SUMMARY OF THE MEDICARE END-STAGE RENAL DISESASE PROSPECTIVE PAYMENT SYSTEM FINAL RULE

On July 26, 2010, the Centers for Medicare and Medicaid Services (CMS) released the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (Final Rule). This memorandum summarizes the key provisions of this rule.[1]

I. Scope of Bundle

A. Composite Rate Services (pages 40-42)

CMS finalizes its proposal to include those items and services that are incorporated in the composite rate for renal dialysis services as of December 31, 2010 in the PPS bundle, including maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies, and staff time. Consistent with the Proposed Rule, CMS also includes payments for items and services authorized in accordance with the composite rate exception provisions in current regulation. The costs for composite rate services are included in CMS' computation of the PPS base rate, as well as in the development of the composite rate regression model used to create patient specific case mix adjusters applied to the base rate.

B. Drugs (pages 43 -127)

1. Oral Drugs with No Injectable Equivalent (Oral-Only)

In the Final Rule, CMS delays inclusion of oral-only drugs in the bundle but reiterates its belief that it has legal authority to include oral-only products in the ESRD bundle and that such a policy is preferable from the patient and program perspective. However, it does concede some shortcomings in available pricing and utilization data related to the drugs in question and, noting the need for reasonable time for providers and Part D plans to prepare for the change in operations, announced that it would delay inclusion of oral-only drugs in the bundle until January 1, 2014. Specifically, it states that a careful assessment of the use of the Medicare Part D Plan Finder as a basis for pricing data is needed before the policy moves forward.

In addition, CMS agrees with recommendations to develop monitoring, tracking and outcomes quality measures prior to oral-only drugs' inclusion in the bundle prior to 2014. To that effect, the CMS notes that such measures are being developed in relation to the initial year of the

[1]The page numbers reference the display copy of the Final Rule.

quality incentives program and that CMS is developing an overall monitoring plan that will include tracking drug utilization under the PPS.

CMS also notes that it anticipates that, on average, beneficiaries would experience lower cost-sharing obligations for oral-only products in the bundle than they do under the current payment model.

2. Oral Drugs With An Injectable Equivalent

CMS adopts its proposal to include oral drugs with an injectable equivalent in the bundle, although it does make some minor modifications. The Agency provides an updated list of current products compiled using 2007, 2008 and 2009 ESRD claims. It relies upon categorizes products based upon the mechanism of action, which it believes will provide more flexibility given the inevitably changing landscape of ESRD treatment .

The Final Rule also indicates a number of drug categories that are specifically excluded from inclusion in the base rate and continue to be billed separately. Examples of these products include:

- Drugs and biologicals listed separately on an ESRD claim where there was no dialysis treatment provided;
- Drugs and biologicals billed using an unclassified or unspecified HCPCS code; and
- Drugs or biologicals classified as chemotherapeutic drugs, immunosuppressant drugs or vaccines.

The Final Rule also includes a comprehensive list of drug products excluded from the calculation of the PPS base rate and a brief explanation of the rationale for their exclusion.

CMS further explains that in its review of oral drugs with injectable equivalents that arebilled separately under the composite rate system and should be considered ESRD-related, it came across a small percentage of billed products that could be ESRD-related but are also commonly used for other clinical purposes. It clarifies that for purposes of the bundle, these products will be presumed to be ESRD-related unless the facility uses a newly-created modifier on the claim to indicate that the product was furnished for a non-ESRD related purpose and should be paid separately from the bundle.

Similarly, CMS clarifies that to the extent that a patient's nephrologist serves a primary care provider and prescribes non ESRD-related drugs or biologicals to a patient, these products can be billed by an ESRD facility using that same modifier approach.

C. Laboratory Tests (pages 127-138; 224-225; 542-560)

1. List of ESRD-Related Laboratory Tests

CMS finalizes a discrete list of 53 ESRD-related laboratory services that will be subject to the new ESRD PPS in Table F of the Final Rule (*See* Appendix A). This list represents the laboratory tests that CMS determined are most commonly ordered for the treatment of ESRD.

According to CMS, the list was based on: (1) the tests most frequently identified by commenters as being related to the treatment of ESRD; (2) input from physicians working with UM-KECC; and (3) a medical review performed by CMS physicians and other medical professionals. For purposes of the ESRD PPS, any tests included on the list will be considered renal dialysis services, as defined by statute, and paid for as part of the bundled payment amount to the facility. Despite the list of ESRD-related laboratory tests, ESRD facilities will still be required to include on their claims all laboratory tests ordered by the monthly capitated payment (MCP) physician. CMS will establish a modifier to identify laboratory tests that are not related to ESRD and, thus, allow ESRD facilities to draw specimens for non ESRD-related tests and to receive separate payments for them.

CMS notes that it will continually monitor the ESRD-related tests reported by ESRD facilities to ensure that the laboratory test list continues to reflect common ESRD-related laboratory tests.

2. Beneficiary Copayments

With respect to laboratory services, CMS reiterates that ESRD-related laboratory tests will be considered part of the payment bundle and, therefore, laboratory services will be subject to the customary 20 percent Part B coinsurance amount.

3. Calculation of Payments

In response to comments that only 80 percent of payments for laboratory tests were included in the calculation of the base rates, CMS explains that it included 100 percent of the payment amounts in the final base rate calculation in order to remain consistent with statute.

4. Laboratory Tests in Definition of Outlier Services

As part of its outlier policy, which is described below, CMS discussed in the proposed rule whether to base eligibility for outlier payments under the ESRD PPS on a comparison of the predicted Medicare allowable payment (MAP) amounts and imputed MAP amounts for items and services that are currently separately billable under Medicare Part B, including ESRD-related laboratory tests. CMS observes in this rule that the need for laboratory testing varies widely depending on changes in a patient's condition and such additional laboratory testing could be costly for the dialysis facility. Accordingly, CMS maintains its view that ESRD-related laboratory testing should remain as one of the separately billable services that comprise the definition of ESRD outlier services. To this end, as noted above, all laboratory tests furnished to ESRD beneficiaries must be specified on the facility claim in order for CMS to determine which tests meet the definition of a separately billable service for the purpose of determining eligibility for potential outlier payments.

5. 50 Percent Rule

In the proposed rule, CMS requested comments regarding the extent to which the 50 percent rule for Automated Multi-Channel Chemistry (AMCC) panels would be relevant under the ESRD PPS. CMS maintains the 50 percent rule at this time because, in its view, the rule is necessary to calculate the basic case-mix adjusted composite rate portion of the blended payment during the three-year transition period. Given that CMS is retaining the 50 percent rule for purposes of the transition period, CMS will also retain the 50 percent rule with respect to outlier services. In other

words, individual laboratory tests that are part of an AMCC panel in which the majority of the laboratory tests are separately billable will be considered all separately billable for the purpose of determining outlier eligibility. To ensure consistency with this policy during the transition period, both ESRD facilities that opt out of the transition period and those that go through the transition will be required to follow the 50 percent rule until the transition period ends on January 1, 2014. CMS intends to reevaluate its position on the 50 percent rule once the transition period is completed.

D. Home Dialysis (pages 145-189)

CMS reiterates the statutory requirement to include payment for home dialysis training, equipment and supplies, and support services in computing the single bundled payment base rate. EPO and the supplies needed to self-administer the drug will be included in the ESRD PPS payment. CMS does not adopt a separate adjustment for ESRD treatment for nursing home patients, concluding no unique costs are associated with nursing home ESRD patients.

CMS indicates that it will increase monitoring to scrutinize the effects of the new ESRD PPS, particularly with respect to home dialysis, consistent with recommendations made in May 2009 by the Government Accountability Office (GAO). CMS will establish a plan that includes the examination of home dialysis utilization after the final ESRD PPS has been implemented.

CMS also indicates that it will consider establishing more specific codes for home dialysis equipment, supplies, and services, for use in the ESRD PPS. These changes will be established in subsequent guidance.

1. Method I and Method II

CMS finalizes its proposal to include all home dialysis services now furnished under Method I and Method II, regardless of home treatment modality, into the bundled payment to the ESRD facility. Under the ESRD PPS, all home ESRD patients will be considered Method I home patients and all Medicare payments for home dialysis services will be made to the facility. This change will take effect January 1, 2011, regardless of whether the facility elects to participate in the transition period or elects to be paid under the ESRD PPS. Durable medical equipment (DME) suppliers will no longer be able to submit claims to DME Medicare Administrator Contractors (MACs) for home dialysis supplies and equipment after January 1, 2011.

After January 1, 2011, a DME supplier will only be permitted to furnish home dialysis equipment and supplies to Medicare home dialysis beneficiaries under an arrangement with an ESRD facility. In this scenario, the facility will be responsible for paying the supplier based upon arrangements between the supplier and facility.

CMS clarifies that renal dialysis services include only DME supplies and equipment necessary for the delivery of home dialysis services under the ESRD PPS. Although CMS does not provide a specific list of applicable supplies and equipment, CMS references the Medicare Claims Processing Manual, Chapter 8, Section 90.3.2, which identifies the home dialysis supplies and equipment that are currently separately billable by DME suppliers.

2. Self-Dialysis Training

CMS acknowledges that the base rate alone does not account for the staffing costs associated with one-on-one focused home dialysis training services that are performed by a registered nurse. As a result, CMS is adopting an add-on payment adjustment of $33.38.[2] This amount will be added to the ESRD PPS rate, or the ESRD PPS portion of the blended payment amount for those ESRD facilities in the ESRD PPS transition, each time a training treatment is furnished by a Medicare-certified ESRD facility. This amount reflects one hour of nursing time to conduct one-on-one training with a patient for either hemodialysis or PD.

The $33.38 add-on adjustment will be adjusted by the geographic area wage index applicable to the ESRD facility to ensure that the adjustment reflects local nursing wages. Based on the proposed wage index values in the CY 2011 Medicare Physician Fee Schedule Proposed Rule, the training add-on amounts after application of the wage index would range from $20.03 to $45.84.

For those ESRD training facilities that opt to go through the ESRD PPS transition, Medicare will continue to pay $20.00 per training treatment for hemodialysis and CCPD and $12.00 for PD for the basic case-mix adjusted composite rate portion of the ESRD PPS blended payment.

ESRD facilities will not receive both the training add-on adjustment and the four-month onset of dialysis adjustment (described below) because CMS has already accounted for training salary costs in the latter adjustment. CMS notes that the training add-on adjustment is not a multiplicative adjustment like the other final adjustments under the ESRD PPS. The training add-on adjustment will be added to the product of the ESRD PPS base rate or blended base rate and other applicable adjustments.

Finally, CMS notes that it will continue its current cap on the number of training treatments at 15 for PD (CAPD and CCPD) and 25 for hemodialysis training. Most commenters indicated they are able to complete training within these parameters.

E. Blood and Blood Products

CMS clarifies in the Final Rule that it does not consider the furnishing of blood and blood products to be renal dialysis services. The furnishing of blood, blood products, and blood supplies in connection with transfusions will remain separately billable when administered in an ESRD facility.

II. General Payment Issues

A. Unit of Payment (pages 189-193)

[2] In a few instances in the Final Rule, CMS uses $33.44 as the training add-on adjustment. We believe this to be an error and the training add-on adjustment is, in fact, $33.38.

CMS finalizes a per treatment unit of payment and explains that Medicare will cover for up to three treatments per week, unless an FI/MAC approves more than three weekly treatments based on medical justification.

CMS acknowledges the Medicare Payment Advisory Commission's (MedPAC) recommendation that the Agency consider a monthly unit of payment (once a strengthened dialysis quality monitoring system is implemented) to ensure that quality of care does not decline. After the transition period ends, the Agency notes it may reconsider the per treatment unit of payment, assessing whether the ESRD PPS has improved clinical outcomes, the degree to which home dialysis has increased, and whether stakeholders favor the per treatment unit of payment or an alternative approach.

B. Adjustments to the Base Rate

1. Base Rate & Standardization Rate

For CY 2011, the ESRD PPS base rate per treatment will be $229.63. This amount is based on the unadjusted CY 2011 average payment per treatment base estimate of $251.60 for all renal dialysis services in the bundle, which will then be adjusted by the following:

- A 5.93 percent reduction to account for standardization to the projected CY 2011 current system payment per treatment, which brings the rate to $236.68. (In the Proposed Rule, this adjustment would have equaled a 21.73 percent reduction.)

- A 1.0 percent reduction to account for outlier payments, which brings the rate down to $234.31.

- A 2.0 percent reduction for the statutorily required 98 percent budget-neutrality, which brings the rate to $229.62.[3]

2. ESRD Bundled Market Basket (pages 634-681)

The statute requires CMS to develop a specific index to reflect changes in prices of the mix of goods and services used to furnish renal dialysis services, sometimes called a "market basket." The rate of increase in the prices of this market basket serves as the starting point for annual updates to the rates. Reductions required to reflect productivity improvements or other factors are deducted to create the ESRD bundled rate market basket increase factor. This increase factor will be used, starting in 2012, for updating the ESRD PPS rates. It will also be used to update the composite rate portion of dialysis payments during the transition period.

The market basket includes 8 categories of inputs: wages and salaries, benefits, pharmaceuticals, supplies, laboratory services, administrative and general and other, housekeeping

[3]CMS notes that the slight difference between the $229.62 and the final $229.63 is due to a failure to round the figures at each step of the calculation.

and operations, and capital-related costs. The rule specifies the weights applied to these categories (summing to 100 percent) and the sources for price proxies used to measure the rate of change in each of these components over time. For instance, the proxy for ESRD drugs is the Producer Price Index (PPI).

CMS adopts 2008 as the base year for construction of the ESRD bundled market basket. CMS expects to revise and rebase the market basket several years in the future but has not established exactly when it expects to do so.

The market basket categories are also used to establish the labor-related share of total payments, which is the fraction of the total payment to which the geographic wage index is applied. For 2011, this value is 41.737 percent of the total.

III. Adjustors

A. Outlier Adjustment (pages 253-254)

CMS maintains its proposal to reduce the base rate by one percent. The outlier adjustment results in a revised base rate of $234.31. In the Final Rule, the Agency notes that the one percent outlier and two percent budget neutrality adjustments are multiplicative and, therefore, the order of the reductions does not affect the final adjusted base rate.

B. Select Case Mix Adjusters

1. Patient Age (pages 294-298)

CMS indicates that age continues to be a strong predictor of variation in composite rate costs and separately billed payments; therefore, it is implementing payment adjustment factors for the same five age groups discussed in the proposed rule.

The final payment adjustment factors are as follows:

Variable	Multiplier
Ages 18-44	1.171
Ages 45-59	1.013
Ages 60-69	1.000
Ages 70-79	1.011
Ages 80+	1.016

2. Patient Sex (pages 298-301)

CMS proposed including a 13.2 percent adjustment for patient sex, but it excludes this adjuster completely in the Final Rule. CMS states that even though patient sex was a "strong predictor" of variation in payments for ESRD patients, patient sex may not be the reason for increased costs; rather, sex-neutral factors may be identified at a later date that would explain the increased cost associated with providing renal dialysis services to members of a certain sex.

3. Body Surface Area (BSA) & Body Mass Index (BMI) (pages 301-305)

CMS retains BMI and BSA, given that its models indicate they are strong predictors of variation in costs and payments for ESRD patients. The case-mix patient-level adjustment for BSA (per $0.1m^2$) is 1.020, and for low BMI (BMI <18.5) the adjustment is 1.025 effective for renal dialysis services provided on or after January 1, 2011.

4. Patient Race (pg. 409-445)

In the Final Rule, CMS again declined to include a patient race adjustment. The Agency states that it is not convinced that race or ethnicity adjustments are necessary to ensure beneficiary access to ESRD services. As with gender, CMS relays that that as yet un-identified race/ethnicity neutral biological factors may be the root cause of any apparent increased cost associated with ESRD care for members of certain races or ethnicities. CMS indicates that if such factors are identified, it may incorporate them into future ESRD PPS modeling. CMS will continue studying the issue and, based on its findings, may re-evaluate utilizing a patient-level case-mix adjustment for race or ethnicity in the future, if warranted.

5. Co-Morbidities (pages 327-404)

CMS adopts 6 of the 11 proposed co-morbidity case mix adjustors. They are:

- pericarditis (acute);
- bacterial pneumonia (acute);
- gastrointestinal tract bleeding with hemorrhage (acute);
- hemolytic anemia with sickle cell anemia (chronic);
- myelodysplastic syndrome (chronic); and
- monoclonal gammopathy (chronic).

It excludes proposed measures for Hepatitis B, cardiac arrest, septicemia, pneumonias/opportunistic infections, HIV/AIDS, cancer, lung abscess, emphysema and alcohol/drug dependence. The corresponding multipliers for these conditions are as follows:

Diagnostic Category	Multiplier
Pericarditis	1.114
Bacterial Pneumonia	1.135
Gastrointestinal Tract Bleeding with Hemorrhage	1.183
Hemolytic Anemia with Sickle Cell Anemia	1.072
Myelodysplastic Syndrome	1.099
Monoclonal Gammopathy	1.024

CMS states that the co-morbidity adjustments included in the ESRD PPS would compel dialysis facilities to monitor their patients more closely, as well as motivate them to collect additional data for payment adjustment purposes. CMS relays that because the Conditions of Coverage

instruct dialysis facilities to assess and record co-morbid medical conditions, the additional burden of tracking co-morbidities for claims purposes will not be as onerous as commenters fear.

Co-morbidity payment adjustments will be based upon the diagnosis codes reported by ESRD facilities on their Medicare claims. CMS plans to use those reported diagnoses for future refinements to the co-morbidity categories and diagnoses.

6. Onset of Dialysis (New Patient Adjustment) (pages 305-327)

CMS includes a payment adjustment for patients at the onset of dialysis, finalizing it at a rate of 1.510 for in-facility and home dialysis patients eligible for the Medicare benefit. Furthermore, CMS stated that onset of dialysis begins with the starting date reported on Form 2728 through the first four months a patient is receiving dialysis.

Facilities receiving the new patient adjustor will not receive the home training add-on adjustment during the first four months, nor will they receive a co-morbidity adjustment for dialysis patients during this period. CMS plans to monitor this adjustment closely to understand its effect on dialysis facility payments as well as patient co-insurance liabilities.

C. Low-Volume Facility Adjuster (pages 460-492)

CMS finalizes a statutorily-prescribed adjustment to reflect the higher costs of low-volume facilities. CMS defines low-volume facilities as those that provided fewer than 4,000 treatments in each of three years preceding the payment year and that have not opened, closed, or received a new provider number during the same period. The proposed rule included a threshold of 3,000 treatments.

The adjustment will be made on the volume of treatments provided and not on the basis of payer mix. CMS uses all treatments including non-Medicare treatments from cost reports to establish the new 4,000 treatment threshold. CMS notes it will use cost reports to confirm facility status as low-volume. CMS finds that the percent of Medicare HD-equivalent dialysis treatments that would qualify for the low-volume adjustment increased from 0.7 percent using a 3,000 treatment threshold to 1.9 percent using a 4,000 treatment threshold. The increase to the base rate for low-volume facilities will be 18.9 percent, slightly lower than the proposed rule's 20.2 percent.

Although CMS notes that is shares commenters' concerns about the potential for gaming as a result of the low-volume adjustment, it limits the non-volume criteria to those set forth in the proposed rule: facilities under common ownership and within 25 road miles of each other will be treated as if they were one unit when applying the low-volume adjustment. Facilities certified for Medicare participation before January 1, 2011, will be exempt for this provision. CMS finalizes a definition of common ownership as involving the same individuals or entities owning five percent or more of each facility.

The Final Rule does not create any special adjustments for facilities in Alaska or Hawaii and rejects a facility-level payment adjustment that is based on a rural location. The Final Rule

incorporates the current law's site-neutral payment policy into the ESRD PPS, which requires a single base rate applicable to both hospital-based and free-standing dialysis facilities.

D. Pediatric Patients (pages 507-537)

CMS revises the pediatric patient payment adjustors to include age (<13, 13-17) and modality (PD or HD). It explains that under the separately billable payment model, without an adjustment for modality for pediatric patients, an underpayment for HD and an overpayment for PD would occur. It believes that a modality payment adjustment for pediatric patients will reduce the incentive to direct patients to a particular modality on the basis of reimbursement. The Agency signals that it may develop pediatric payment adjustors based on co-morbidities in future refinements to the pediatric payment adjustors.

CMS determines that the combined composite rate and separately billable average payments per treatment in CY 2007 for pediatric patients compared to adult patients differed by 10.5 percent. Thus, the Agency includes in the pediatric adjusters a 10.5 percent increase to reflect the higher costs for services provided to pediatric patients.

CMS does not apply caps to the computation of separately billable MAPs for pediatric patients in developing the pediatric payment adjustors, with the exception of EPO and ARANESP®. CMS states that the low-volume adjustment will not apply to pediatric patients. Facilities that treat both adult and pediatric patients and qualify for the low-volume adjustment will receive the low-volume adjustment for adult dialysis patients only.

E. Wage Index (pages 449)

Consistent with the proposed rule, CMS finalizes the use of wage index values based on the most current hospital wage data, without regard to geographic reclassifications, and utilizes pre-floor hospital data that are unadjusted for occupational mix, based on the Office of Management and Budget Office's CBSA-based geographic area designations to define urban/rural areas and corresponding wage index values.

CMS adopts a CY 2011 wage index floor of 0.60 for the case mix portion of the blended payment for purposes of the transition. The Final Rule includes special provisions for facilities in Puerto Rico and for areas with ESRD facilities that have no hospital data, including rural Massachusetts; Hinesville, Georgia; and Anderson, South Carolina.

IV. Outlier Policy (pages 538-633)

CMS finalizes the proposed eligibility for an outlier payment as when a facility's imputed, average per treatment costs for ESRD outlier services furnished to a beneficiary exceed the predicted per treatment MAP amount for outlier services plus the fixed dollar loss amount. Because blood and blood products, including blood transfusion procedures, will be excluded from the ESRD PPS payment bundle, they will not be considered outlier services. As noted previously, the Agency retains the 50 percent rule to determine whether Automated Multi-Channel Chemistry (AMCC) panel tests would be considered composite rate or separately billable for the ESRD PPS portion of the blended payment and laboratory tests as outlier services.

CMS defines outlier services as the following items and services that are included in the ESRD PPS bundle: (1) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related lab tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) medical/surgical supplies used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable; and (4) renal dialysis service drugs that were or would have been, prior to January 1, 2011, covered under Part D (this category does not include ESRD-related oral-only drugs). CMS intends to publish a list of currently eligible separately billable outlier services in guidance. The outlier services payment adjustments are based only on the items and services that were, prior to January 1, 2011, separately billable under Part B.

As noted above, CMS adopts separate outlier services MAP amounts for adult and pediatric patients. The final average outlier services MAP amounts are $53.06 for patients < 18 and $82.78 for patients age 18 and older. CMS finalizes the bases for estimating imputed outlier services MAP amounts as: (1) Part B drugs that were or would have been separately billable prior to January 1, 2011, will continue to be priced on the most current ASP+6; (2) laboratory tests that were or would have been separately billable prior to January 1, 2011, will continue to be price based on the most current laboratory fee schedule; (3) ESRD-related supplies used to administer separately billable Part B drugs that prior to January 1, 2011, were or would have been separately billable will continue to be priced as they are currently; and (4) renal dialysis drugs and biologicals that prior to January 1, 2011, were or would have been separately covered under Part D will be priced by NDC code.

CMS finalizes the proposed fixed dollar loss amounts of $155.44 for adult patients and $195.02 for pediatric patients. Medicare will pay 80 percent of the costs of a particular case that exceed the fixed dollar loss amount.

The Agency will use the ESA Claims Monitoring Policy edits for the purpose of calculating the case-mix adjusted composite payment portion of the blended payment during the transition period and for determining the eligibility of ESA payments for outlier payments.

V. Transition Budget Neutrality Adjustment (pages 257-265)

The statute permits facilities to elect to receive payments entirely determined by the ESRD PPS system immediately in January 2011 or to receive a blend of payments under the new and old systems over a four-year period. CMS establishes a "transition budget neutrality adjustment" designed to ensure overall program spending does not increase as a result of this provision. In the Final Rule, this reduction is set at 3.1 percent for 2011. CMS will apply this reduction to all payments to ESRD facilities, including both payments under the ESRD PPS and blended payments, regardless of the election made by an individual facility. CMS estimates that 43 percent of facilities will choose to be excluded from the transition, while 57 percent will elect to be paid under blended rates. CMS plans to update this adjustment in the following years of the transition, reflecting updated information. Acknowledging the impossibility of predicting which facilities will elect the transition, CMS is considering whether to make a prospective correction in 2012 if its estimate of the number of transitioning facilities is incorrect.

VI. Beneficiary Impact (Co-Insurance) (Pages 695-715)

The Final Rule applies the standard Part B 20 percent beneficiary co-insurance to the ESRD PPS payment for renal dialysis services, inclusive of all applicable payment adjustments, even though some of those items and services, such as laboratory tests and Part D drugs, currently have different beneficiary co-insurance structures. CMS does not limit beneficiaries' co-payment responsibility to 20 percent of the base rate payment amount only, contending that it does not have the authority to determine how beneficiary co-insurance liability is applied.

In response to commenter's concerns about the potential for non-recovery of co-insurance payments for patients who are dually eligible under Medicare and Medicaid, CMS notes that it has "already begun" outreach efforts with the States to ensure that State Medicaid Agencies understand their responsibilities to adjust their systems so that co-insurance amounts are properly determined and paid appropriately for dually-eligible beneficiaries upon implementation of the PPS. CMS does not create a new billing code that would make it easier for States to determine whether they have an obligation to pay co-insurance on behalf of a patient with ESRD. It notes that line item billing by date of service (when each renal dialysis service is itemized on a claim) will continue to be necessary in order for blended payments to be made during the transition and for the identification of outlier services. CMS states that is does not expect the policies of Medigap or other private insurance plans with respect to coverage of beneficiary co-insurance and copayment obligations to change under the ESRD PPS bundle.

Beneficiaries' financial liability for co-insurance, in particular co-insurance for laboratory tests, will change under the PPS system. CMS estimates that beneficiaries will have a 1.2 percent increase in their cost-sharing obligations.

VII. Claims Processing and Consolidated Billing (pages 715-748)

The ESRD PPS requires a single payment to be made for renal dialysis services and other items and services related to home dialysis through the ESRD facility. As such, the implementation of the ESRD PPS necessitates changes to the way in which CMS will process its claims. These changes will largely involve establishing consolidated billing rules and edits and changes to the data elements reported on claims. Under the consolidated billing approach, the Medicare billing responsibility for all of the renal dialysis services that patients receive is shifted onto the ESRD facility. Therefore, payment for these services will only be made to the ESRD facility to prevent duplicate Medicare payments. In the event that providers of services, other than the ESRD facility, inadvertently bill Medicare for ESRD-related services paid under the ESRD PPS, consolidated billing edits will prevent payment for those services.

A. Laboratories

Independent laboratories will not be permitted to bill Medicare for ESRD-related services paid under the ESRD PPS as of January 1, 2011. In other words, laboratory tests included on CMS' discrete list of ESRD-related laboratory tests, if furnished to ESRD patients by the facility directly or under arrangement, will be considered renal dialysis services (unless otherwise specified as being performed for non-ESRD-related conditions) and be covered under the ESRD PPS bundled payment. However, as noted earlier, if a laboratory test is furnished by the ESRD facility or by an

independent laboratory for reasons that are not ESRD-related, then the laboratory test can be billed with a modifier, which would allow for separate payment.

B. Drugs and Biologicals

Given that CMS is delaying payment under the bundle for ESRD-related oral-only medications until January 1, 2014, CMS provides few details with respect to consolidated billing for drugs and biologicals. However, in response to commenters' concerns that bundling oral medications into the ESRD PPS would create confusion between Part B and Part D for patients, ESRD facilities, pharmacies, and Part D sponsors, CMS states that it intends to implement an ESRD indicator. The indicator will store a beneficiary's ESRD status in Part D systems. Part D sponsors will be expected to share the information with their claims processing contractors for purposes of claims adjudication. Importantly, the indicator will allow contracted pharmacies to correctly bill ESRD-related drugs to the ESRD facility and non-ESRD-related drugs to Part D.

C. Home Dialysis

CMS reiterates that all home dialysis items and services will be covered under the ESRD PPS payment and no separate payments will be made. To the extent that supplies or equipment are used for non-ESRD-related purposes, those supplies or equipment could be billed separately by utilizing a modifier that indicates that the supply or equipment is not ESRD-related.

D. Expansion of the Data Elements Reported on Claims

According to CMS, all commenters agreed that it was necessary to expand the data elements required on ESRD claims in order to effectively make refinements to the ESRD PPS payment model in the future. In response to these comments, CMS notes it will consider commenters' suggestions when it is time to initiate changes to the data elements required on claims.

VIII. Quality Incentives in the End-Stage Renal Disease (ESRD) Program (pages 797)

CMS issued a separate Proposed Rule[4] to detail its plans to implement an ESRD quality incentive program (QIP); however, CMS finalized the three quality measures for the initial performance period in the Final Rule. CMS also notes that it plans to expand CROWNWeb reporting to additional facilities "as soon as practicable." CMS explains that payment reductions for failure to meet or exceed performance standards will be up to 2.0 percent.

For the initial performance period, CMS adopts three measures, which can be calculated using Medicare claims data and are currently used for Dialysis Facility Compare:

- Anemia Management – Percentage of patients treated at a provider/facility whose hemoglobin levels were less than 10 g/dL;
- Anemia Management – Percentage of patients treated with ESAs at a provider/facility whose hemoglobin levels were greater than 12 g/dL; and

[4]We circulated a separate summary on the QIP proposed rule earlier today.

- Hemodialysis Adequacy – Percentage of hemodialysis patients at a provider or facility whose urea reduction ration (URR) is 65 percent or greater.

Anemia management measures will be calculated using hemoglobin data for Medicare patients who have been diagnosed with ESRD for at least 90 days and whose Medicare claims indicated the use of an ESA during the 90-day period. The anemia management measure calculation will exclude data from: patients younger than 18 years of age, because there is no consensus on the appropriate hemoglobin range for this age group; patients whose dialysis starts before day 90 or who have hemoglobin values of less than 5 g/dL or greater than 20 g/dL; and patients who are not receiving ESAs (data excluded for the hemoglobin levels greater than 12 g/dL measure only).

The hemodialysis adequacy measure will be calculated using data for Medicare patients who have been diagnosed with ESRD and received maintenance dialysis for at least 183 days from the date they first received dialysis treatment and whose claims include a value for URR. Due to different frequencies of treatment, hemodialysis adequacy measure calculation will exclude data from peritoneal, home hemodialysis, and all pediatric patients, for whom a URR greater than 65 percent is an invalid measure. Because Medicare claims now require Kt/V (K-dialyzer clearance of urea; t-dialysis time; V-patient's total body water) reporting for all modalities, CMS anticipates that Kt/V will replace URR in future QIP performance periods.

CMS will calculate anemia management measures using a yearly average, consistent with the specifications for the Dialysis Facility Compare. CMS asserts that it has the authority to update the specifications of quality measures when selected specifications do not result in useful or accurate information.

CMS, in the Final Rule, explains that it did not adopt measures on iron management, bone mineral metabolism, and vascular access for the initial performance period because the Agency is not collecting data that would enable calculation of provider and facility-specific performance. CMS did not adopt a patient satisfaction measure due to the lack of a validated data collection tool. However, CMS will address measures beyond the three adopted at present in future rulemaking.

Appendix A

Table F: ESRD-Related Laboratory Tests

CPT/ HCPCS	Short Description
82040	Assay of serum albumin
82108	Assay of aluminum
82306	Vitamin d, 25 hydroxy
82310	Assay of calcium
82330	Assay of calcium, Ionized
82374	Assay, blood carbon dioxide
82379	Assay of carnitine
82435	Assay of blood chloride
82565	Assay of creatinine
82570	Assay of urine creatinine
82575	Creatinine clearance test
82607	Vitamin B-12
82652	Vit d 1, 25-dihydroxy
82668	Assay of erythropoietin
82728	Assay of ferritin
82746	Blood folic acid serum
83540	Assay of iron
83550	Iron binding test
83735	Assay of magnesium
83970	Assay of parathormone
84075	Assay alkaline phosphatase
84100	Assay of phosphorus
84132	Assay of serum potassium
84134	Assay of prealbumin
84155	Assay of protein, serum
84295	Assay of serum sodium
84466	Assay of transferrin
84520	Assay of urea nitrogen
84540	Assay of urine/urea-n
84545	Urea-N clearance test
85014	Hematocrit
85018	Hemoglobin
85025	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count) and automated differential WBC count.
85027	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count)
85041	Automated rbc count

CPT/ HCPCS	Short Description
85044	Manual reticulocyte count
85045	Automated reticulocyte count
85046	Reticyte/hgb concentrate
85048	Automated leukocyte count
86704	Hep b core antibody, total
86705	Hep b core antibody, igm
86706	Hep b surface antibody
87040[1]	Blood culture for bacteria
87070[1]	Culture, bacteria, other
87071[1]	Culture bacteria aerobic othr
87073[1]	Culture bacteria anaerobic
87075[1]	Cultr bacteria, except blood
87076[1]	Culture anaerobe ident, each
87077[1]	Culture aerobic identify
87081[1]	Culture screen only
87340	Hepatitis b surface ag, eia
G0306	CBC/diff wbc w/o platelet
G0307	CBC without platelet

[1] Only ESRD-related when testing is related to the dialysis access site

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