

## PROPOSED ESRD FOR FY 2011

The Centers for Medicare and Medicaid Services (CMS) published its proposed rule documenting significant changes to the ESRD prospective payment system (PPS) for FY 2011 in the *Federal Register* on September 29, 2009. Proposed changes will not take effect until January 1, 2011.

In 1972, amendments to the Social Security Act created the end-stage renal disease (ESRD) program under Medicare. This law extended Medicare coverage to people who have permanent kidney failure requiring either dialysis or kidney transplantation to live, and who meet certain other eligibility criteria. The program was implemented on July 1, 1973, providing benefits to about 11,000 people with ESRD. In calendar year 1974, the ESRD program paid benefits of approximately \$229 million for dialysis, transplant, and related services. By 2007, the number of ESRD beneficiaries had grown to 330,000 with payments reaching \$9.2 billion.

Currently, Medicare ESRD payment is based on a single composite weighted formula entitled the "composite rate." Each facility receives a composite rate per dialysis treatment that is adjusted for geographic differences in area wage levels for the treatment furnished in the facility or at home. The composite payment system reimburses facilities for the costs of furnishing outpatient maintenance dialysis and includes some routinely provided drugs, laboratory tests, and supplies, furnished by hospital-based and independent facilities. Home dialysis in this context refers to Method I in which home dialysis equipment and supplies are furnished by a facility. In the other home dialysis option, Method II, the beneficiary obtains the supplies and equipment needed directly from a durable medical equipment supplier.

A substantial portion of renal dialysis related services, such as epoetin alfa (EPO), are excluded from the composite payment system. Excluded services are paid through fee schedules or other payment methodologies. These separately billable services comprise about 40 percent of total spending for outpatient maintenance dialysis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required a report to Congress detailing the elements and features for the design and implementation of a bundled ESRD PPS, which had to include the bundling of separately billed drugs, clinical laboratory tests, and other items "to the maximum extent feasible". MMA also dictated many of the provisions in this proposed rule.

## PROPOSED 2011 ESRD PPS

The Medicare Improvements for Patients and Providers Act (MIPPA), enacted July 15, 2008 requires the implementation of an ESRD bundled payment system effective January 1, 2011. MIPPA specifies the following:

- The payment system must provide a single bundled payment with a four-year transition (phase-in) period.
- A definition must be provided for the "renal dialysis services" that are included in the bundle.
- Total payments under the new system must be equal to 98 percent of the estimated payments under the current system.
- The system must include adjustments for case-mix variables, high cost outlier payments, and low-volume facilities.
- All facilities need to be transitioned into the new system by January 1, 2014. ESRD facilities

may make a one-time election before January 1, 2011, to be paid under the new system and skip the transition period.

- The ESRD PPS may include other adjustments including the use of a geographic index, and adjustments for pediatric patients and rural dialysis centers.
- Medicare may specify the unit of payment (for example, per treatment or per unit of time).
- Payment must be annually increased by an ESRD bundled market basket beginning in 2012.

In response, CMS published a proposed rule that intends to implement a case-mix adjusted bundled PPS for Medicare outpatient ESRD dialysis patients beginning January 1, 2011. This ESRD PPS would replace the current composite rate payment system and methodologies for the separately billable outpatient ESRD services. This payment system, as proposed, will include the methodology described below.

### **BASE RATE**

The base composite rate will apply to Medicare patients receiving dialysis in facilities and to patients who have elected Method I home dialysis. The proposed 2011 standardized base rate is \$198.84 per treatment. Based on MIPPA defined “renal dialysis services”, the base composite rate will include:

- All maintenance dialysis treatments, and all associated services included in the composite rate as of December 31, 2010 including equipment, supplies, staff time and self-dialysis training services.
- Erythropoiesis stimulating agents (ESAs) that are furnished to individuals for the treatment of end stage renal disease. If new ESA drugs or biologicals become available prior to the implementation of the new system, these agents would be considered renal dialysis services that are bundled into the base composite rate.
- Other historically defined separately payable dialysis-related drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease. Previously payment may have been made separately prior under either Medicare part B or Part D.
- Diagnostic laboratory tests and other items and services not described in the first bullet that are furnished to individuals for the treatment of end stage renal disease. This would include laboratory tests ordered by a physician who receives monthly capitation payments (MCPs) that are separately billed by independent laboratories.

Under the current ESRD composite payment system, ESRD facilities generally do not furnish oral drugs and biologicals. ESRD patients obtain these drugs and biologicals either through Medicare Part D, private insurance, or independently. The proposed ESRD PPS will include renal dialysis service drugs currently covered under Part D. ESRD facilities would be required to furnish these and any other self-administered ESRD-related drugs to beneficiaries either directly or under arrangement.

### **Unit of Payment**

MIPPA allows the ESRD PPS to provide payment on the basis of renal dialysis services furnished during a week, or month, or such other appropriate unit of payment. CMS proposes to continue the current per treatment basis of payment in which ESRD facilities would be paid for up to three treatments per week, unless medical necessity justified more treatments. ESRD facilities treating patients on peritoneal dialysis would also receive payments for up to three treatments for each week of dialysis, unless medical necessity justified the furnishing of additional treatments. CMS reserves the right to reconsider the per treatment payment methodology after the transition period has ended.

## **Market Basket**

MIPPA requires that the ESRD bundled payment amounts be annually increased by an ESRD market basket increase factor minus 1.0 percentage point beginning in 2012. The statute further mandates that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services. The ESRD bundled rate market basket will also be used to update the composite rate portion of ESRD payments during the PPS phase-in period from 2011 through 2013.

As required, effective for CY 2012, CMS has developed an all inclusive ESRD bundled rate (ESRDB) input price index. The market basket denotes the input price index, which is comprised of cost categories, their respective weights, and price proxies. CMS is proposing a single payment rate for both operating and capital-related costs, and the market basket for ESRD facilities includes both operating and capital-related costs

The 2007-based market basket costs were used to determine the proposed labor-related share for ESRD facilities under a bundled system. Under the proposed market basket, the labor-related share for ESRD facilities is 38.160.

## **PATIENT LEVEL ADJUSTMENTS**

CMS believes that the following characteristics are strong predictors of variation in payments for ESRD patients. Some of these are the same patient demographic variables used in connection with the current system—patient age, body surface area (BSA), and body mass index (BMI).

### **Patient Age**

The age model indicates that one of the largest increments in cost is for pediatric patients. Analysis of pediatric patient costs is limited by the small fraction of pediatric patients in most ESRD facilities. Pediatric patients will be addressed separately. The following Age adjustment variables are proposed in the ESRD PPS:

<b>Variable</b>	<b>Multiplier</b>
Ages 18–44	1.194
Ages 45-59	1.000
Ages 60-69	1.012
Ages 70-79	1.057
Ages 80+	1.076

### **Patient Sex**

When patient sex was considered as a variable for the current composite rate system, male patients were consistently more costly than females. The sex of the patient was viewed as a surrogate measure for body size, which could not be reported previously. The addition of value codes for patient height and weight allowed CMS to calculate body size (BSA and BMI). A recent analysis reveals that costs are higher for female patients even when body size measures are included. Females were found to be 13.2 percent more costly on a per treatment basis than males primarily due to differences in use of ESAs between male and female patients. This leads CMS to propose an adjustment of 13.2 percent for female patients.

### **Body Surface Area (BSA)**

The analysis using the current system indicates that costs rise as a patient's BSA increases. The payment adjustment factor for BSA in the current composite payment system is 1.037. The proposed system reflects slightly different costs related to BSA. The BSA payment adjustment factor for the proposed system PPS is 1.034. The patient-specific BSA adjuster is derived from the equation  $1.034$  raised to the power of  $(\text{patient's BSA}-1.84)/0.1$ .

**Body Mass Index (BMI)**

The current composite payment system includes a payment adjustment for low BMI .The payment adjuster factor for low BMI in the current composite rate system is 1.112. CMS proposes 1.020 as a payment adjustment factor for low BMI for the new system.

**Onset of Dialysis**

CMS proposes an adjustment of 1.473 for patients in their first four months of dialysis. This adjustment factor will be applied to both in-facility and home dialysis patients. The onset of dialysis is defined as the starting date as reported on the ESRD Medical Evidence Report Form through the first four months a patient is receiving dialysis. This adjustment only applies during the period when the patient is covered under the Medicare ESRD benefit.

**Comorbidities**

Comorbidities are specific patient conditions that are secondary to the patient's principal ESRD diagnosis, but have a direct affect on dialysis. CMS proposes adjustments for the following eleven comorbidity categories under the proposed ESRD PPS.

**Comorbidity Case-mix Adjustment**

<b>Comorbidity</b>	<b>Proposed Adjustment</b>
Alcohol/Drug Dependence	1.150
Cardiac Arrest	1.032
Pericarditis (0–3 months ago)	1.195
HIV/AIDS	1.316
Hepatitis B	1.089
Septicemia (0–3 months ago)*	1.234
Bacterial Pneumonia and Other Pneumonias/Opportunistic Infections*	1.307
Gastrointestinal Tract Bleeding (0–3 months ago)	1.316
Hereditary hemolytic or sickle cell anemia	1.226
Cancer since 1999 (excluding non-melanoma skin cancer)	1.128
Myelodysplastic Syndrome	1.084
Monoclonial Gammopathy	1.021

\*These are two components of the category "Infections"

CMS is proposing that in order to be eligible for the proposed comorbidity payment adjustment, the comorbid condition must exist presently, or within the previous three months, and must affect treatment. For each claim, an ESRD facility may receive only one comorbidity case-mix adjustment per comorbidity category, but it may receive an adjustment for more than one comorbidity category. The appropriate ICD–9–CM code that corresponds to the specific condition or disease that results in increased costs to ESRD facilities is to be placed on the claim.

CMS has proposed eliminating specific ICD–9–CM codes associated with specific diseases or conditions that would not be recognized for purposes of a comorbidity payment adjustment. Please see the *Federal Register* for complete lists of corresponding codes. Conditions or diseases that are acute, many of which are highly communicable, will not be recognized for purposes of the proposed co-morbidity adjustment. ICD–9–CM codes or diagnoses designated as not otherwise specified (NOS); not elsewhere classified (NEC) or are unspecified will not be recognized for comorbidity case-mix adjustment. Benign tumors will not be recognized for the proposed cancer comorbidity payment adjustment.

### **Self-Dialysis Training**

Medicare covers home dialysis training. A patient can only perform home dialysis and self-dialysis after completion of an appropriate course of training. Medicare pays the ESRD facility its current composite rate plus \$12 per training treatment for CAPD and \$20 per training treatment for CCPD. For HD training, Medicare pays the ESRD facility its case-mix adjusted composite rate plus \$20 per training treatment. Effective January 1, 2011, the proposed ESRD PPS would no longer provide add-on payments for the costs of training. The costs of training would be included in the PPS bundled payment.

## **FACILITY LEVEL ADJUSTMENTS**

### **Wage Index**

The current system uses an index based on hospital wage and employment data from Medicare cost reports. ESRD composite rate wage adjustments are CBSA-based geographic area designations that do not take into account geographic reclassifications, and utilize pre-floor hospital data that are unadjusted for occupational mix. The current system applies the wage index to a 53.711 labor share of the composite rate. For the proposed system, CMS intends to use the same method and source of wage index values.

Urban/rural areas and corresponding wage index values will continue to be defined based on the OMB's CBSA-based geographic area designations. Consistent with OMB definitions, urban area means a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions). A rural area is any area outside an urban area.

Under the current system, a floor is applied as a substitute wage index for areas with very low wage index values. However, the ESRD wage index floor had been reduced to 0.70 in CY 2009. For the ESRD PPS proposed rule, CMS is not planning on adopting a wage index floor for the new system.

CMS proposes to use the labor share as measured by the proposed ESRD bundled market basket, which is 38.160 percent. Note that this labor-related share value is lower than the labor-related share from the existing ESRD composite rate index (53.711 percent). This is because there are no labor costs associated with the separately billable portion of the proposed ESRD bundled market basket.

The ESRD PPS will be implemented in and use CY 2011 wage index values. However, the wage data will not yet be available when the ESRD PPS final rule is published. The proposed CY 2011 ESRD PPS wage index data will be published in the CY 2011 Physician Fee Schedule proposed rule, which is expected in the summer of 2010. Final ESRD PPS wage indices along with the CY 2011 final rule update to the existing composite payment system will be published in the CY 2011 Physician Fee Schedule final rule, expected in November of 2010.

### **Low-Volume Adjustment**

CMS proposes a “low-volume facility” adjustment for an ESRD facility that furnished less than 3,000 treatments in each of the three years preceding the payment year; and has not opened, closed, or received a new provider number due to a change in ownership during the three years preceding the payment year. The term “year” is established by the ESRD facility’s final-settled cost report, where the final-settled cost report reports costs for 12-consecutive months.

If an ESRD facility provides 3,000 or more treatments during their payment year, they would no longer be eligible for the low-volume adjustment and the adjustment would stop at the time they reach treatment 3,000. When a change of ownership occurs, and the new owner receives a new provider number during the three-year period, the ESRD facility would not be eligible for the adjustment until it demonstrates that it meets the low-volume criteria under its new provider number. CMS is proposing a 20.2 percent increase to the base rate to account for the costs incurred by low-volume facilities for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014.

### **EXCEPTIONS IN THE CURRENT PAYMENT SYSTEM**

The proposed ESRD PPS creates a bundled prospective payment that CMS feels addresses the higher costs relating to case-mix through the patient characteristic adjustments and outlier adjustments. This leads CMS to propose the elimination of the isolated essential facility, self dialysis training costs, atypical service intensity (patient mix) and pediatric facility exceptions effective for ESRD renal dialysis services furnished on or after January 1, 2014 (at the conclusion of the transition). No further exception windows would be open effective for ESRD treatment furnished on or after January 1, 2011, the effective date of the ESRD PPS.

Facilities opting for 100 percent ESRD PPS would lose any existing exceptions. In the event that an ESRD facility with exceptions elects to receive transition payments, any existing exceptions would be recognized for purpose of the current composite payment system portion of the blended payment through the transition.

### **PEDIATRIC PATIENTS**

Due to the relative costliness of pediatric ESRD patients, CMS felt that it was appropriate to develop a temporary methodology applicable to ESRD facilities, which furnish outpatient dialysis to pediatric patients, regardless of whether the facility met the CMS definition of a pediatric facility. The current system has a pediatric adjustment factor of 1.62 that was temporary and was planned for elimination once an appropriate methodology could be developed.

CMS is proposing a pediatric payment adjustment that uses two age categories (<age 13, age 13–17), two comorbidity categories (none, and one or more co-morbidities from among the following diagnoses: HIV/AIDS, septicemia, cardiac arrest, and diabetes), and dialysis modality (HD and PD), as the bases for classifying pediatric patients into one of eight groups. Multipliers for these groups range from 0.963 to 1.215. These are the proposed pediatric patient-specific case-mix adjustment factors that would be applied to the base rate under the ESRD PPS.

### **OUTLIER POLICY**

The new ESRD PPS must include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including the amount of ESAs necessary for anemia management. Any outlier payment due would be added to the per treatment, patient and facility-level adjusted ESRD PPS payment amount.

CMS proposes that the ESRD outlier policy parallel the outlier policies adopted for other Medicare PPS. CMS proposes to limit the ESRD outlier policy to those items and services that currently are separately billable under Part B and D.

An ESRD facility would be eligible for an outlier payment when its imputed Medicare allowable payment amount per treatment for the outlier services exceeds the outlier threshold, or the facility's predicted Medicare allowable payment amount per treatment for the outlier services plus the fixed dollar loss amount. The proposed outlier payment would be equal to 80 percent of the amount by which the facility's imputed costs exceeds the outlier threshold.

CMS is considering the exclusion of the 50 percent rule that pertains to the Automated Multi-Channel Chemistry (AMCC) separately billable laboratory tests under the current payment system. Medicare would not make separate payment for laboratory tests under the proposed system which renders the 50 percent rule irrelevant for payment purposes.

### **Predicted ESRD Outlier Services Amounts**

Predicted outlier service allowable amounts for a patient would be determined by multiplying the adjusted average outlier services Medicare allowed amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers.

It is possible to predict patient specific separately billable Medicare allowed amounts for these services by multiplying the average separately billable Medicare allowed amounts by the separately billable case-mix adjusters. Drugs and biologicals currently covered under Medicare Part D are not included in the proposed Medicare allowed amounts. For the final rule CMS will incorporate these drugs and derive a comprehensive predicted Medicare allowable payment (MAP) amount for all proposed outlier services.

The facility's imputed Medicare allowed amount per treatment for the ESRD outlier services is necessary to determine outlier status. CMS is proposing to estimate a renal dialysis facility's imputed costs for the ESRD outlier services based on available data rather using a provider-specific cost-to-charge ratio. The imputed separately billable Medicare allowed amounts would be based on current pricing mechanisms. CMS proposes to use the Average Sales Prices (ASP) data for the Part B ESRD-related drugs, which is updated quarterly, and annual laboratory fee schedules for the previously separately billable laboratory tests. For medical/surgical supplies used to administer separately billable drugs, estimated Medicare allowed amounts would be based on the predetermined fees that apply under the current composite payment system. For example, Medicare pays \$0.50 for each syringe identified on an ESRD facility's claims. For other medical/surgical supplies such as IV sets and gloves, Medicare contractors can currently elect among various options to price these supplies. CMS proposes that the FI/MAC would continue to use the pricing mechanisms that are currently in place for items and services that currently are separately billable under Part B to estimate costs for these other medical/surgical supplies.

Finally, payment for blood, supplies used to administer blood, and blood processing fees furnished by hospital-based ESRD facilities under the current composite payment system is based on a reasonable cost basis. Payment for blood, supplies used to administer the blood, and blood processing fees, on behalf of patients in independent renal dialysis facilities currently is made at the lower of the actual charge on the bill, or a reasonable charge that the MAC/FI determines. CMS proposes to estimate hospital-based and independent ESRD facilities' costs for blood, supplies used

to administer blood, and blood processing fees using the current pricing mechanisms for items and services that currently are separately billable under Part B.

CMS is not specifying the mechanism by which it proposes to estimate the imputed MAP amounts for drugs formerly covered under Medicare Part D. CMS has put forth several methods and requests public comment on the potential approaches.

The majority of the Part D covered renal dialysis service drugs proposed have clinical treatment indications beyond ESRD. These drugs will continue to be covered under Part D for these other indications. Part D pricing information would continue to be available for these drugs and could be used in the computation of outlier eligibility and payment..

### **Per Treatment Outlier Amounts**

ESRD facilities currently submit claims on a monthly basis that identify line item dates of service. For purposes of determining proposed outlier eligibility, ESRD facilities would need to identify by line item all ESRD outlier services furnished to the patient in the month. CMS could then estimate the imputed Medicare allowed amount for these services by aggregating costs and then dividing by the corresponding number of treatments identified on the claim to arrive at the amount per treatment. An ESRD facility would be eligible for an outlier payment if the imputed average outlier services Medicare allowed amount per treatment exceeds the sum of the predicted outlier services Medicare allowed amount per treatment and the fixed dollar loss amount.

Payments for outlier cases must be applied in a budget neutral manner. CMS proposes to reduce the base rate by the proposed outlier percentage. CMS is proposing that the outlier percentage would be 1 percent of total ESRD PPS payments. The fixed dollar loss amounts that would be added to the predicted outlier services Medicare allowed amounts would differ for adult and pediatric patients. CMS proposes separate fixed dollar loss amounts, \$134.96 for adult patients and \$174.31 for pediatric patients.

The loss sharing percentage is the percentage of costs exceeding the fixed dollar loss amount that is paid by Medicare. CMS proposes an 80 percent loss sharing percentage. For treatments eligible for outlier payments, the proposed per treatment outlier payment would equal 80 percent of the imputed average ESRD outlier service MAP amounts in excess of the sum of the predicted outlier services Medicare allowed amount per treatment and the fixed dollar loss amount. When a treatment is eligible for the outlier payment, the outlier payment would be added to the ESRD PPS per treatment payment amount. The agency proposes to implement an annual monitoring process that would identify patterns of increased utilization of outlier services.

As required by regulation, the proposed ESRD PPS includes a four-year transition period. During the transition, ESRD facilities would receive a blended rate based in part on the payment rates under the current composite rate payment system and proposed ESRD PPS. Renal dialysis facilities may make a one time election to be excluded from the transition. CMS proposes that for those ESRD facilities that do not elect to be excluded from the four-year transition, outlier payments would be limited to the portion of the blended rate based on the ESRD PPS payment rates.

### **Home Dialysis Patients**

Currently, hemodialysis (HD), 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 select between Method I and Method II payments.

CMS is proposing that payment for all Method I home dialysis services, excluding physicians' services, would be included in the proposed bundled payment to the ESRD facility. CMS also proposes to eliminate the current form of Method II reimbursement. Method I would continue in its present form. Since Method II will no longer be available effective January 1, 2011, a supplier could only furnish home dialysis equipment and supplies to a Medicare home dialysis beneficiary under an arrangement with the ESRD facility. The supplier would then need to look to the ESRD facility for payment.

**TRANSITION.**

MIPPA provides a four-year transition period, in equal increments for the implementation of the ESRD PPS. ESRD facilities can elect to be excluded from the transition period. The transition payments beginning January 1, 2011 and ending December 31, 2013, must consist of a blend of the payment amounts under the new system and the prior payment rates in the following proportions:

<b>Effective</b>	<b>New PPS (percent)</b>	<b>Prior payment amounts (percent)</b>
1/1/2011	25	75
1/1/2012	50	50
1/1/2013	75	25
1/1/2014	100	0

CMS must 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.

CMS also proposes an add-on payment of \$14 during the transition. The \$14 add-on is for ESRD related drugs and biologicals that are currently separately paid under Part D and are being proposed for inclusion in the ESRD PPS base rate.

For the years of the transition, the composite rate portion of the blended payment must be updated annually by the market basket minus 1.0 percentage point. Payments for items and services furnished to dialysis patients that are paid separately under Part B in the current composite payment system, such as ESRD-related laboratory tests, drugs, and supplies, blood, and blood products would no longer be paid separately. .

There are renal dialysis 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. Any existing exception amount would not be updated by the market basket throughout the transition.

Maintaining the 98 percent budget neutrality during the first year of the transition period requires CMS to propose to reduce all payments to ESRD facilities in CY 2011 by 3.0 percent. For 2011, a 3.0 percent reduction will apply to all payments to facilities. Similar factors for CYs 2012 and 2013 will be calculated to allow a blended payment system to be budget neutral to a fully implemented 100 percent ESRD PPS.

**BENEFICIARY CHARGES**

Certain items and services, such as laboratory tests and Part D drugs, have different beneficiary coinsurance structures. After the implementation of the ESRD PPS, these items and services would be considered renal dialysis services when furnished by an renal 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. A facility receiving an ESRD PPS payment may charge the Medicare beneficiary or other person only for the applicable deductible and coinsurance amounts. The services included in the blended monthly payment amount would be subject to a 20 percent beneficiary coinsurance.

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 the specific beneficiary are greater than the amount the ESRD facility would be paid under the proposed ESRD PPS.

### **CLAIMS PROCESSING**

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. CMS proposes to continue this monthly billing and payment.

ESRD facilities would receive an all-inclusive payment during the transition for all renal dialysis services and home dialysis items and services which means that 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.

### **Consolidated Billing**

The renal dialysis facility itself would be responsible for virtually all of the services 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 renal dialysis facility so that duplicate payment is not made by Medicare.

Therefore, suppliers, laboratories, and Part D plans would not be permitted to bill Medicare for renal dialysis services and items that they furnish to ESRD beneficiaries. The ESRD facility assumes the Medicare billing responsibility for all of the renal dialysis services that its patients receive.

### **LABORATORY TESTS**

ESRD patients generally have many comorbid conditions that are treated by other specialists. 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. CMS is exploring the use of modifiers to identify those services furnished to ESRD beneficiaries, which are excluded from the proposed ESRD PPS.

During the transition period, the 50 percent rule would continue to apply to the current composite payment system portion of the blended payment. If proposed consolidated billing provisions are finalized, the ESRD facility itself would assume the Medicare billing responsibility for all of the renal dialysis services that its patients receive, including laboratory tests. As a result, the ESRD facilities would apply the 50 percent rule billing procedures, including application of the relevant modifiers.

Under the proposed PPS, Medicare would not make separate payment for laboratory tests, rendering the 50 percent rule irrelevant for payment purposes. The 50 percent rule's relevance would be limited to its use in determining eligibility for outlier payment. Preliminary analyses reveal a small impact upon removing from eligibility for outlier services the AMCC tests to which the 50 percent rule applies. As a result, CMS is considering excluding AAMC tests to which the 50 percent rule applies from the definition of outlier services, thus negating the need to apply the 50 percent rule under the proposed ESRD PPS.

### **Drugs and Biologicals**

MIPPA requires that the ESRD PPS include all drugs and biologicals used for the treatment of ESRD, including drugs and biologicals that were formerly covered under Medicare Part D. Therefore, CMS would include these drugs as part of the consolidated billing mechanism. 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.

### **Home Dialysis**

MIPPA 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. The Method II home dialysis approach in its present form would no longer exist effective January 1, 2011. This proposal does not eliminate Method II in its present form. A supplier could furnish home dialysis equipment and supplies to a Medicare home dialysis beneficiary only under arrangement with the ESRD facility, and the supplier would have to look to the ESRD facility for payment.

### **Expansion of the Claim Data Elements**

Under the current composite rate system, ESRD facilities are paid the 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 items and services included in the composite rate, but not captured on the claims, are: time on machine, nutritional services, social work services, and nursing services.

The collection of additional data at patient-level is necessary for refinements to the proposed case-mix adjustments of the proposed ESRD PPS payment model. While no additional reporting requirements are proposed at this time, new reporting requirements may be implemented when relevant for future case-mix refinements. Detailed instruction as to how claims would be processed under the proposed ESRD PPS will be provided in future guidance.

### **Self Administered ESRD-Related Drugs and Biologicals**

Renal dialysis services include certain drugs and biologicals, including drugs and biologicals that were separately payable under Parts B and D. Under the current 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.

The proposed ESRD PPS requires ESRD facilities to assume responsibility for the provision of drugs that were formerly furnished by the Part D plans, whether furnished directly or under arrangement. CMS believes that some of the Part D provisions would become relevant for ESRD facilities. CMS is particularly interested in assuring beneficiary access to these drugs. Consistent with the Part D

patients' rights processes and the governance processes CMS would expect that the ESRD facilities would update their grievance processes to account for all self-administered ESRD-related drugs.

### **CONTINUING ESRD POLICIES**

With the advent of the new ESRD PPS, CMS will maintain the current ESA monitoring policy, bad debt policy, Medicare secondary payer (MSP) policies, and the 50-cent deduction to fund the ESRD Networks. CMS is considering the extent to which the laboratory services 50 percent rule would continue to apply under the proposed ESRD PPS.

ESRD networks are funded by a 50 cent deduction made from the amount of each payment for each treatment (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis). The reduction amount applies to all treatment modalities. CMS plans to continue this deduction with the ESRD PPS effective for services provided on or after January 1, 2011.. For facilities that elect to receive ESRD payment during the transition, the reduction methodology would be applied to the blended payment amount during the transition.

If an ESRD facility meets specific requirements as set forth in the Provider Reimbursement Manual, Part 1 (PRM) (CMS Pub. 15-1), Medicare recognizes a facility's Medicare bad debts at the end of the ESRD facility cost reporting period. CMS reimburses ESRD facilities for its allowable bad debt up to the facility's costs as determined under Medicare principles.

Per MIPPA, under the proposed ESRD PPS, bad debt payments will continue to be made for the unpaid Medicare deductibles and coinsurance amounts for only those items and services associated with the basic case-mix adjusted composite rate. However, since the proposed single ESRD payment rate is for items and services included in the composite rate and for drugs and laboratory tests, CMS proposes to use only the composite rate portion of the proposed single ESRD payment rate to determine bad debt payments. Bad debt payments for ESRD facilities would continue to be capped.

### **QUALITY INCENTIVES**

MIPPA requires that CMS develop a quality incentive program (QIP) that will result in payment reductions to providers of services and dialysis facilities that do not meet or exceed a total performance score with respect to performance standards established. The payment reductions can be up to 2.0 percent of the payments otherwise made to providers and facilities. It will apply to renal dialysis services furnished on or after January 1, 2012. The total performance score that providers and facilities must meet or exceed in order to receive their full payment will be based on a specific performance period prior to this date. The payment reductions will apply with respect to the year involved and will not be taken into account when computing future payment rates.

CMS is committed to developing and implementing an ESRD QIP, and intends to issue a subsequent proposed rule that includes detailed proposals on how this plan will be implemented.

### **FOR FURTHER INFORMATION**

Be sure to check the Ingenix Web site for up-to-date information and additional ***Industry Insights*** on Medicare regulatory issues. You will find ***Industry Insights***, as well as source documents and relevant statistics, under "News & Events" (<http://www.ingenix.com/News/Industnews/>). New ***Industry Insights*** are posted on a regular basis, often in advance of formal notification of their availability.