DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 352-G
200 Independence Avenue, SW
Washington, DC 20201

FACT SHEET

FOR IMMEDIATE RELEASE
July 2, 2014

Contact: CMS Media Relations
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CMS PROPOSALS TO UPDATE POLICIES AND PAYMENT RATES FOR END-STAGE RENAL DISEASE PROVIDERS FOR CY 2015 AND PROPOSALS FOR IMPLEMENTATION OF COMPETITIVE BIDDING-BASED PRICES FOR DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES

OVERVIEW: On July 2, 2014, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would update payment policies and rates under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for renal dialysis services furnished to beneficiaries on or after January 1, 2015. This proposal would introduce new quality and performance measures to improve the quality of care by outpatient dialysis facilities treating patients with end-stage renal disease and proposes to implement the Affordable Care Act mandate to bring more competitive bidding for durable medical equipment.

The rule also proposes changes to the ESRD Quality Incentive Program (QIP), including for payment year (PY) 2017 and PY 2018, under which payment incentives are applied to dialysis facilities to improve the quality of dialysis care. Under the ESRD QIP, facilities that do not achieve a minimum total performance score with respect to quality measures established in regulation receive a reduction in their payment rates under the ESRD PPS. This rule also addresses issues related to the coverage and payment of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

This Fact Sheet addresses the general payment provisions of the ESRD PPS for CY 2015 and the issues related to DMEPOS in the proposed rule. A separate fact sheet addressing the quality provisions of the ESRD PPS for CY 2015 can be found here: http://www.cms.gov/Newsroom/Newsroom-Center.html

ESRD PPS BACKGROUND: Section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended the Social Security Act to require CMS to implement a fully bundled PPS for renal dialysis services furnished to Medicare beneficiaries for the treatment of ESRD effective January 1, 2011. The bundled payment under the ESRD PPS includes all renal dialysis services furnished for outpatient maintenance dialysis, including ESRD-related drugs and biologicals (with the exception of oral-only ESRD drugs until 2024 as required by section 217(a)(1) of the Protecting Access to Medicare Act of 2014 (PAMA)) and other ESRD-related items and services that were formerly separately payable

under the previous payment methodologies. The bundled payment rate is case-mix adjusted for a number of factors relating to patient characteristics, and there are additional adjustments for ESRD facilities that have a low patient volume and for facilities that offer home dialysis training. For high-cost patients, an ESRD facility may be eligible for outlier payments. Under the ESRD PPS, Medicare pays approximately $8.5 billion a year to 5,996 ESRD facilities for the costs associated with furnishing chronic maintenance dialysis services.

PROPOSED PAYMENT CHANGES TO THE ESRD PPS FOR CY 2015:

Updated Payment Rates for the ESRD PPS: CMS projects that the ESRD bundled market basket adjusted for multifactor productivity (MFP) update would have been 1.6 percent. However, section 217(b) of the PAMA requires the CY 2015 ESRD payment update to be 0.0 percent. In addition, CMS would apply a proposed wage index budget-neutrality adjustment factor of 1.001306, resulting in a CY 2015 ESRD PPS base rate of $239.33.

Updated ESRD Bundled Market Basket Adjusted for MFP:

CMS proposes to rebase and revise the ESRD bundled market basket. Rebasing involves using the most recent year of available data, CY 2012, to reflect the input costs faced by ESRD providers under the bundled system compared to 2008 data used for the current market basket. The proposed major revisions to the market basket include changing the price measure for pharmaceuticals from a more general index (PPI pharmaceuticals for human use, prescription) to a more specific index (PPI vitamins, nutrients, and hematinic preparations) that reflects drugs similar to those used in the treatment of ESRD, and updating the price measure used for compensation costs to better reflect the occupational mix in the ESRD setting. As a result of the update to the cost weights from 2008 to 2012, the proposed labor-related share is higher, driven mainly by a drop in the drug cost share due to declines in drug utilization and a subsequent rise in compensation cost share.

Outlier Policy: Under the ESRD PPS, ESRD facilities may qualify for outlier payments for high cost patients. For CY 2015, CMS proposes to use CY 2013 claims data to update the outlier services' fixed-dollar loss and Medicare Allowable Payment (MAP) amounts. As a result, CMS is proposing to update the fixed-dollar loss amount for pediatric patients from $54.01 to $56.30, and the MAP amount will increase from $37.29 to $40.05. For adult patients, CMS is proposing to update the fixed-dollar loss amount from $98.67 to $85.24 and increase the MAP amount from $51.97 to $52.61. CMS believes this update to the outlier MAP and fixed dollar loss amounts for CY 2015 will increase payments to ESRD facilities for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier policy.

Wage Index: In CY 2015, CMS is not proposing any changes to the application of the wage index and will continue to apply the adjustment to the labor-related share portion of the base rate when making payments under the ESRD PPS. However, CMS is proposing to update the Core Based Statistical Areas (CBSA) with the Office of Management and Budget (OMB) issued Bulletin No. 13-01 and 2010 US Census Data. We are proposing to implement the new CBSA delineations with a transition in which payments

will be based on 50% of the CY 2014 CBSA delineations and 50% of the proposed CY 2015 CBSA delineations in CY 2015 and 100% of the proposed CY 2015 CBSA delineations in CY 2016.

Labor-Related Share: In CY 2015, based on updated data, CMS is proposing to update the labor-related share value from 41.737 to 50.673 percent. This significant change to the labor-related share would have a negative impact on payments for ESRD facilities located in rural areas and the island of Puerto Rico. As a result of the negative payment impacts to some ESRD facilities, CMS is proposing the increase to the labor-related share value to be implemented with a 2-year transition in which payments will be based on 50% of the old labor-related share and 50% of the new labor-related share in CY 2015 and 100% on the new labor-related share in CY 2016. Thus, the labor-related share value proposed for CY 2015 is 46.205 percent, and for CY 2016 is 50.673 percent. We are proposing that the labor-related share will remain 50.673 percent until such time in the future as the labor-related share value is again updated.

Impact Analysis: CMS projects that the proposed updates for CY 2015 would increase the total payments to all ESRD facilities by 0.3 percent compared with CY 2014. For hospital-based ESRD facilities, CMS projects an increase in total payments of 0.5 percent, while for freestanding facilities; the projected increase in total payments would be 0.3 percent. CMS also projects that urban ESRD facilities will receive an estimated increase in payments of 0.4 percent while rural facilities will receive a decrease of 0.5 percent. CMS projects that ESRD facilities in Puerto Rico and the Virgin Islands will receive a 3.6 percent decrease in estimated payments.

Timing of the Application of ICD-10: On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93) was enacted, which said that the Secretary may not adopt ICD-10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services expects to release an interim final rule in the near future that will include a new compliance date that would require the use of ICD-10 beginning October 1, 2015. The rule will also require HIPAA covered entities to continue to use ICD-9-CM through September 30, 2015. For CY 2015, we are also proposing corrections for several typographical errors and omissions in the tables that appeared in the CY 2014 ESRD PPS final rule.

Low Volume Payment Adjustment (LVPA): In this rule, CMS is clarifying the eligibility criteria for the LVPA and proposing to amend the supporting regulations in the Code of Federal Regulations.

Payment for Oral-only Drugs under the ESRD PPS: Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA, which now provides that the Secretary "may not implement the policy under section 413.1744(f)(6) of title 42, Code of Federal Regulations (relating to oral-only ESRD drugs in the ESRD prospective payment system), prior to January 1, 2024." Accordingly, CMS proposes that the payment for ESRD-related oral-only drugs will not be made under the ESRD PPS prior to January 1, 2024.

PROPOSED CHANGES REGARDING DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) FOR CY 2015:

Propose the methodology for making national price adjustments based upon information gathered from the DMEPOS Competitive Bidding Program: This rule proposes methodologies to implement the

use of information from the DMEPOS CBP to adjust the fee schedule amounts for DME in areas where competitive bidding programs (CBPs) are not implemented. The major provisions in this proposal are:

- Adjust fee schedule amounts for states in different regions of the country based on competitive bidding pricing from competitions in these regions. The regional prices would be limited by a national ceiling (110% of the average of regional prices) and floor (90% of the average of regional prices)
- Use national ceiling as adjusted fee for states that are predominantly rural or sparsely populated (frontier states).
- Adjust fee schedule amounts for non-contiguous areas based on the average of competitive bidding pricing from these areas or the national ceiling, whichever is higher.

Propose phase in of special payment rules in a limited number of areas under the CBP for certain DME and enteral nutrition: This rule proposes a limited phase in of bundled monthly payment amounts for the equipment, supplies, accessories and any necessary maintenance and repairs for enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, hospital beds, continuous positive airway pressure devices and respiratory assist devices furnished under the CBP in place of capped rental policies. Extending the use of these payment rules to additional competitive bidding areas and/or items would be addressed through future notice and comment rulemaking.

Clarification of the statutory Medicare hearing aid coverage exclusion stipulated at Section 1862(a)(7): This rule proposes to codify the specific exceptions when a device could be considered a prosthetic device and not subject to the hearing aid exclusion.

Update the definition of minimal self-adjustment of orthotics at 42 CFR §414.402: This rule proposes to update the regulation to reflect program guidance on what specialized training is needed to provide custom fitting services if providers are not certified orthotists.

Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business: Current rules prohibit the sale of a competitive bidding contract. However, CMS may permit the transfer of a contract to an entity that merges with or acquires a competitive bidding contract supplier if the new owner assumes all rights, obligations, and liabilities of the competitive bidding contract. This proposed rule would establish an exception to the prohibition against subdividing a contract that would allow a contract supplier to sell a distinct company (e.g., an affiliate or subsidiary) which furnishes a specific product category (PC) or a specific competitive bidding area (CBA). Under this exception, CMS would sever the CBAs and PCs that the company serves, along with that company's location(s), from the original contract; incorporate those CBAs, PCs, and locations into a new contract; and transfer the contract to a new owner under specific circumstances. This change to the regulation would apply to all current and future rounds.

CMS will accept comments on the proposed rule until September 2, 2014. The proposed rule will

appear in the July 11, 2014 Federal Register and can be downloaded from the Federal Register at: http://www.ofr.gov/inspection.aspx?AspxAutoDetectCookieSupport=1.

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CMS PROPOSALS TO UPDATE QUALITY MEASURES FOR END-STAGE RENAL DISEASE PROSPECTIVE PAYMENT SYSTEM FOR CY 2015

OVERVIEW: On July 2, 2014, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would update payment policies and rates under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for renal dialysis services furnished to beneficiaries on or after January 1, 2015. This proposal would introduce new quality and performance measures to improve the quality of care by outpatient dialysis facilities treating patients with end-stage renal disease and proposes to implement the Affordable Care Act provision to bring more competitive bidding for durable medical equipment.

The rule also proposes changes to the ESRD Quality Incentive Program (QIP), including for payment year (PY) 2017 and PY 2018, under which payment incentives are applied to dialysis facilities to improve the quality of dialysis care. Under the ESRD QIP, facilities that do not achieve a minimum total performance score with respect to quality measures established in regulation receive a reduction in their payment rates under the ESRD PPS. This rule also addresses issues related to the coverage and payment of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

This Fact Sheet addresses the general quality provisions of the ESRD PPS for CY 2015. A separate fact sheet addressing the payment provisions of the ESRD PPS for CY 2015 can be found here: http://www.cms.gov/Newsroom/Newsroom-Center.html.

ESRD QIP BACKGROUND: Section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended the Social Security Act to require CMS to create an ESRD QIP that selects measures, establishes performance standards, specifies a performance period for each PY, assesses the total performance of each facility, applies an appropriate payment reduction to each facility that does not meet a minimum total performance score, and publicly reports the results. The ESRD QIP is intended to promote high-quality care by dialysis facilities treating patients with ESRD. The first of its kind in Medicare, this program changes the way CMS pays for the treatment of ESRD patients by linking a portion of payment directly to facilities' performance on quality measures. The ESRD QIP will reduce

payments by up to 2 percent to ESRD facilities that do not meet or exceed a certain total performance score.

PROPOSED QUALITY CHANGES TO THE ESRD PPS:

PROPOSED CHANGES TO THE PY 2017 ESRD QIP: CMS is proposing that the PY 2017 ESRD QIP measure set will contain eight clinical measures and three reporting measures for PY 2017 encompassing anemia management, dialysis adequacy, vascular access type, patient experience of care, infections, hospital readmissions, and mineral metabolism management.

Clinical Measures: Five of the proposed PY 2017 clinical measures would be captured in two clinical measure "topics" or categories (Kt/V Dialysis Adequacy and Vascular Access Type). The proposed Standardized Readmission Ratio (SRR) measure is new, and CMS is proposing to revise the National Healthcare Safety Network (NHSN) Bloodstream Infection in Hemodialysis Outpatients measure to calculate facility performance using the Adjusted Ranking Metric. CMS is not proposing to make any changes to the Hypercalcemia measure or to the measures in the Kt/V Dialysis Adequacy measure topic or Vascular Access Type measure topic. The rule also proposes to remove the Hemoglobin Greater than 12 clinical measure because the measure is "topped out".

Reporting Measures: The three proposed reporting measures include the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS), Anemia Management, and Mineral Metabolism. CMS is not proposing to make any changes to the specifications for the Anemia Management and Mineral Metabolism reporting measures, and it is not proposing any changes to the way the three reporting measures are scored. However, CMS is proposing that facilities will no longer have the option to attest that they only had one qualifying case to avoid being scored on the reporting measures.

PROPOSED CHANGES TO THE PY 2018 ESRD QIP: CMS is proposing that the PY 2018 ESRD QIP measure set will contain eleven clinical measures and five reporting measures encompassing anemia management, dialysis adequacy, vascular access type, patient experience of care, infections, mineral metabolism management, safety, pain management, depression management, and hospital readmissions. This represents an evolution of the program that encompasses quality-of-care issues.

Clinical Measures: In an effort to align the ESRD QIP with other Value-Based Purchasing (VBP) and quality reporting initiatives, CMS is proposing to organize the clinical measures into a Clinical Measure-Domain with component subdomains tracking to the CMS Quality Strategy.

- The proposed Safety subdomain, accounting for 20% of the Clinical Measure Domain score, would include the NHSN Bloodstream Infection in Hemodialysis Outpatients measure.
- The proposed Patient and Family Engagement/Care Coordination subdomain, accounting for 30% of the Clinical Measure Domain score, would include the ICH CAHPS measure and the SRR measure.
- The proposed Clinical Care subdomain, accounting for 50% of the Clinical Measure Domain score, would include the Standard Transfusion Ratio (STrR) measure, the Kt/V Dialysis Adequacy measure topic, the Vascular Access Type measure topic, and the Hypercalcemia measure.

New clinical measures proposed for PY 2018 include ICH CAHPS (converted from a previous reporting measure), STrR, and Pediatric Peritoneal Dialysis (part of the Kt/V Dialysis Adequacy measure topic).

Reporting Measures: The rule proposes to adopt five reporting measures. CMS is proposing to continue using the Anemia Management reporting measure, but is proposing to revise the Mineral Metabolism measure revised to allow facilities to submit serum and plasma phosphorus data. CMS is also proposing to adopt three new reporting measures, which are Pain Assessment and Follow-Up, Clinical Depression Screening and Follow-Up, and NHSN Healthcare Personnel Influenza Vaccination.

Measure Scoring:

Under the proposed rule, reporting measure scores would be totaled for the facility's Reporting Measure Domain score. CMS would then calculate the facility's Reporting Measure Adjuster by subtracting the facility's Reporting Measure Domain score (i.e., the sum of all reporting measure points received) from its total eligible reporting measure points (e.g., 50, if the facility is eligible for all five reporting measures), and then multiplying that total by a coefficient of 5/6.

CMS proposes to calculate a facility's total performance score by subtracting the facility's Reporting Measure Adjuster from its Clinical Measure Domain score.

ADDITIONAL ESRD QIP PROPOSALS: The proposed rule discusses proposals relating to when a measure should be removed or replaced due to being "topped out," continuing CMS's data validation pilot program, beginning an NHSN data validation study, and exceptions to ESRD QIP compliance as a result of "extraordinary circumstances."

CMS will accept comments on the proposed rule until September 2, 2014. The proposed rule will appear in the July 11, 2014 Federal Register and can be downloaded from the Federal Register at: http://www.ofr.gov/inspection.aspx?AspxAutoDetectCookieSupport=1.

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