

MEDICARE NEWS

FOR IMMEDIATE RELEASE
July 26, 2010

Contact: CMS Office of Media Affairs
(202) 690-6145

CMS ANNOUNCES NEW PROSPECTIVE PAYMENT SYSTEM FOR END-STAGE RENAL DISEASE FACILITIES

PROGRAM WOULD REWARD EFFICIENT, HIGH QUALITY CARE FOR PEOPLE WITH END-STAGE RENAL DISEASE

The Centers for Medicare & Medicaid Services (CMS) today issued a final rule that will change how Medicare pays for dialysis services for Medicare beneficiaries who have end-stage renal disease (ESRD). CMS also issued a proposed rule that would establish a new quality incentive program (QIP) to promote high quality services in dialysis facilities by linking a facility's payments to performance standards. The QIP is the first pay-for-performance program in a Medicare fee-for-service payment system.

"The new payment system and quality incentive program for dialysis services have significant potential to improve patient outcomes and promote efficient delivery of health care services," said CMS Administrator Donald Berwick, M.D. "In addition, for the first time in any of our payment systems, the quality of care facilities furnish to patients will be reflected in their payment rates." Currently, facilities only report on whether they have complied with quality measures.

The final rule establishing the new prospective payment system (PPS) provides for a payment adjustment for home dialysis training when clinically appropriate. This adjustment, which CMS adopted in response to public comments on the ESRD PPS proposed rule that strongly supported home dialysis, will help ensure that ESRD patients are learning the skills and techniques they need to properly receive their dialysis treatment at home.

Both the new prospective payment system and the proposed QIP were required by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The law requires the ESRD PPS to pay dialysis facilities a single bundled rate for renal dialysis services and home dialysis, while the proposed QIP promotes quality of service furnished by these facilities by creating payment incentives for them to take steps to improve patient outcomes.

ESRD was the first category for Medicare eligibility based on a specific diagnosis, without regard to the age of the patient. Patients are diagnosed with ESRD when their kidneys are no longer able to perform the function of removing excess fluids and toxins from their blood. The only cure for ESRD is a kidney transplant, but in the absence of a transplant, the patient must rely on dialysis

to filter his/her blood. There are more than 330,000 individuals in the United States with ESRD, of whom the great majority are Medicare beneficiaries.

Currently, Medicare pays for certain dialysis services under a partial bundled rate, referred to as the composite rate. Payments for these composite rate services represent about 60 percent of total Medicare payments to ESRD facilities. The remainder of Medicare spending for dialysis services is for separately billable items such as drugs, supplies and non-routine laboratory testing. In 2007, there were about 600 hospital-based and 4,330 freestanding ESRD facilities furnishing outpatient maintenance dialysis services to nearly 330,000 Medicare patients. Total Medicare payments for these services were \$9.2 billion including the dialysis treatments and other ESRD-related items such as drugs.

The new ESRD PPS provides a single bundled case-mix adjusted payment to dialysis facilities for renal dialysis services such as dialysis treatments and supplies, certain ESRD-related drugs, and ESRD-related clinical laboratory tests beginning on Jan. 1, 2011. Although CMS has determined that the definition of renal dialysis services includes ESRD-related oral drugs without injectable equivalents (or other forms of administration), CMS is delaying paying for those drugs under the ESRD PPS until Jan. 1, 2014.

The final rule sets a base payment rate of \$229.63 for each dialysis treatment. This payment rate includes payment for the services in the current composite rate, as well as most items and services that are currently paid separately. The base rate was derived from 2007 claims data for both composite rate and separately billable services and updated to reflect projected 2011 prices.

The base payment rate would be adjusted for case-mix factors including patient's age, body size, and time on dialysis. By accounting for more characteristics of patients, the new PPS will target payments more appropriately, paying higher rates to those facilities with the most costly dialysis patients. Separate case-mix adjustments will apply to pediatric patients. In the final rule, CMS also adopts facility level adjustments including a geographic wage index and an adjustment for low-volume facilities that furnish fewer than 4,000 dialysis treatments and meet certain other criteria. The final rule also includes an outlier payment policy that will pay facilities more for patients whose care is significantly more costly than the Medicare payment amount.

In the ESRD PPS final rule, CMS also has reduced the number of case-mix co-morbidity adjustments. In addition, at this time, CMS is not finalizing a case-mix payment adjustment based on the patient's sex, race or ethnicity. CMS has been reviewing and updating its processes for collecting and validating patient-level race and ethnicity data from dialysis facilities, which will ensure that CMS has the most accurate information possible for the races and ethnicities of all patients with ESRD. As this work continues, CMS will assess whether this effort will position the Agency to incorporate such an adjuster for payment in the future. CMS plans to continue studying the issue to ensure that all beneficiaries with ESRD have access to quality care, and in the meantime, plans to implement an active monitoring program to respond to concerns about disparities in access to care.

In addition to finalizing the ESRD PPS payment policies and rates for calendar year 2011, CMS issued a proposed rule that would establish performance standards and a scoring methodology

for the Quality Incentive Program required by MIPPA to ensure quality of care for patients with ESRD.

“The ESRD QIP is a critical tool for encouraging and supporting dialysis facilities to focus their energies thoroughly on the quality of the dialysis care they provide to Medicare beneficiaries,” said Berwick.

In the ESRD PPS final rule, CMS adopted the three quality measures that will be used in the initial implementation of the QIP. Two of these measures reflect whether patients are receiving appropriate treatment for anemia – that is, whether the amount of iron in the blood is neither too low, nor too high. The third measure captures patients’ urea reduction ratio, which indicates how well dialysis treatments are removing wastes from patients’ bodies. The law requires CMS to reduce the payment rates to a dialysis facility by up to 2.0 percent if that facility fails to meet or exceed the established performance scores with regard to performance standards established for each quality measure.

Facilities failing to meet or exceed specified total performance scores will receive reduced reimbursement for dialysis services furnished on or after Jan. 1, 2012.

The QIP proposed rule also discusses options for making individual facility performance scores available both to dialysis patients and to the general public as required by the law.

CMS will accept comments on the QIP proposed rule until Sept. 24, 2010, and will respond to them in a final rule to be issued later this year.

To view the ESRD PPS Final Rule and the QIP Proposed Rule, see: http://www.ofr.gov/OFRUpload/OFRData/2010-18466_PI.pdf or www.ofr.gov/inspection.aspx

For more information, please see: www.cms.gov/center/esrd.asp

###

MEDICARE FACT SHEET

FOR IMMEDIATE RELEASE
July 26, 2010

Contact: CMS Office of Media Affairs
(202) 690-6145

**NEW BUNDLED PROSPECTIVE PAYMENT SYSTEM FOR
END-STAGE RENAL DISEASE FACILITIES DESIGNED TO PROMOTE
EFFICIENT CARE AND IMPROVE PATIENT OUTCOMES**

OVERVIEW: The Centers for Medicare & Medicaid Services (CMS) issued a final rule on July 23, 2010 that creates a new bundled prospective payment system (PPS) for facilities that furnish renal dialysis services and home dialysis to Medicare beneficiaries with End-Stage Renal Disease (ESRD). Under the new ESRD PPS, CMS will make a single bundled payment to the dialysis facility for each dialysis treatment that will cover all renal dialysis services and home dialysis. The new bundled payment system will be effective for dialysis treatments furnished to beneficiaries on or after Jan. 1, 2011. It replaces the current system which pays facilities a composite rate for a defined set of items and services, while paying separately for drugs, laboratory tests, or other services that are not included in the composite rate.

At the same time, CMS issued a proposed rule that would create a new Quality Incentive Program (QIP) for dialysis services that will link a facility's payment to how well it meets the QIP performance standards. The QIP, which is the first pay-for-performance program in a Medicare fee-for-service payment system, will affect payments for dialysis services beginning on or after Jan. 1, 2012. The QIP is discussed in a separate fact sheet also issued today.

BACKGROUND: Medicare makes payments for dialysis services to approximately 600 hospital-based and 4,300 independent ESRD facilities. Currently, Medicare makes a composite rate payment to ESRD facilities for furnishing outpatient maintenance dialysis in the facility or in the beneficiary's home. The composite rate payment covers dialysis treatment costs and certain routinely furnished ESRD-related drugs, laboratory tests, and supplies. The composite rate is adjusted by a drug add-on payment that accounts for changes in the drug pricing methodology that occurred in 2005, and by basic case-mix adjustment factors including age and body size. A special adjustment is applied for services to pediatric patients. In addition, the composite rate is adjusted for geographic differences in costs using a wage index. For 2010, the unadjusted composite rate is \$135.15 and the drug add-on payment is \$20.33.

The composite rate does not include a number of other ESRD-related items and services, particularly injectable drugs, such as erythropoietin (EPO) to treat ESRD-associated anemia, iron sucrose, vitamin D, and non-routine laboratory tests. These items and services are currently paid separately under Medicare. Over time, payments for separately billed items and services have increased dramatically. In 2007 (the base utilization year used by CMS to determine the new ESRD PPS payment rates), Medicare paid approximately \$9.2 billion for dialysis and related services, of which about \$5.7 billion, or 62 percent, was paid under the composite rate, while about \$3.5 billion, or 38 percent, was paid for separately billable ESRD-related items and services, including injectable drugs, non-routine laboratory tests, supplies and services for home dialysis patients who deal directly with a durable medical equipment supplier, and ESRD-related drugs that are currently covered under Part D.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended the Social Security Act to require CMS to develop a new, fully bundled prospective payment system for renal dialysis services to replace the existing composite rate payment methodology. MIPPA also mandated that the estimated total amount of payments for renal dialysis services for 2011 be 98 percent of the estimated total amount of payments that would have been made in 2011 if the ESRD

PPS had not been implemented. MIPPA also required that CMS develop and implement a QIP to improve the quality of care facilities provide to dialysis patients. Beginning for services on or after Jan. 1, 2012, facilities that failed to meet the QIP performance standards would have their payments reduced.

The law further required CMS to phase in the new bundled payment system over a four-year period. However, facilities will be given the opportunity to choose to be paid entirely under the new payment system beginning on January 1, 2011.

SUMMARY OF FINAL RULE FOR ESRD PROSPECTIVE PAYMENT SYSTEM: CMS

received nearly 1500 public comments in response to the ESRD PPS proposed rule that appeared in the September 29, 2009 *Federal Register*. Among the major concerns raised by the comments were the proposals surrounding payment for home dialysis training; inclusion of additional payment adjustments for patient characteristics in the payment methodology; and inclusion of former Part D prescription drugs related to ESRD treatment in the payment bundle. As will be discussed in greater detail below, in the final rule CMS:

- · Creates a home or self-care dialysis training payment adjustment specifically directed to patients trained by facilities certified to provide home dialysis training.
- · Finalizes payment adjustments for dialysis treatments furnished to adults for patient age, body surface area, and body mass index, onset of dialysis, and certain co-morbidities, but does not finalize adjustments for the patient's sex or the patient's race or ethnicity.
- · Finalizes a payment adjustment for dialysis treatments furnished to pediatric patients, based on patient age and dialysis modality, but not co-morbidities.
- · Finalizes a definition for renal dialysis services that includes ESRD-related oral-only drugs, but postpones payment for such drugs under the ESRD PPS until Jan. 1, 2014.

ESRD Base Rate And Bundle Of Services: The final budget-neutral standardized base rate per dialysis treatment for 2011 is \$229.63. The amount represents the single Medicare payment for all services in the bundle prior to adjustments for case-mix and the wage index, including the former composite rate services and services that were previously separately billable, such as non-routine laboratory services and all ESRD-related Part B drugs and their equivalent forms covered under Part D.

The final budget-neutral standardized base rate was computed as follows: The unadjusted cost per treatment in 2011 was estimated to be \$251.60. This amount was reduced by (a) 5.94 percent to standardize the rate to account for the patient and facility adjustments; (b) 1.0 percent to account for the outlier policy, and (c) 2.0 percent to make projected payments in 2011 equal to 98 percent

of the estimated total amount of payments that would have been made in 2011 under the previous payment system. The final base rate would then be multiplied by the patient and facility-specific adjustments to determine the per treatment payment amount under the ESRD PPS. The base rate would be increased by the ESRD market basket to determine the base rate for years after 2011.

Patient-Level Adjustments: MIPPA requires that the bundled payment system “include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors.” In the final rule, CMS finalizes case-mix payment adjusters for age, body surface area (BSA), and body mass index (BMI). In the final rule, CMS also adopts a “new patient adjustment” that recognizes that patients have higher costs in their first four months of maintenance dialysis. In addition, the final rule creates a payment adjustment for treatment of pediatric patients, based on two age categories and the patient’s dialysis modality. Finally, in the final rule CMS finalizes six co-morbidities categories (three acute and three chronic) for the co-morbidity case-mix adjustment.

At this time, CMS is not finalizing case-mix payment adjustment factors for patient sex or race/ethnicity. CMS has been reviewing and updating its processes for collecting and validating patient-level race and ethnicity data from dialysis facilities, which will ensure that CMS has the most accurate information possible for the races and ethnicities of all patients with ESRD. As this work continues, CMS will assess whether this effort will position the Agency to incorporate a case-mix adjustment factor for race or ethnicity in the future. CMS plans to continue studying the issue to ensure that all beneficiaries with ESRD have access to quality care, and in the meantime, plans to implement an active monitoring program to respond to concerns about disparities in access to care.

Facility-Level Adjustments: MIPPA requires an adjustment of at least 10 percent for low-volume facilities until Jan. 1, 2014, and gives the Secretary discretion to adopt additional facility-level adjustments. The final rule defines low-volume facilities as those facilities that: (1) furnished fewer than 4,000 treatments in each of the three years preceding the payment year; and (2) have not opened, closed, nor received a new provider number due to a change in ownership during the three years preceding the payment year. The low-volume facility adjustment is not applied to pediatric claims.

MIPPA also authorizes the Secretary to apply other payment adjustments that the Secretary determines appropriate including a geographic index. CMS is finalizing a wage index using the core-based statistical area (CBSA) definitions developed by the Office of Management and Budget. The wage index values will be based on the most current hospital wage data, prior to application of the rural floor and occupational mix adjustments, and geographic reclassifications.

Training Adjustment: The final rule provides a payment adjustment for dialysis training treatments for home or self dialysis for both hemodialysis and peritoneal dialysis modalities. The ESRD training add-on adjustment will target payments for training to those ESRD facilities that actually conduct training treatments rather than including such training in the base rate for all facilities. A home dialysis training adjustment of \$33.38 will be added on to the per treatment ESRD PPS payment each time training is conducted. The training adjustment will be adjusted by the geographical wage index based on the location

of the ESRD facility. The home or self-dialysis training adjustment is not available, however, during the four-month new patient adjustment for the onset of dialysis.

Outlier Policy: MIPPA requires additional payments, called outlier payments, to ESRD facilities that treat high-cost patients — patients who use more than the predicted amount of services, including variation in the amount of erythropoietin stimulating agents (ESAs) used to manage dialysis-related anemia. CMS is finalizing the outlier percentage as 1.0 percent. As noted previously, since outlier payments increase total spending, and since the system is required to be budget-neutral, CMS is reducing the standardized base rate payment amount for all dialysis treatments by 1.0 percent, to fund the 1.0 percent outlier policy under the new ESRD PPS. CMS is setting the fixed dollar loss amount at \$155.44 for adult and \$195.02 for pediatric dialysis patients. Once the fixed dollar loss amount is met, CMS will pay 80 percent of the ESRD facility's outlier service costs. CMS projects that approximately 4.7 percent of adult and 2.2 percent of pediatric patient months would qualify for outlier payments.

Annual Payment Rate Updates: As required by MIPPA and Patient Protection and Affordable Care Act, beginning in CY 2012, the ESRD PPS base rate will be updated annually by an ESRD market basket index reduced by a productivity adjustment. The final rule describes how the ESRD market basket was constructed.

Beneficiary Coinsurance: Under the ESRD PPS, the beneficiary coinsurance amount will be 20 percent of the ESRD PPS bundled payment amount, including applicable case-mix and facility-level adjustments and outlier payments. For those beneficiaries served by facilities that are going through the four-year transition period, the coinsurance would be 20 percent of the blended payment amount. Although clinical laboratory services are not currently subject to coinsurance, laboratory services that are bundled would be subject to the 20 percent coinsurance obligation as part of the bundled set of renal dialysis services under the ESRD PPS. Similarly, drugs being bundled that are currently payable under Medicare's prescription drug program and subject to a separate coinsurance structure, would be subject to the 20 percent coinsurance as part of the set of bundled renal dialysis services under the ESRD PPS.

Final Measures For Quality Improvement Program: MIPPA requires CMS to adopt under the ESRD QIP quality measures for dialysis treatment that include measures of anemia management and dialysis adequacy. In the final rule, CMS is adopting the following three measures for use in the QIP for payment consequence year 2012:

- Hemodialysis Adequacy: Achieved urea reduction ratio (URR) of 65 percent or more; and
- Anemia Management: Controlled anemia, as shown in two measures:
 - the percentage of patients at a facility whose hemoglobin levels were less than 10 grams per deciliter (g/dL), and
 - the percentage of patients at a facility whose hemoglobin levels were greater than 12 g/dL.

These measures were chosen because they are relevant to the adequacy of dialysis and health of the Medicare beneficiary receiving dialysis services, have been used by dialysis facilities since 2001, and facilities are familiar with them. In addition, these measures are currently collected from dialysis facility claims, relieving the facilities of the need to report them separately. Finally, CMS has already been collecting data on these measures since 2001.

Transition Period: As required by the law, the final rule provides a four-year phase-in (transition) of the payments under the ESRD PPS, with the phase-in occurring in equal increments until CY 2014 when payments would be based entirely on the ESRD PPS. For CY 2011, transition payments consist of 75 percent based on the payment rate under the current basic case-mix adjusted composite payment system and 25 percent based on the ESRD PPS payment amount. Dialysis facilities will have opportunity for a one-time election to be excluded from the transition and paid entirely under the new ESRD PPS. The rule requires that this election be made by Nov. 1, 2010.

The new payment system would apply to renal dialysis services and home dialysis furnished to Medicare beneficiaries on or after Jan. 1, 2011.

For a copy of the final rule, please see: http://www.ofr.gov/OFRUpload/OFRData/2010-18466_PI.pdf or www.ofr.gov/inspection.aspx

For more information on the ESRD PPS, please see: www.cms.gov/center/esrd.asp

###

MEDICARE FACT SHEET

FOR IMMEDIATE RELEASE
July 26, 2010

Contact: CMS Office of Media Affairs
(202) 690-6145

MEDICARE PROPOSES NEW QUALITY INCENTIVE PROGRAM FOR END-STAGE RENAL DISEASE SERVICES

OVERVIEW: Today the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would establish a quality incentive program (QIP) for facilities that furnish renal dialysis services to Medicare beneficiaries who are diagnosed with end-stage renal disease (ESRD). The QIP would apply to both hospital-based and freestanding facilities. The QIP, which was required by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), is designed to foster improved outcomes for ESRD patients by establishing performance standards for dialysis facilities.

Section 153(c) of MIPPA specifically requires that CMS incorporate measures based on hemodialysis adequacy and anemia management into the QIP. CMS proposed three initial quality measures, one on hemodialysis adequacy and two on anemia management, for the QIP in the ESRD prospective payment system (PPS) proposed rule, and finalized these measures in the ESRD PPS final rule, also issued today. In the QIP proposed rule, CMS is proposing the performance standards, how these measures will be scored, and how the scores will affect the facility's payment rates in 2012.

Under the new ESRD QIP, CMS would evaluate a facility's performance year to year on specific performance measures. Those facilities that do not meet or exceed certain performance scores with regard to performance standards established for specified quality measures could potentially have their payments for dialysis services reduced by up to 2 percent, beginning for services on or after Jan. 1, 2012.

BACKGROUND: The QIP continues a long tradition of work by CMS to improve the quality of care for beneficiaries with ESRD. Since 1978, Medicare has worked through ESRD Network Organizations to monitor and improve the quality of care furnished to ESRD beneficiaries.

Since 2001, CMS has published information for consumers about the quality of dialysis care through Dialysis Facility Compare at www.medicare.gov.

The QIP, which is the first pay-for-performance program in a Medicare fee-for-service payment system, builds on existing quality improvement efforts that seek to transform Medicare from a passive payer of claims based on the volume of services facilities provide to beneficiaries to an active purchaser of health services based on the quality of care beneficiaries receive.

Section 153(c) of MIPPA requires, among other things, that CMS select measures, develop a scoring methodology, and implement a payment reduction scale that relates to facilities' performances. Under the proposed QIP, a percentage of the facility's dialysis payment would be contingent on the facility's actual performance on a specific set of performance standards. Payment consequences are to begin on Jan. 1, 2012 based on facilities' performances during a performance period before 2012 that is established in this proposed rule.

FINAL QIP MEASURES: The ESRD PPS final rule issued today finalizes the following three measures for use in the first year of the QIP:

- Hemodialysis Adequacy: Achieved urea reduction ratio (URR) of 65 percent or more; and
- Anemia Management: Controlled anemia, as shown in two measures:
 - the percentage of patients at a facility whose hemoglobin levels were less than 10 grams per deciliter (g/dL), and
 - the percentage of patients at a facility whose hemoglobin levels were greater than 12 g/dL.

Facilities have already been reporting these measures on claims, and the results for each facility are available to the public on the Dialysis Facility Compare (DFC) website on Medicare.gov at:

www.medicare.gov/Dialysis/Include/DataSection/Questions/SearchCriteria.asp?version=default&browser=IE%7C7%7CWinXP&language=English&defaultstatus=0&pagelist=Home.

As required by MIPPA, CMS will reduce the payment rates for facilities that do not meet or exceed proposed total performance scores. CMS is proposing to create a sliding scale of reductions, depending on the facility's total performance score, with a maximum reduction of 2.0 percent.

PROPOSED PERFORMANCE STANDARDS AND SCORING:

Proposed Performance Period: CMS proposes a performance period for the entire calendar year (CY) 2010. Although QIP payment reductions do not occur until Jan. 1, 2012, the

performance period would need to occur before 2012 to allow enough time for claims processing and to evaluate facilities' performance. The CY 2010 claims would be the most recent full set of accurate data upon which to assess provider/facility performance.

Performance Standard And Base Utilization Year: As required by MIPPA for the first year of the QIP, CMS proposes to use as the performance standards, the lesser of (a) the national performance rates for each measure or (b) the facility's actual performance rate in 2007, which is the base utilization year established in the ESRD PPS, for each measure. The national performance rate for the first year of the QIP will be based on 2008 data (the most recent data available).

Weights Of Performance Standards: The statute allows CMS to assign different weights to the measures to reflect priorities for quality improvement, giving providers strong incentives to meet or exceed a certain performance standards. As such, CMS is proposing to give a weight of 50 percent of the total performance score to the hemoglobin less than 10 g/dL measure, and to give weights of 25 percent to each of the other two measures (Dialysis Adequacy [URR] at least 65% and hemoglobin greater than 12 g/dL).

Total Performance Scoring Methodology: CMS is proposing to set a maximum score of 10 points for each measure, with a total performance score of 30 points possible. For every 1.0 percentage point an individual facility's performance falls below the scale of standards to be established, CMS is proposing to subtract 2 points from the maximum points for each measure. CMS is then proposing to calculate a total weighted performance score by applying the weights of each measure to each individual performance score. The resulting scores for the individual measures would then be used to determine a facility's Total Performance Score.

Payment Reduction Scale: CMS is proposing the following scale for reducing the facility's payment rate based on the Total Performance Score as follows:

SCORE	REDUCTION
26-30 points	0.0 percent
21-25 points	0.5 percent
16-20 points	1.0 percent
11-15 points	1.5 percent
0-10 points	2.0 percent

Program Monitoring and Evaluation: CMS plans to have a comprehensive monitoring plan in place when the ESRD PPS begins on Jan. 1, 2011. The monitoring program will ensure continued access to and quality of care for beneficiaries with ESRD. CMS will utilize its existing infrastructure for quality oversight in the ESRD facilities as the new system is implemented.

CMS will accept public comments on the proposed rule through Sept. 24, 2010. CMS will review all comments and respond to them in a final QIP rule scheduled to be released by the end of 2010.

To view the ESRD QIP proposed rule, please see: http://www.ofr.gov/OFRUpload/OFRData/2010-18466_PI.pdf or www.ofr.gov/inspection.aspx

For more information about CMS' ESRD programs, please visit www.cms.gov/center/esrd.asp

###