

American Nephrology Nurses' Association Comments on CMS' 2015 ESRD Prospective Payment System and Quality Incentive Program

CY 2015 ESRD PPS System Proposed Rule	ANNA Comments	CY 2015 ESRD PPS System Final Rule
<p>ESRD PPS base rate for CY 2015:</p> <ul style="list-style-type: none"> • \$239.33. • When the wage index budget neutrality adjustment factor is applied, the rate is \$239.02. 	<p>ANNA agrees with interpretation of provisions of Protecting Access to Medicare Act of 2014 (PAMA).</p> <p>ANNA has concerns with the impact of payment decisions on patient care and availability of services: Believes payment rates currently proposed for small and rural facilities do not provide resources necessary to ensure quality care in underserved areas.</p>	<p>Sets the rate for CY 2015 at \$239.43, reflecting a 0 percent update as required by PAMA.</p> <p>When the wage index budget neutrality adjustment factor is applied, the rate is \$239.02.</p>

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<p>Routine updates and proposed policy changes to CY 2015 ESRD PPS:</p> <ul style="list-style-type: none"> • Changes to the ESRD Bundled Market Basket and Labor-Related Share • Proposed Corrections to the Outlier Policy 	<p>Notes that when dialysis facilities face potential payment reductions, they often respond by reducing their staffing ratio. This presents a risk to patient safety.</p> <p>Urges CMS to ensure the most accurate and consistent data are used in rebasing the ESRD market basket rate.</p> <p>Supports KCP’s comments regarding exceptions to revisions to cost centers and weights.</p> <p>Urges CMS to use consistent information from all providers to ensure accuracy of data.</p> <p>Recommends CMS make an effort to provide education to providers to help them better understand proposed changes.</p> <p>ANNA shares KCP’s concerns with respect to underlying problem with outlier pool and that the pool has yet to be paid out in its entirety.</p>	<p>For CY 2015, CMS is rebasing and revising the ESRDB market basket; which entails an update to the base year of the ESRDB market basket from 2008 to 2012. The CY 2015 market basket less MFP adjustment would have been 1.6 percent, but PAMA requires the market basket less MFP adjustment be 0.0 for CY 2015.</p> <p>CMS updates the outlier services fixed-dollar loss and Medicare Allowable Payments (MAPs) amounts for adult and pediatric patients for CY 2015 using 2013 claims data. Based on this, the fixed-dollar loss amount for pediatric beneficiaries will increase from \$54.01 to \$54.35 and the MAP amount will increase from \$40.49 to \$43.57. For adults, the fixed-dollar loss amount will decrease from \$98.67 to \$86.19 and the MAP amount will increase from \$50.25 to \$51.29.</p>

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<p>Clarification of policy regarding payments for more than three dialysis treatments per week.</p>	<p>Agrees with CMS that the payment policy should be flexible to adjust to the individual needs of patients.</p>	<p>CMS reiterates it is not changing its policy for reporting extra dialysis sessions. ESRD facility claims should continue to include all dialysis treatments furnished during the month on claims, but payment is limited to three dialysis treatments per week.</p>
<p>Barriers to home dialysis:</p> <ul style="list-style-type: none"> • “Modality choice does not constitute medical justification.” 	<p>Feels the statement that “modality choice does not constitute medical justification” ignores the importance of patient outcomes.</p> <p>ANNA supports efforts to provide access to their preferred treatment modality and encourages CMS to find ways to reduce barriers patients face in selecting home dialysis.</p>	<p>CMS agrees with ANNA comments about removing barriers to home modalities-CMS believes its ESRD PPS payment policies have contributed to the increase in utilization of home dialysis modalities.</p> <p>CMS notes that modality choice does not constitute medical justification.</p> <p>CMS’ intent in clarifying its policy is to remind facilities and MACs of the Medicare ESRD benefit,</p>

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		<p>which only allows for the payment of three weekly dialysis treatments, and that additional weekly dialysis treatments may be paid for if there is documented medical justification.</p> <p>CMS believes its ESRD PPS payment policies have contributed to the increase in utilization of home dialysis modalities.</p> <p>ESRD facility claims should continue to include all dialysis treatments furnished during the month on claims, but payment is limited to three dialysis treatments per week.</p>

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Payment of Drugs.	<p>Supports comments provided by KCP and urges CMS to consider seven principle drug designation process suggested by KCP:</p> <ul style="list-style-type: none"> a. Establish clear definition of drugs; b. Establish criteria related to frequency with which a drug or biological may be used within ESRD population; c. Establish criteria for determining when drugs are equivalent with existing products; d. Utilize rulemaking process when considering changes to bundle; e. Establish clear process for transitioning new drugs into ESRD bundle; f. Track costs of new drugs before adding to the bundle; g. Increase bundled payment rate to cover costs of providing such products. 	<p>CMS states that oral-only drugs used for the treatment of ESRD are an essential part of the ESRD PPS payment bundle and should be paid for under the ESRD PPS bundle as soon as possible.</p> <p>CMS indicates it will a propose designation processes to determine when a product is no longer an oral-only drug and for including new injectable and intravenous products into the bundled payment system.</p>

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Payment of Drugs.	Supports comments provided by KCP and urges CMS to consider seven principle drug designation process suggested by KCP.	CMS will take the seven principles into consideration when they propose a designation process in the CY 2016 proposed rule.
CMS will delay the adoption of measures specific to conditions treated with oral-only drugs until 2024.	Supports interpretation of requirement in PAMA for Secretary to delay adoption of measures specific to conditions treated with oral-only drugs until 2024.	<p>CMS modifies the effective date for providing payment for renal dialysis oral-only drugs and biological under ESRD PPS from January 1, 2016 to January 1, 2024.</p> <p>CMS states that PAMA will require it to use the most recently available data when implementing the oral-only drug policy in the future.</p> <p>CMS determines it is not feasible to adopt an outcome-based measure on this topic because it was not aware of any outcome measures developed on the topic.</p> <p>CMS will take comments into</p>

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		account and will evaluate what measures might satisfy PAMA.
Low-volume payment adjustor.	<p>Supports efforts of CMS to allow MACs to consider other data to verify a facility meets low-volume criteria.</p> <p>Encourages CMS to consider travel time and distance in consideration of aggregate number of treatments furnished by ESRD facilities within 25 miles of each other under common ownership.</p>	<p>CMS will finalize the provisions as proposed.</p> <p>Clarifies that MACs can consider supporting data from hospital-based ESRD facilities to verify the facility's total treatment count.</p> <p>MACs can add or pro-rate treatment counts from non-standard cost reporting periods where there is a change in ownership that does not result in a new Provider Transaction Access Number.</p> <p>CMS will consider commenters' suggestions in computing a low-volume payment adjustment in the future, and will consider these comments for purposes of refinement in CY 2016.</p>

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ESRD QIP.	<p>ANNA supports QIP and joins with KCQA to move towards consensus-based quality measures validated by NQF endorsement process.</p> <p>ANNA has concerns that CMS lacks overall strategic vision for future use of quality metrics to improve care for ESRD beneficiaries and encourages CMS to consider work and recommendations from KCQA when adding or altering quality metrics.</p>	<p>CMS believes the development of an ESRD QIP that is successful in supporting the delivery of high-quality healthcare services in dialysis facilities is paramount.</p> <p>Seeks to adopt measures for ESRD QIP that promote better, safer, and more coordinated care.</p> <p>Will post measure specifications on a CMS website.</p>

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<p>Seeks to adopt measures that promote safer, better, more coordinated care.</p>	<p>Expresses concern that CMS' focus on coordinated care does not provide more details about how QIP, Dialysis Facility Compare, 5-Star Quality Rating System, and state surveyor expectations under Core ESRD will work together to improve patient care.</p> <p>ANNA encourages CMS to ensure all proposed quality measures can be linked to national priorities and based upon valid and reliable evidence.</p>	<p>Final rule fails to provide more details about how QIP, Dialysis Facility Compare, 5-Star Quality Rating System, and state surveyor expectations will work together to improve patient care.</p> <p>*5-Star Quality Rating System will be implemented in January 2015.</p>
<p>Use of NHSN Bloodstream Infection as a clinical measure in PY 2016.</p>	<p>Does not support use of NHSN Bloodstream Infection as a clinical measure in Payment Year 2016.</p> <p>Believes targets must be identified prior to migration of a reporting measure to a clinical measure.</p>	<p>CMS states the adoption of the NHSN Bloodstream Infection as a clinical measure in PY 2016 is justified because they wish to begin assessing facilities on the number of the events as soon as possible, rather than merely assessing whether facilities report these events.</p>

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<p>Use of NHSN Bloodstream Infection as a clinical measure in PY 2016:</p> <ul style="list-style-type: none"> Adjusted Ranking Metric (ARM) to calculate facility performance on the NHSN Bloodstream Infection clinical measure. 	<p>Expresses concern with Adjusted Ranking Metric (ARM).</p>	<p>CMS does not finalize the proposal to adopt the ARM reliability adjustment for purposes of calculating facility performance on the NHSN clinical measure. Instead, facility performance on this measure will be calculated as finalized in the CY 2014 ESRD PPS final rule, using the Standardized Infection Ratio.</p>

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<p>Revision to ICH CAHPS Reporting Measure: Change the requirement of 30 eligible patients to 30 submitted surveys.</p> <ul style="list-style-type: none"> Twice per year survey. 	<p>ANNA has concerns that dialysis facilities may not be able to quickly determine the number of survey-eligible patients they have treated during eligibility period. Encourages CMS to provide more detail on what is needed for facilities to meet requirements of measure.</p> <p>ANNA has concerns that requiring the survey twice per year does not allow facilities enough time to make changes which might be needed based survey responses.</p> <p>Requests CMS reduce the fielding requirement to once annually so facilities have time to implement strategies.</p>	<p>Finalizes the scoring methodology for the ICH CAHPS measure as proposed for PY 2018 program and future years.</p> <p>CMS states that facilities with high non-response rates will not be penalized on the basis of their survey response rate; instead, scores on ICH CAHPS reporting measure are based on whether the facility administers the survey on a twice-yearly basis using a third party.</p> <p>Does not believe it is appropriate to include deceased or mentally/physically incapable of completing the survey in the ICH CAHPS survey at this time.</p> <p>CMS finalizes the expanded ICH CAHPS reporting measure as proposed for the PY 2017 ESRD QIP and for future payment years.</p>

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<p>(Continued) Revision to ICH CAHPS Reporting Measure: Change the requirement of 30 eligible patients to 30 submitted surveys.</p> <ul style="list-style-type: none"> Twice per year survey. 		<p>A facility will receive a score of zero under ICH CAHPS measure if it does not meet the survey administration and reporting requirements finalized in the CY 2014 ESRD PPS Final Rule.</p>

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<p>PY 2016 Measure Being Eliminated in PY 2017 and beyond:</p> <ul style="list-style-type: none"> Retirement of Hgb > 12 g/dL. 	<p>Requests CMS to ensure the reporting measure for number of months for which facilities report ESA dosage and Hgb/HCT for each Medicare patient meets statutory requirements for a measure of anemia management and an additional measure is not required.</p>	<p>Finalizes the removal of Hemoglobin Greater than 12 g/dL measure from the ESRD QIP, beginning with the PY 2017 program.</p> <p>Also finalizes as proposed the statistical criteria for determining when a measure is topped out in the ESRD QIP.</p> <p>CMS will continue to use 10 of the 11 measures finalized in CY 2014 ESRD PPS Final Rule for the PY 2016 ESRD QIP.</p> <p>CMS does not finalize its proposal to retain a clinical measure that is statistically topped out if it determines that to continue including it will continue to set a high standard of care for dialysis facilities.</p>

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<p>New SRR clinical measure for PY 2017.</p>	<p>Does not support this measure and has concerns because it has not been endorsed by NQF.</p> <p>a. Measure includes readmissions that are not related to ESRD.</p> <p>b. Unclear how SRR measure will be calculated.</p>	<p>Finalizes the SRR clinical measure as proposed.</p> <p>CMS adopts the SRR clinical measure for PY 2017, which assesses care coordination.</p> <p>CMS states the hospital readmissions are not beyond the control of dialysis facilities.</p> <p>SRR measure assesses the risk of readmission within 30 days of discharge from an acute care hospital.</p> <p>A readmission ratio of greater than 1.0 reflects that a facility's patients are at higher risk for readmissions; a score below 1.0 reflects that a facility's patients are at lower risk for readmissions.</p>

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Continuation of validation pilot study.	<p>Does not support this.</p> <p>Believes a reduction of 10 points from TPS for not sending medical records within the 60 day time period is too harsh.</p> <p>Opposes deduction of 10 TPS points for NHSN validation study.</p>	<p>CMS notes that CDC’s NHSN provides detailed trainings, protocols, and guidance for users to follow to ensure that data are reported in a standardized manner.</p> <p>CMS disagrees the 60 day time frame is too short for facilities to respond to requests. CMS continues to believe that assessing penalties on a facility’s TPS is the surest way to ensure that facilities provide the medical records needed to complete the studies.</p> <p>CMS finalizes, as proposed, the CROWNWeb pilot data validation program and the feasibility study for validating data reported to CDC’s NHSN Dialysis Event Module for the NHSN Bloodstream Infection clinical measure.</p>

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<p>Monitoring Access to Dialysis: Monitoring Admission and Discharge:</p> <ul style="list-style-type: none"> Proposes to initiate a monitoring program focused on access to dialysis therapy. 	<p>Urges CMS to provide more information about how a monitoring proposal will be accomplished.</p>	<p>CMS is still in the process of finalizing the methodology for the proposed access study.</p> <p>CMS will conduct a study to determine the impact of adopting the SRR and STTrR measures on access to care. Further details about the study and its methodology will be made available on a CMS website.</p>
<p>Extraordinary circumstances exception:</p> <ul style="list-style-type: none"> Exempt a facility from all requirements of ESRD QIP clinical and reporting measures during the time the facility was forced to close temporarily due to a natural disaster or other extraordinary circumstances. 	<p>Supports this exception.</p> <p>ANNA urges CMS to recognize that data submission would be problematic during and immediately following a disaster.</p> <p>Supports proposal to allow 90 days to submit a disaster extension/exception request form.</p>	<p>Finalizes the proposal to adopt an Extraordinary Circumstance Exception in the ESRD QIP, beginning with PY 2017.</p> <p>CMS exempts dialysis facilities from all requirements of ESRD QIP clinical and reporting measures during the months in which they are forced to close due to a natural disaster or other extraordinary circumstance.</p>

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<p>PY 2018 QIP:</p> <ul style="list-style-type: none"> • Addition of five new measures in one year. • STrR. 	<p>Urges CMS to consider phasing in additional measures over several years. Addition of five new measures in one year seems overly ambitious.</p>	<p>For PY 2018, CMS adopts two new clinical measures-the STrR and Pediatric Peritoneal Dialysis Adequacy, and three new reporting measures: Pain assessment and follow-up, clinical depression screening and follow-up, and NHSN Healthcare Personnel Influenza Vaccination.</p> <p>Also converts the ICH CAHPS survey reporting measure to a clinical measure.</p>

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STrR as clinical measure.	<p>Does not support this measure, as it does not adjust for multiple variables and have several concerns:</p> <p>a. Facilities will be held responsible for a measure for which they do not have data access;</p> <p>b. Will reason for transfusion be considered? (Often not clear reason);</p> <p>c. Hospitals frequently do not continue ESA doses during hospitalization, which leads to need for transfusion;</p> <p>Overall concern that STrR may unfairly punish a facility for an outcome that is impacted by multiple variables.</p>	<p>Finalizes the measure as proposed.</p> <p>CMS finalizes STrR for PY 2018 and future years. The measure is a ratio of the number of observed eligible blood transfusions occurring in patients receiving dialysis at a facility to the number of eligible transfusions that would be expected.</p> <p>Calculates the ratio of the number of observed transfusions to the number of expected transfusions. The ratio is greater than one for facilities that have more transfusions than would be expected for an average facility with similar cases, and less than one if the facility has fewer transfusions than would be expected for an average facility with similar cases.</p>

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Pediatric peritoneal dialysis adequacy clinical measure.	Supports use of measure and appreciates exclusion criteria of a patient treated in a facility few than two times per claim month.	Finalizes the measure as proposed and adds the measure to the Dialysis Adequacy Measure Topic.
<p>ICH CAHPS clinical measure:</p> <ul style="list-style-type: none"> Two surveys per year requirement. 	<p>Does not support the two surveys per year without evidence to support a positive impact to patient outcomes.</p> <p>Requests maintaining annual surveys.</p>	<p>Finalizes the rule as proposed.</p> <p>Revises the ICH CAHPS reporting measure to determine facility eligibility for the measure based on the number of survey-eligible patients treated during the eligibility period, which is defined as the Calendar Year (CY) that immediately precedes the performance period.</p> <p>Beginning with PY 2017, facilities will be eligible to receive a score on the ICH CAHPS measure if they treat 30 or more survey eligible patients during the eligibility period.</p> <p>CMS notes that semi-annual surveys improve the reliability of results.</p>

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<p>Screening for Clinical Depression and Follow-Up Reporting Measure.</p>	<p>Does not support screening for depression as a reporting measure.</p> <p>Concerns:</p> <ul style="list-style-type: none"> a. Lack of clarity regarding expected screening tool to be used; b. Complicated “choices” of responses c. Staff education will be necessary to ensure appropriate patient assessment and data entry. <p>Consider whether depression management is ESRD based or part of an integrated care model.</p> <p>Additional resources are essential to administer tool.</p> <p>ANNA has concerns the required follow-up would likely be completed by someone outside evaluated facility.</p>	<p>CMS finalizes the measure as proposed.</p> <p>CMS believes that screening patients for clinical depression is not outside the scope of practice for dialysis facilities.</p> <p>The measure does not require facilities to select any particular screening tool because it believes each facility should select the tool most appropriate for each of their patients.</p>

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<p>Pain Assessment and Follow-Up Reporting Measure:</p> <ul style="list-style-type: none"> Pain assessment using a standardized tool and documentation of a follow-up plan when pain is present. 	<p>Does not support as a reporting measure. Believes that a pain assessment at the time of one treatment would be relevant to that individual's experience of pain at another treatment time.</p> <p>Rule is unclear.</p> <p>Urge CMS to explain expected outcome of collecting this data and information.</p>	<p>Finalizes the measure as proposed.</p> <p>The measure is intended to assess overall pain-acute and chronic. This measure will improve quality of life because it will increase the likelihood that patients who suffer from pain will be identified and referred to an appropriate practitioner.</p>

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<p>NHSN Healthcare Personal Influenza Vaccination Reporting Measure:</p> <ul style="list-style-type: none"> • Use a measure based on an NQF-endorsed measure of the percentage of qualifying HCP who are vaccinated. • For PY 2018, facilities must submit on an annual basis, an HCP Influenza Vaccination Summary Form to CDC's NHSN System. 	<p>Concerns about administrative elements facing outpatient dialysis clinics in collection of data to complete report. Urges CMS to clarify before implementation.</p>	<p>Finalizes the measure as proposed.</p> <p>Under this measure, the performance period for the denominator is from Oct. 1 to March 31. The numerator measurement (vaccination status) includes vaccines obtained as soon as vaccine is available.</p> <p>Facilities are required to report healthcare personnel working in the facility for one day or more from Oct. 1 to March 31 because this more accurately captures healthcare personnel in the facility at risk of acquiring or transmitting influenza.</p> <p>Notes that because NHSN and the Vascular Access Type measure serve different purposes, and because the methods used to calculate the measures have shown to be reliable, CMS does not believe there is sufficient technical rationale to justify aligning these administrative tasks at this time.</p>

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<p>Proposal for Scoring the PY 2018 QIP:</p> <ul style="list-style-type: none"> Scoring Facility Performance on Clinical Measures Based on Achievement. Will continue to use this methodology for all clinical measures except ICH CAHPS clinical measure. Scoring Performance Based on Improvement: Score is calculated by comparing its performance on the measure during CY 2016 to its performance rate in CY 2015. Scoring the ICH CAHPS Clinical Measure: Score the measure on the basis of three composite measures and three global ratings. 	<p>ANNA does not support the two surveys per year requirement.</p> <p>ANNA has concerns about how the ICH CAHPS scores will be calculated.</p>	<p>Finalizes as proposed.</p> <p>In the CY 2014 ESRD PPS Final Rule, CMS finalized a policy for scoring performance on clinical measures based on achievement. In determining a facility's achievement score for each measure under the PY 2018 ESRD QIP, CMS proposed to continue using this methodology. Under this method, facilities receive points along an achievement range based on their performance for each measure, which is defined as a scale between the achievement threshold and the benchmark.</p> <p>Clinical measures will be weighted as finalized for the clinical domain score was 90% of the facility's TPS and reporting measures will be weighted equally to form 10% of the TPS.</p>

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(Continued) Proposal for Scoring the PY 2018 QIP:		Survey responses from the two survey administrations will be compiled together into a single dataset, which will then be used to calculate facility scores on the ICH CAHPS clinical measure (responses to the first and second survey administrations will be combined to produce a facility's ICH CAHPS score).

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<p>Calculating Clinical Measure Domain Score.</p> <ul style="list-style-type: none"> • Clinical measure domain is broken down into safety, patient and family engagement/care coordination, and clinical care. • Safety weight: 20% • Patient and Family Engagement/Care Coordination: 30% • Clinical care: 50% 	<p>Supports KCP comments.</p> <p>Urges CMS to maintain a consistent payment methodology for the QIP; this can best be accomplished by changes to the weights assigned to measures and updating the benchmarks and thresholds.</p>	<p>Finalizes its proposal to establish a clinical measure domain score.</p> <p>To weight the Clinical Measure Domain subdomains using three criteria: the number of measures and measure topics in a proposed subdomain; how much experience facilities have had with the measures and measure topics in a proposed subdomain; and how well the measures align with CMS' highest priorities for quality improvement for patients with ESRD.</p> <p>Facility scores on clinical measures will be divided into subdomains that align with National Quality Strategy (NQS) domains and weighted according to the number of measures in a subdomain, facility experience with the measure, and the measure's alignment with CMS priorities for quality improvement.</p>

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