ANNA
Established in 1969
American Nephrology Nurses' Association

September 2, 2014

Marilyn B. Tavenner, BSN, MHA
Centers for Medicare and Medicaid Services
Department of Health
ATTN: CMS-1614-P
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1614-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
79 Federal Register 40207 (July 11, 2014)

Dear Administrator Tavenner,

On behalf of the American Nephrology Nurses' Association (ANNA), I am writing to share our comments on the proposed rule for the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), Quality Incentive Program (QIP), and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. 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 CMS by KCP.

II. Calendar Year (CY) 2015 End-Stage Renal Disease (ESRD) Prospective Payment System

CMS proposes to set the ESRD PPS base rate for CY 2015 at $239.33, the same as the CY 2014 rate, based upon the Agency's interpretation of the Protecting Access to Medicare Act of 2014 (PAMA). ANNA joins with the broader kidney community in agreeing with the interpretation of the payment provisions of PAMA. However, ANNA continues to have concerns about the impact of these payment decisions on patient care and availability of services, particularly for smaller dialysis facilities and those in rural areas. ANNA feels strongly that the payment rates currently proposed for both small and rural facilities do not provide the resources necessary to ensure quality care in underserved areas.

B. Routine Updates and Proposed Policy Changes to the CY 2015 ESRD PPS

ANNA is concerned that payment reductions for certain types of 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. 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 their facilities, or choose to limit their hours of operation. Closure of a dialysis facility in a rural area can result in patients having to drive a significant distance to obtain dialysis services. This burden is exacerbated by the need to undergo numerous treatments per week.

Proposed changes to the ESRD Bundled Market Basket and Labor-Related Share: 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 within the proposed rule. However, ANNA urges CMS to ensure that the most accurate and consistent data are used in rebasing.

ANNA supports KCP's comments regarding the exceptions to the revisions to the cost centers and weights.

CMS derives base weights for wages and salaries, employee benefits, medical supplies, laboratory services, and other areas. ANNA is concerned that what goes into each of the provided categories is not standardized. ANNA believes that the Agency should use consistent information from all providers to ensure the accuracy of the data. Smaller dialysis facilities, especially those in rural areas, will likely struggle to collect this information. ANNA encourages CMS to make an effort to provide education to providers to help them better understand these proposed

changes. ANNA would recommend that the Medicare Administrative Contractors reach out and work with the facilities on this effort.

Proposed Corrections to the Outlier Policy: ANNA recognizes that CMS needs 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 with respect to the underlying problem with the outlier pool and the fact that the pool has yet to be paid out in its entirety. Facilities continue to be unable to obtain necessary documentation from hospitals to support outlier status for patients who may, in fact, qualify as outliers. ANNA recognizes that changes in the Medicare Hospital Condition of Participation of Discharge Planning may, in time, ensure more timely and meaningful communication between hospitals and outpatient facilities, but this change is not likely to be in effect for 2015-2017.

C. Policy Regarding Reporting and Payment for More than Three Dialysis Treatments per Week and Barriers to Home Dialysis

ANNA supports the Agency's clarification of its policy regarding payments for more than three dialysis treatments per week. We agree that the payment policy should be sufficiently flexible to adjust to the individual needs of patients and appreciate CMS stating that more frequent dialysis is medically justifiable for some patients. There have been a number of studies that have found that more frequent dialysis may result in fewer hospitalizations. A significant article published in The New England Journal of Medicine in 2010, "In Center Hemodialysis Six Times per Week versus Three Times per Week," reported the following:

> *"Several uncontrolled studies showed that there were significant improvements in patient-reported outcomes and results in laboratory tests when patients were treated with more frequent in-center or at-home hemodialysis."*[1]

ANNA does have concerns with certain statements within the proposed rule. The paramount concern of nephrology nurses is the health of the patients they treat. CMS has maintained that quality of care and patient outcomes are the most important factors in the ESRD benefit. The statement that "modality choice does not constitute medical justification" ignores the importance of patient outcomes. It seems inconsistent for CMS to require that all dialysis treatments should be reported, while limiting payment to three times per week. We hope that data on improved outcomes for patients choosing more frequent dialysis will eventually result in a change in the payment system.

ANNA further supports efforts to provide access to their preferred treatment modality. We encourage the Agency to find ways to reduce the barriers that patients face in selecting home dialysis.

[1] The FHN Trial Group (2010). In-Center Hemodialysis Six Times per Week versus Three Times per Week. *New England Journal of Medicine* 363:2287-2300.

E. Payment of Drugs

ANNA supports the detailed comments provided by KCP on this issue. We encourage the Agency to consider the following seven principles suggested by KCP:

- Establishment of a clear definition of what drugs and biologicals are in the ESRD PPS;
- Establishment of criteria related to the frequency with which a drug or biological may be used within the ESRD population;
- Establishment of clear criteria for determining when drugs or biologicals are equivalent with existing products;
- Utilizing the rulemaking process when considering changes to the bundle;
- Establishment of a clear process for transitioning new drugs and biologicals into the ESRD bundle;
- Tracking the costs of new drugs and biologicals before adding them to the bundle; and
- Increasing the bundled payment rate to cover the costs of providing such products.

F. Low Volume Payment Adjustor

ANNA applauds CMS for taking steps to address issues raised with the low-volume adjustor. ANNA supports the efforts of CMS to allow Medicare Administrative Contractors to consider other supporting data to verify that a facility meets the low-volume criteria. ANNA encourages CMS to consider travel time as well as distance in their consideration of the aggregate number of treatments furnished by ESRD facilities within 25 miles of each other under common ownership.

III. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

ANNA has been a strong proponent of the QIP from its inception as a legislative concept and has supported the program's implementation. ANNA has joined with the kidney community to create the Kidney Care Quality Alliance (KCQA) to help move towards consensus-based quality measures that are validated by the National Quality Forum (NQF) endorsement process. However, we are very concerned that while the kidney community is making every effort to support the best quality metrics possible, the Agency lacks an overall strategic vision for the future use of quality metrics to improve care for ESRD Medicare beneficiaries. Therefore, we strongly encourage CMS to consider the work and recommendations from KCQA when adding or altering quality metrics.

B. Considerations in Updating and Expanding Quality Measures under the ESRD QIP

ANNA applauds CMS for seeking to adopt measures that "promote better, safer and more coordinated care."[2] As you know, nurses play a critical leadership role in the coordination of care for ESRD Medicare beneficiaries. According to an American Academy of Nursing article titled, "The value of nursing care coordination: A white paper of the American Nurses Association,"

> *"Patient-Centered care coordination is a core professional standard and competency for all nursing practice. Registered nurses understand that they are an essential component of the care coordination process to improve patients' care outcomes, and decrease costs across patient population and health care settings."*[3]

ANNA does have concerns that the Agency's focus on coordinated care does not provide more details about how QIP, Dialysis Facility Compare, the new Five-Star Quality Rating System, as well as state surveyor expectations under the Core ESRD Survey Process will work together to improve patient care. Many of our members have expressed concern and frustration with the many overlapping and, in some cases, contradictory expectations. While we understand that the Agency is not required to use only measures that have been reviewed or approved by NQF, ANNA encourages CMS to ensure that all proposed quality measures can be linked to national priorities and are based upon valid and reliable evidence. NQF and the guidance provided by the Technical Expert Panels (TEP) organized by the Agency can be valuable resources in the addition of quality measures.

D. Updating the NHSN Bloodstream Infection in Hemodialysis Outpatients Clinical Measure for the PY 2016 ESRD QIP and Future Payment Years

ANNA recognizes the importance of infection reduction in quality care and improved outcomes, but ANNA did not and does not support the National Healthcare Safety Network (NHSN) Bloodstream Infection as a clinical measure in Payment Year (PY) 2016. We believe the targets must be identified prior to migration of a reporting measure to a clinical measure. We do, however, support its continued use as a reporting measure as data is collected to establish thresholds, performance standards, and benchmarks. While the proposed rule indicates that the Adjusted Ranking Metric (ARM) has been endorsed by NQF,[4] it is our understanding that there are substantial differences between the NQF approved measure and what is being proposed.

E. Oral-Only Drug Measures in the ESRD QIP

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[2] Center for Medicare and Medicaid Services (2014). CMS-1614-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. *79 Federal Register* 40207: 121.
[3] Camica, M. et al (2013). The value of nursing care coordination: A white paper of the American Nurses Association. *American Academy of Nursing on Policy Nursing Outlook,* 61: 490-501.
[4] *Centers for Disease Control and Prevention* (2014). Bloodstream Infection in Hemodialysis Outpatients. *National Quality Forum.* Retrieved from: http://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=1460&print=1&entityTypeID=1.

ANNA supports the Agency's interpretation of the requirement in PAMA for the Secretary to delay the adoption of measures specific to conditions treated with oral-only drugs until 2024.

F. Proposed Requirements for the PY 2017 ESRD QIP

ANNA greatly appreciates having the opportunity to provide comments on the QIP proposal for PY 2017. ANNA found many of the proposed measures to be consistent with what the Agency described in the final rule for 2013.

However, there are some specific areas where we have questions, concerns, and suggestions for improvements. Nephrology nurses remain the linchpin in the collection and processing of these important data points and it is crucial that our members understand the Agency's overall vision for the QIP.

Proposed Revision to the Expanded ICH CAHPS Reporting Measure: ANNA recognizes the importance of capturing the patients' experience in order to ensure quality care but does not support the expanded reporting measure. ANNA was encouraged by the proposal to change the requirement of 30 eligible patients to 30 submitted surveys. However, ANNA is concerned that dialysis facilities may not be able to "quickly determine the number of survey-eligible patients they have treated during the eligibility period." ANNA encourages the Agency to provide more detail on what is needed for facilities to meet the requirements of the measure, including clarity on the number of times a patient would need to be treated at a facility to be included as an "eligible patient."

ANNA is also concerned that requiring the survey twice per year does not allow facilities sufficient time to make changes which might be needed based on responses to the survey. We recognize that the hospital CAHPS surveys are done monthly; however, the patient population in hospitals changes from day-to-day, while the patient population in chronic dialysis facilities is stable from month to month. Neither the measure description nor the explanation in the proposed rule clearly defines the expected timing for these two surveys, and neither explains a purpose for the second survey. The process should not be a burden to the patients or dialysis facilities. Additionally, we are not aware of any evidence that performing the survey twice per year is of benefit to patient care or patient outcomes. ANNA is requesting that CMS reduce the fielding requirement to once annually so that facilities have time to implement strategies for any needed improvement to the delivery of patient care and to minimize the burden on patients.

PY 2016 Measure Being Eliminated in PY 2017 and Beyond: ANNA has several concerns related to how this change will impact other elements of the QIP. ANNA wants to ensure the reporting measure for the number of months for which facilities report Erythropoiesis Stimulating Agent (ESA) dosage and Hgb/HCT for each Medicare patient meets the statutory requirements for a measure of anemia management and an additional measure is not required. ANNA strongly opposes the Standardized Transfusion Ratio clinical measure. As we previously have stated, we question how

the proposed changes in this rule fit into a larger strategy and vision for the future of the QIP and are concerned about the lack of clarity for the rules for measure retirement. For example, does the retirement of the Hgb> 12g/dL measure require the development of a replacement anemia management measure? If the rules for measure retirement are to be followed, why is CMS not retiring the Kt/V measure, which meets the same "retirement" criteria but continues to be included in proposed measures for both PY 2017 and 2018?

New Standardized Readmissions Ratio (SRR) Clinical Measure for PY 2017: ANNA does not support this measure and has a number of concerns about the Agency moving forward with this measure, especially since it has yet to been endorsed by NQF. In addition, we are still waiting for the report from the most recent TEP which CMS convened on this topic.

Specifically, ANNA is troubled by the use of a measure which has only a "moderate degree of reliability."[5] ANNA is concerned that the measure includes readmissions that are not related to ESRD. It is our understanding that 45% of readmissions of ESRD patients are not associated with ESRD issues.

We are unclear on a number of key issues related to how the SRR measure will be calculated. For example, will less than 24 hour stays, observation days, and/or day surgeries be counted in the measure? Without complete definitions of terms provided in the proposed rule and a lack of clarity on key elements of the measure, we cannot support the implementation of the SRR clinical measure at this time.

Data Validation: ANNA does not support the Agency's continuation of its validation pilot study as proposed. We believe the reduction of 10 points from a facility's Total Performance Score (TPS) for not sending medical records within the 60 day time period is too harsh a penalty, and discriminates against the small number of facilities selected to participate in these studies. ANNA also opposes the deduction of 10 TPS points for the NHSN validation study.

Monitoring Access to Dialysis: ANNA urges the Agency to provide more information about how this proposal for monitoring admission and discharge practices will be accomplished. We are concerned that this proposal will result in an additional data collection burden for nurses working in dialysis.

Extraordinary Circumstances Exception: ANNA supports the Extraordinary Circumstances Exception and appreciates the Agency's recognition that data submission would be problematic during and immediately following a disaster. ANNA also supports the Agency's proposal to allow 90 days to submit a Disaster Extension/Exception Request form.

G. Proposals for the PY 2018 QIP

[5] Center for Medicare and Medicaid Services (2014). CMS-1614-P *79 Federal Register* 40207: 135.

Proposed New Measures for PY 2018 and Beyond: ANNA understands that the Agency is proposing these measures a year in advance and while we appreciate having the opportunity to prepare for the changes, we urge CMS to consider phasing-in these additional measures over several years. The addition of five new measures in one year seems to be overly ambitious and could make implementation problematic. Many nurses are already overly burdened by multiple reporting obligations to state and federal agencies and this can negatively impact their ability to focus needed attention on direct patient care.

Standardized Transfusion Ratio (STrR): ANNA does not support the STrR as a clinical measure. ANNA does recognize the need to protect patient safety with the changes in dosing of an ESA due to label changes mandated by the Food and Drug Administration. ANNA appreciates CMS's intent to exclude transfusion events for certain diagnoses that frequently require transfusions. However, the measure as proposed does not adjust for the multiple variables in this complex issue and we have several concerns regarding the proposed measure. First, we are concerned that facilities will be held responsible for a measure for which they do not have data access. Few, if any, transfusions are administered in an ESRD facility, and as mentioned earlier in this comment letter, communication with hospitals remains problematic. Second, will the reason for the transfusion be considered? It is often not clear if patients receive transfusions because of inadequate anemia management in the outpatient facility, other chronic illness, or due to an acute problem during hospitalization. Third, in the experience of our members, hospitals frequently do not continue ESA doses during a patient's hospitalization, which can lead to the need for transfusion, unrelated to the care provided in the ESRD facility. We are concerned that the use of the STrR as a clinical measure may unfairly punish a facility for an outcome which is impacted by multiple variables that are beyond their control.

Pediatric Peritoneal Dialysis Adequacy Clinical Measure: ANNA supports the use of this measure and appreciates the exclusion criteria of a patient treated in a facility fewer than twice during a claim month.

ICH CAHPS Clinical Measure: ANNA does not support the two surveys per year without evidence to support a positive impact to patient outcomes and requests CMS to maintain annual surveys.

Screening for Clinical Depression and Follow-Up Reporting Measure: ANNA is well aware that many individuals requiring maintenance dialysis have significant depression and agrees that this is an important concept related to quality of life. ANNA does not support it as a reporting measure. Our concerns include the lack of clarity regarding the expected screening tool to be used, the rather complicated "choices" of responses, and the staff education that will be necessary to ensure appropriate patient assessment and data entry. Consideration needs to be given to whether depression management is to be ESRD based or part of an integrated care model with broader goals and resources. We believe additional resources and staff are essential to administer the tool, conduct the follow-up, and enter the required data. The availability of funding for additional staff with the proposed PPS payment

is unlikely. We are also concerned that the required follow-up would likely be completed by someone outside the evaluated facility. These concerns become more critical if CMS expects, as has historically occurred, that this measure will be considered as a clinical measure in the future.

Pain Assessment and Follow-Up Reporting Measure: ANNA does not support the measure as proposed as a reporting measure. Pain is a complex issue in the dialysis setting. We believe that providing a pain assessment every six months is not sufficient. There is no reason to expect that a pain assessment at the time of one treatment would be relevant to that individual's experience of pain at another treatment time. The proposed rule is not clear if the focus of this measure deals with acute or chronic pain, dialysis related or not. Further, we urge CMS to explain the expected outcome of collecting this data and information. ANNA believes this measure needs to be further developed and we are concerned that this measure as it is proposed does not provide value to the patient or relate to quality care.

NHSN Healthcare Personnel Influenza Vaccination Reporting Measure: ANNA strongly supports efforts to ensure health professionals, other personnel, and volunteers are all vaccinated. However, we have some concerns about the administrative elements facing outpatient dialysis clinics in the collection of the necessary data to complete the required report. For example, what would be the documentation requirements? Would facilities be able to accept a verbal confirmation of a vaccination or would all individuals involved have to provide written evidence? Also, can a vaccination be received prior to October of each year, particularly since the vaccination period often begins as early as late August? ANNA urges CMS to clarify these issues before moving forward with the implementation of this measure.

Proposal for Scoring the PY 2018 QIP: As previously stated, ANNA does not support the two surveys per year requirement. Additionally, if the proposed frequency is implemented we are concerned about how the ICH CAHPS scores will be calculated. For example, will the score be based upon improvements by the facility between the first and second survey results? Will the scores from the two surveys be averaged or will CMS select the top score?

Calculating the Clinical Measure Domain Score: ANNA reiterates its support of the comments provided by KCP on this issue. ANNA urges the Agency to maintain a consistent payment methodology for the QIP and we believe this can be best accomplished by changes to the weights assigned to measures and updating the benchmarks and thresholds.

ANNA greatly appreciates the opportunity to share our comments on the Medicare proposed rule for the ESRD PPS for PY 2015 and QIP for PY 2017 and 2018. 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,

Sharon Longton, RN, BSN, CNN, CCTC
2014-2015 National President