of the Act. At this time, we do not intend to significantly modify payment for physicians' services. Any changes with regard to the payment for physicians' services related to renal dialysis would be addressed in future rulemaking. Therefore, the scope of this proposed rule generally will be limited to payment for home dialysis and renal dialysis services furnished by ESRD facilities.

IV. Unit of Payment

Under section 1881(b)(14)(C) of the Act, as added by section 153(b) of MIPPA, the ESRD PPS may provide for payment on the basis of renal dialysis services furnished during a week, or month, or such other appropriate unit of payment as the Secretary specifies. Approximately 92 percent of ESRD beneficiaries requiring outpatient dialysis undergo hemodialysis (HD), usually furnished in a facility. A small but increasing number of patients perform HD at home. The most typical schedule is 3 treatments per week, with each treatment averaging 3 to 4 hours. The remaining 8 percent of patients use peritoneal dialysis (PD). PD is usually done at home, with or without machine assistance. Unlike HD, which involves the circulation of the patient's blood and filtration of toxins using an artificial kidney machine, PD removes blood toxins through the draining of the dialysate from the lining of the abdomen or peritoneum several times a day. A form of PD, sometimes referred to as continuous cycling PD, is done with machine assistance while the patient sleeps, either at home or in specially designated areas at the ESRD or facility.

Since the inception of the composite payment system in 1983, ESRD facilities have been reimbursed the applicable