ANNA
Established in 1969
American Nephrology Nurses' Association

August 24, 2015

Andy Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1628-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program
80 Federal Register 37808 (July 1, 2015)

Dear Acting Administrator Slavitt,

On behalf of the American Nephrology Nurses' Association (ANNA), I am writing to share our comments on the proposed rule for the *Calendar Year (CY) 2016 End-Stage Renal Disease* (*ESRD*) *Prospective Payment System* (*PPS*) *and Quality Incentive Program* (*QIP*). We appreciate the opportunity to provide our comments on this important issue.

ANNA promotes excellence in and appreciation of nephrology nursing so that we can make a positive difference for people with kidney disease. Established as a nonprofit organization in 1969, ANNA has a membership of approximately 10,000 registered nurses in almost 100 local chapters across the United States. We are the only professional association that represents nurses who work in all areas of nephrology, including hemodialysis, chronic kidney disease, peritoneal dialysis, acute care, and transplantation. Most of our members work in freestanding dialysis units, hospital outpatient units, and hospital inpatient dialysis units.

ANNA develops and updates standards of clinical practice, educates practitioners, stimulates and supports research, disseminates knowledge and new ideas, promotes interdisciplinary communication and cooperation, and monitors and addresses issues encompassing the breadth of practice of nephrology nursing.

ANNA is a member of Kidney Care Partners (KCP) and has actively participated in the development of their comment letter. The following comments are in addition to the comments submitted to the Centers for Medicare and Medicaid Services (CMS) by KCP.

ANNA is committed to improving the quality of outcomes for patients and providing greater health care efficiencies through care coordination that is centered on the needs and preferences of patients and their families. ANNA believes the coordination of care between inpatient facilities and outpatient facilities is essential to improving quality of care and outcomes of beneficiaries. Healthcare providers often struggle to satisfy CMS' documentation requirements, and we applaud CMS for recognizing the burden on kidney dialysis facilities associated with meeting documentation requirements. ANNA advises CMS to continue to develop initiatives designed to reduce administrative burdens placed on providers.

I. CY 2016 ESRD PPS

CMS proposes to set the ESRD PPS base rate for CY 2016 at $230.20, which reflects a reduced market basket increase, application of the wage index budget-neutrality adjustment factor, and a refinement budget-neutrality adjustment factor. ANNA joins with the broader kidney community in agreeing with the calculation of the CY 2016 ESRD PPS base rate. However, ANNA continues to have concerns about the impact of these payment decisions on patient care and availability of services. ANNA feels strongly that the payment rate currently proposed does not provide the resources necessary to ensure the provision of quality care.

A. Provisions of the Proposed Rule

ANNA is concerned that payment reductions for dialysis facilities could negatively impact nephrology nurses' ability to adequately care for their patients. As ANNA has stated in previous comment letters to CMS, when dialysis facilities face potential payment reductions, they often respond by reducing their staffing ratios.[1] This presents a risk to patient safety, as there are no federal requirements for facilities to maintain minimum staffing ratios.

Many dialysis providers operate on very narrow profit margins and will likely be unable to absorb a significant reduction in their Medicare reimbursement rates. ANNA is concerned that payment reductions will cause some dialysis providers to close facilities, or choose to limit hours of operation. Closure of a dialysis facility can result in patients having to drive a significant distance to obtain dialysis services. This burden is exacerbated by patients' needs to undergo numerous treatments per week.

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[1] Letter from ANNA to CMS Regarding Proposed Rule on ESRD PPS, QIP, and DMEPOS (CMS-1614-P) (September 2, 2014); *see also* Letter from ANNA to CMS Regarding Proposed Rule: Changes to ESRD Prospective Payment System (CMS-1526-P) (August 30, 2013).

1. Analysis and Proposed Revision of the Payment Adjustments under the ESRD PPS

i. Adult Case-Mix Payment Adjustments
a. Patient age
ANNA is unclear as to the significant increase in value of the age adjustor, as there is not data to justify such a large increase. We also urge CMS to maintain the current (CY 2015) reference group – ages 60-69. In our experience, the patient population ages 70-79 often has greater needs and suffers more complications than younger adults. To ensure the nephrology community can continue to provide high-quality and cost-effective care, we must be furnished with the necessary resources to adequately treat populations with complex needs.

b. Body Surface Area (BSA) and Body Mass Index (BMI)
ANNA supports KCP's comments on the BSA and BMI adjusters. We encourage CMS to work with the kidney community to develop adjusters that accurately reflect the costs of providing dialysis services.

c. Onset of Dialysis
ANNA supports the Agency's proposal to continue to include the onset of dialysis adjuster for the ESRD PPS, but caution CMS against further reductions in this adjuster.

d. Comorbidities
We praise the Agency's acknowledgement of the challenges on dialysis facilities associated with meeting documentation requirements for bacterial pneumonia and monoclonal gammopathy. Given the difficulty in obtaining the results of an x-ray, sputum culture, positive serum test, or a bone marrow biopsy test, we support the Agency's elimination of the case-mix payment adjustments for the comorbidity categories of bacterial pneumonia and monoclonal gammopathy beginning in CY 2016.

However, it is our belief that the often futile efforts to obtain the documentation to meet the requirements associated with the comorbid case-mix adjusters outweigh the benefit of any payment adjustment. As stated by KCP, the four remaining comorbid case-mix adjusters do not serve a policy purpose. ANNA urges CMS to remove the four remaining comorbid case-mix adjusters: Pericarditis; Gastrointestinal (GI) Tract Bleeding with Hemorrhage; Hereditary Hemolytic or Sickle Cell Anemia; and Myelodysplastic Syndrome.

ii. Proposed Refinement of Facility-Level Adjustments

a. Low Volume Payment Adjustment
ANNA applauds CMS for taking steps to address issues raised with the low-volume payment adjustor (LVPA). Providing low-volume providers with an adjusted payment ensures patient access. We encourage CMS to maintain the LVPA, and

consider implementing KCP's proposal to implement a two-tiered low-volume adjuster policy.

b. Geographic Proximity Mileage Criterion
ANNA supports the five mile road criterion, but encourages CMS to consider travel time as well as distance in their consideration of the aggregate number of treatments furnished by ESRD facilities. ANNA also recommends a transition period prior to implementation of the new geographic proximity criterion for the 30 facilities that will lose the LVPA.

c. Geographic Payment Adjustment for ESRD facilities in Rural Areas
Rural providers serve a large geographic area with a low population density and face a unique set of challenges. We support KCP's comments on this issue and believe CMS should implement a two-tiered low-volume adjuster policy, which more accurately captures units with additional costs.

2. Proposed CY 2016 ESRD PPS Update

i. Proposed Market Basket Update Increase Factor and Labor-Related Share for ESRD Facilities for CY 2016
As stated above, ANNA is very concerned by the reduction of the base rate for CY 2016. Healthcare providers must have sufficient resources and predictable and stable reimbursement levels so patients can continue to have access to the quality care they need and deserve. ANNA understands the need for CMS to rebase the ESRD market basket rate on a regular basis and we support several of the key elements of this plan within the proposed rule. ANNA urges CMS to ensure the most accurate and consistent data are used in rebasing this rate.

ii. The Proposed CY 2016 ESRD PPS Wage Indices
ANNA supports the Agency's methodology for determining wage indices.

iii. CY 2016 Update to the Outlier Services MAP Amounts and Fixed-Dollar Loss Amounts
ANNA recognizes it is necessary to update the fixed dollar loss amounts that are added to the Medicare Allowable Payment (MAP) amounts per treatment to determine the outlier thresholds. However, ANNA shares KCP's concerns regarding the underlying problem with the outlier pool, including concerns that the pool has not been paid out as anticipated. Moreover, dialysis facilities continue to report issues with being unable to obtain necessary documentation from healthcare facilities (e.g., hospitals, nursing homes, and rehabilitation facilities) to support outlier status for patients who may, in fact, qualify as such outliers.

3. Section 217(c) of Protecting Access to Medicare Act (PAMA) and the ESRD PPS Drug Designation Process
ANNA supports the implementation of a process that would allow CMS to include new injectable and intravenous pharmaceuticals into the ESRD PPS bundled

payment when an oral-only dialysis service drug or biological is no longer oral only. We recommend CMS take into consideration KCP's proposal to add a new drug or biological to the bundle only after a transition period during which its utilization and costs would be determined.

B. Clarifications Regarding ESRD PPS

1. Laboratory Renal Dialysis Services
ANNA supports the Agency's proposal to remove the lipid panel test from consolidated billing. Patients benefit by having laboratory testing collected during dialysis, preventing extra travel and additional venipunctures. By allowing separate billing for laboratory tests for conditions outside of ESRD, CMS supports coordinated, patient-centered care.

II. ESRD QIP

ANNA is a strong proponent of the QIP and has supported the program's implementation. We reiterate KCP's comments on the proposals to modify the ESRD QIP, and recommend CMS work with the Kidney Care Quality Alliance (KCQA) and the nursing community when developing and implementing quality measures to improve the quality of care provided to ESRD patients. We encourage the adoption of evidence-based ESRD QIP measures that promote the delivery of high-quality care and improved patient outcomes.

A. Proposal to Use Hypercalcemia as a Measure Specific to the Conditions Treated with Oral-Only Drugs

ANNA does not support this proposal and supports KCP's objections to the use of hypercalcemia as a measure of a condition treated with oral-only drugs. ANNA continues to agree with the kidney community in the belief that the hypercalcemia measure does not provide value to the patient or relate to the provision of quality care. The National Quality Forum (NQF) Renal Standing Committee has determined the hypercalcemia measure is topped out and its initial recommendation for the hypercalcemia measure is against current endorsement. We encourage CMS to work with ANNA and the kidney community to develop and seek NQF approval of a measure specific to conditions treated with oral-only drugs.

B. Sub-Regulatory Maintenance in the ESRD QIP

ANNA appreciates the intent to develop an ESRD Measures Manual that will include the ESRD QIP measure specifications, with the expectation that such a manual will add clarity as well as provide answers to questions. For example, CMS has yet to specify how the scores of the two surveys that will comprise the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH

CAHPS) clinical measure will be weighted or used in the determination of a final score on that measure.

Additionally, ANNA encourages CMS to include contact information for Agency staff (by responsibility/position) within the ESRD Measures Manual. Providers frequently have questions regarding interpretation of measures, and it is important to have a point-of-contact within the Agency who is available to answer stakeholders' questions.

C. Proposed Revision to the Requirements for the PY 2017 ESRD QIP

Proposal to reinstate qualifying patient attestations for the ICH CAHPS Clinical Measure
ANNA supports the Agency's proposal to reinstate qualifying patient attestations for the ICH CAHPS clinical measure in PY 2017, as we anticipate it will add clarity to which facilities qualify to participate in this measure.

D. Proposed Requirements for the PY 2018 ESRD QIP

ANNA greatly appreciates having the opportunity to provide comments on the QIP elements for PY 2018 included in this proposed rule. Because nephrology nurses remain the linchpin in the collection and processing of these important data points, it is crucial that our members understand the Agency's overall vision for the QIP, and that the Agency recognize that the burden of data collection may take time away from direct patient care.

Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the Clinical Measures Finalized for the PY 2018 ESRD QIP
ANNA supports the continuation of the 2017 Performance Standards, Achievement Thresholds and Benchmarks. While we agree in principle with the Agency that the ESRD QIP should not have lower performance standards than in previous years, ANNA is unable to provide informed comments on the Agency's proposed change to the threshold until the Agency publishes the performance standards for the current year. It is unfortunate the scoring methodology is so complex that facilities are not afforded the opportunity to make immediate adjustments to care when minimum scores are not met.

Proposed Modification to Scoring Facility Performance on the Pain Assessment and Follow-Up Reporting Measure
As stated in our comments to the proposed rule in CY 2015,[2] ANNA does not support the Pain Assessment and Follow-Up Reporting Measure as currently specified. Pain is a complex issue in the dialysis setting. We oppose this measure, as we do not believe this measure provides value to the patient or relates to quality

[2] Letter from ANNA to CMS Regarding Proposed Rule on ESRD PPS, QIP, and DMEPOS (CMS-1614-P) (September 2, 2014).

care. We support KCP's remarks on this issue. We appreciate CMS' proposal to modify the scoring of a facility and allow a facility to participate in this measure if they have sufficient qualified patients for only one of the six-month periods.

Proposed Payment Reductions for the PY 2018 ESRD QIP
ANNA greatly appreciates the Agency's clarification on how to account for measures in the minimum total performance score when CMS lacks the baseline data necessary to calculate a numerical performance standard. However, we have concerns that the minimum TPS to avoid a payment reduction in PY 2018 has been lowered from 60 to 39. This is especially troublesome and confusing since CMS has requested comments on potentially raising the performance threshold to the 25th percentile. ANNA requests CMS provide clarification on how the minimum TPS for PY 2018 was calculated.

Data Validation
ANNA objects to the Agency's proposal to randomly select only nine facilities to participate in the feasibility study for data reported in CY 2016. ANNA believes the number of dialysis facilities must be reflective of a representative population of dialysis facilities, and selecting such a small number of facilities to participate in the study may be inadequate to validate data reported to CDC's National Health Safety Network (NHSN) Dialysis Event Module for the NHSN Bloodstream Infection clinical measure. We encourage the Agency to reconsider the proposed sample size. Further, ANNA encourages CMS to publish the results of the ongoing validation study discussed in the CY 2015 ESRD PPS Final Rule and publish a timeline for the expected release of such results.

E. Proposed Requirements for the PY 2019 ESRD QIP

ANNA recognizes the importance of infection reduction in quality care and improved outcomes. As we have commented previously,[3] ANNA supports the National Healthcare Safety Network (NHSN) Bloodstream Infection measure as a reporting measure. However, we continue to have serious concerns with the NHSN Bloodstream Infection measure as a clinical measure due to the inclusion of the Adjusted Ranking Metric (ARM).

Proposed Replacement of the Four Measures Currently in the Dialysis Adequacy Clinical Measure Topic Beginning with the PY 2019 Program Year
Given that CMS intends to pool the scores of all patients from the four dialysis populations, ANNA cannot support the replacement of the four measures in the Kt/V Dialysis adequacy measure topic with a single measure. A facility's quality cannot be accurately assessed with a measure comprised of pooled adult and

[3] Letter from ANNA to CMS Regarding Proposed Rule on ESRD PPS, QIP, and DMEPOS (CMS-1614-P) (September 2, 2014).

pediatric populations due to the vast differences between these two groups of patients.

ANNA also has recognized concerns within the adequacy measure in those patients who change modalities from hemodialysis (HD) to peritoneal dialysis (PD). When a prevalent patient transitions from HD to PD, the scoring methodology assumes there is a PD Kt/V within the last four months, without recognition that the patient has recently transitioned to PD. Consequently, dialysis facilities are forced to attempt to immediately conduct a PD adequacy test, without a sufficient stabilization period in the new treatment modality. If the patient is in training for PD during the last week of the month, the facility will not be able to complete the adequacy test, resulting in a negative score for that patient for dialysis adequacy. ANNA urges CMS to recognize that patients who transfer from one modality to another be considered a new patient in that modality for adequacy scoring.

We also request that CMS define the minimum number of treatments for PD patients when calculating the adequacy measures. The HD measure requires a minimum of seven treatments per month under the care of a facility for a patient's adequacy score to be included. Seven HD treatments are equivalent to approximately 14 PD treatment days. We encourage CMS to implement an equivalent number of minimum treatment days under a facility's care for an adequacy score for PD patients.

Proposed Measures for the PY 2019 ESRD QIP - Proposed New Reporting Measures Beginning with the PY 2019 ESRD QIP

i. Proposed Ultrafiltration Rate Reporting Measure
ANNA objects to the Agency's proposal to adopt #2700, *Ultrafiltration rate > 13 ml/kg/hr*, which was presented to NQF but not endorsed. ANNA supports the KCQA Measure, presented to NQF and endorsed as #2701, *Avoidance of Utilization of High Ultrafiltration Rate (>/=13 ml/kg/hour)*, which uses an average across treatments and better defines quality.

ii. Proposed Full-Season Influenza Vaccination Reporting Measure
ANNA opposes the full-season influenza vaccination reporting measure as currently proposed. While we strongly support efforts to ensure patients with ESRD are vaccinated, we have concerns regarding the administrative burden facing dialysis clinics in the collection of the necessary data to complete the required report, particularly because many patients will obtain the influenza vaccine elsewhere. Moreover, the measure as proposed is not aligned with NQF-endorsed specifications for influenza measures, particularly in regards to the window for administration of immunizations. Facilities should not be penalized if patients choose to receive the vaccine as soon as it is available. ANNA supports KCQA's proposed NQF Measure #0226, *Influenza Immunization in the ESRD Population (Facility Level)* and encourages CMS to consider adoption of NQF #0226.

Proposal for Scoring the PY 2019 ESRD QIP

Scoring the ICH CAHPS Clinical Measure
ANNA recognizes the importance of capturing the patients' experience in order to ensure quality care and supports the ICH CAHPS as a reporting measure. However, we oppose the ICH CAHPS as a clinical measure. The nursing community has expressed concerns with patients' inability to complete the survey due of its length. In addition, the twice annual survey requirement does not allow sufficient time for facilities to make improvements based on the first survey responses before the second survey is due to be conducted. We believe CMS' purpose in requiring this survey is to improve the patient experience; this timing is contrary to that purpose. ANNA urges CMS to reconsider the requirement for two surveys annually and modify the measure prior to transitioning the ICH CAHPS survey to a clinical measure.

We also request the Agency clarify the scoring methodology of the ICH CAHPS clinical measure, as the Agency's proposal is unclear. For example, will the scores be weighted? How will the scores from each of the two surveys be used in determining a final score?

Weighting the Clinical Measure Domain and Total Performance Score
ANNA supports the dialysis adequacy measure weighted at 18% of a facility's clinical measure domain score. We also appreciate the continuation of a lower value for the hypercalcemia measure. Additionally, ANNA endorses the Agency's proposal to maintain its policy that the clinical domain score will comprise 90% of a facility's TPS.

F. Future Achievement Threshold Policy Under Consideration

We support KCP's position that it is not necessary to move the Achievement Threshold from the 15th to the 25th percentile, given that there has been consistent improvement in the Achievement Threshold. ANNA urges CMS to publish the data used in consideration of drafting this proposal.

G. Monitoring Access to Dialysis Facilities

ANNA is pleased that CMS has acknowledged in the CY 2016 ESRD PPS proposed rule that it intends to publish the methodology for studying the adoption of the standardized readmission ratio (SRR) and standardized transfusion ratio (STrR) clinical measures and the impact of these QIP measures on access to care. ANNA recommends that CMS exclude the SRR and STrR clinical measures from the QIP while the Agency studies the impact of their adoption as clinical measures. Further, we reiterate that in order to properly evaluate the impact of measures and provide informed comments, all data used by CMS in developing the proposed rule must be

made available. ANNA urges CMS to publish the results of all studies it has undertaken related to the PPS and the QIP.

Conclusion

ANNA greatly appreciates the opportunity to share our comments on the Medicare proposed rule for the ESRD PPS for CY 2016 and QIP for PY 2019. As the leading professional association representing nephrology nurses, we look forward to continuing to work with your Agency on these important issues. Please feel free to contact me directly if you have any questions or would like to discuss these issues in greater detail.

Sincerely,

Cindy Richards, BSN, RN, CNN
President, 2015-2016
American Nephrology Nurses' Association