September 10, 2018

Ms. Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-1691-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

Re: CMS-1691-P; Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program; 83 Fed. Reg. 139 (July 19, 2018)

Dear Administrator Verma:

On behalf of the American Nephrology Nurses Association (ANNA), I am writing to share our comments on the proposed rule for the “Medicare Program; End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI), and End-Stage Renal Disease Quality Incentive Program (QIP)” for Calendar Year (CY) 2019.

ANNA is a professional association that represents nurses working in all areas of nephrology. Established as a nonprofit organization in 1969, ANNA has a membership of more than 8,000 registered nurses in 81 local chapters across the United States. Members practice 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 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.
The demand for high-quality nephrology patient care will continue to grow in the future as the number of patients with kidney disease increases and especially with the many changes occurring within health care and, specifically, within the specialty of nephrology. We believe that our nurses are qualified and in a unique position to enhance the quality of care delivered to individuals with kidney disease. We actively support research to both develop evidence-based practice and advance nursing science. We believe in a team approach to patient care and support interdisciplinary collaboration as essential to the delivery of cost-effective, high-quality patient care.

ANNA is a member of Kidney Care Partners (KCP) and the Alliance for Home Dialysis (jointly known as the kidney community) and has actively participated in the development of their comment letters. The following comments are in addition to the comments submitted to the Centers for Medicare and Medicaid Services (CMS or Agency) by KCP and the Alliance for Home Dialysis.

I. Calendar Year (CY) 2019 ESRD Prospective Payment System (PPS) Update to the ESRD PPS Base Rate for CY 2019

The Agency is proposing a CY 2019 base rate of $235.82 and proposing to rebase the ESRD market basket rate to the base year of CY 2016. We appreciate the Agency’s adjustment to the base payment rate. However, we join with the kidney community in being concerned about other policies in the ESRD PPS and QIP that may result in reductions to the already limited resources used by nephrology nurses to provide high-quality care to Medicare ESRD beneficiaries.

In the years since the implementation of the ESRD PPS, nephrology nurses have been forced to balance the constant increases in demands for data collection and the time required to provide quality patient care to a population of individuals with complex care needs. Nephrology nurses understand the increased administrative burden placed on dialysis facilities in meeting regulatory documentation requirements and are often the collectors and providers of this data at the unit level.

Drug Designation Process

ANNA joins with the kidney community in recognizing and supporting efforts by the Agency to identify, develop, and provide innovative clinical treatments for patients with ESRD. We were pleased with the announcement of the Kidney Accelerator (KidneyX) by the Department of Health and Human Services (HHS). ANNA has long advocated for increased funding for prevention, treatment, and research programs overseen by HHS. We commit to working with the other stakeholder organizations and support Congressional funding for KidneyX and other efforts by HHS to innovate care for patients with kidney failure.
However, ANNA also joins its kidney community colleagues in being concerned that the current payment system and certain policies within the proposed rule limit the expansion of technology innovation in ESRD treatments. Clinical innovation is directly related to the daily care provided to patients with kidney failure by nephrology nurses. Improvements in the efficiency of care delivery, the elimination of redundancies, and policies limiting administrative burdens will allow nephrology nurses to invest more time on direct patient care and therefore improve quality and outcomes for Medicare ESRD beneficiaries.

The lack of technology innovation in the treatment of kidney failure over the past several decades and the shrinking nephrology health professional workforce, especially the reports we receive from our members about a shortage of nephrology nurses, makes the need for breakthroughs even more significant. ANNA supports the kidney community’s recommendation of ensuring the alignment of the Medicare ESRD payment system and a long-term funding strategy that encourages and supports the development of innovative treatment methods.

**Transitional Drug Add-on Payment Adjustment (TDAPA)**

ANNA joins with KCP in encouraging the Agency not to apply the Transitional Drug Add-on Payment Adjustment (TDAPA) to generic or biosimilar drugs, but rather to encourage new, innovative drug treatments. ANNA also supports KCP’s recommendation for new funding to support the use of new drugs and biologicals that are different than those already in a functional category. In addition, ANNA opposes the use of the outlier payment policy as a method for paying for new drugs and biologicals.

The proposed rule calls for a modification of TDAPA policy which would move Average Sales Price (ASP) + 6 percent to ASP + 0 percent. Based upon the analysis provided by KCP, ANNA believes that it is not the correct time to change the ASP + 6 percent policy, as this proposal could result in creating a disincentive for the adoption and development of new drugs and biologicals. ANNA supports the recommendation of the kidney community to modify the proposed rule to evaluate whether new drugs or biologicals that come with a functional category should be added to the bundle with recommended “guardrails” in place.

ANNA continues to support CMS using at least two full years of claims data before folding a drug into the bundle. We join with KCP in urging CMS to ensure they have accurate and complete data when making decisions about new products or changes to the payment rate. Similarly, ANNA supports and appreciates the Agency’s policy to continue to reimburse calcimimetics at a rate of ASP + 6 percent and agrees with the
kidney community’s recommendation that CMS obtain at least two full years of claims data before ending the TDAPA period.

**Case-Mix Adjusters and Outlier Policy**

ANNA remains very concerned about the Agency’s use of case-mix adjusters in the ESRD PPS. In several previous comment letters, ANNA has expressed its concerns about the problems associated with certain case-mix adjusters and we again join with the kidney community in reiterating these concerns.

ANNA supports a call for CMS to eliminate the use of all co-morbidity case-mix adjusters for CY 2019. We also agree with KCP that there is overlap with the rural and low-volume adjusters, and we recommend eliminating the rural adjuster and developing a two-tiered low-volume adjuster. In addition, ANNA supports the recommendation to suspend the use of age and weight patient characteristics until a single equation model can be developed.

**Solicitation for Information on Transplant and Modality Requirements**

We appreciate having the opportunity to respond to the Agency’s request for information about the kidney transplants and modality choice. While nephrology nurses play an essential role in raising awareness and educating patients about transplants and modality choices, their available time for patient education is severely limited by other administrative and data collection responsibilities referenced in detail in forthcoming sections of this letter.

Nephrology nurses are key members of the clinical team at transplant centers and play an important role in educating patients on dialysis and their families about the kidney transplant process. ANNA agrees with KCP’s recommendation that a transplant measure included in the QIP should be actionable by dialysis facilities. In addition, ANNA has been a longtime supporter of extending the length of Medicare coverage for immunosuppressive drug coverage for kidney transplant patients. ANNA members have joined with others in the kidney community in supporting legislation to change this policy and we too encourage the Agency to work with Congress to take action to address this issue.

Nephrology nurses also invest a great deal of time and effort ensuring patients requiring dialysis and their caregivers receive information about the various modality options available to them. ANNA encourages the Agency to refine its policies to improve modality selection. We support KCP’s recommendation of a pilot program to provide reimbursement for Kidney Disease Education services that can help properly account for the number of beneficiaries who choose home dialysis.
II. Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

ANNA appreciates the Agency’s recognition of the unique characteristics of patients with AKI and the significant differences in care between the patient populations with AKI and ESRD. The care of a patient with AKI requires intensive oversight, enhanced intervention, and greater coordination among the clinical team. However, the majority of these patient care responsibilities can only be performed by specialized nephrology nurses.

The clinical condition of patients with AKI can change rapidly, requiring regular modifications to their care plan. The nephrology nurse must provide careful patient monitoring and frequent lab testing. These care requirements are vastly different than those provided to a stable patient with ESRD. For example, the average patient with ESRD may need their blood pressure checked approximately every 30 minutes, while a patient with AKI may need their blood pressure checked every 10 to 15 minutes. This relatively short interval of time may seem to be a minor adjustment, but these treatment differences have a significant impact on an already stretched nursing staff.

This high level of treatment, diagnostic testing, and monitoring can make the difference between a patient with AKI recovering or progressing to ESRD and requiring lifelong dialysis services, resulting in additional costs to the Medicare ESRD PPS. The care required is extremely complex and the payment system should support and encourage nephrology nurses to provide this high level of care.

The administrative burdens and data collection requirements detailed later in this letter and in previous comment letters present substantial barriers to the treatment of patients with AKI. ANNA strongly urges CMS to continue to consider the specialized high-quality care provided by nephrology nurses to patients with AKI as this part of the payment system evolves.

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

ANNA appreciates the opportunity to provide comments on the QIP section of the proposed rule. ANNA supports the goals of the QIP and we have played an active role in the measure development process with the kidney community, Kidney Care Quality Alliance (KCQA), and National Quality Forum (NQF). However, ANNA remains concerned about the total amount of time nephrology nurses spend collecting data for submissions and validation of measures.
ANNA and the kidney community urge CMS to focus on ensuring all of the quality measures are valid, evidence-based, and reliable; promote the delivery of high-quality care; and strive to improve patient outcomes. However, there are a number of quality measures that, without modifications or changes in policy, will continue to impose significant administrative burden on dialysis facilities and especially nephrology nurses.

The ability of nephrology nurses to provide high quality care is directly linked to the amount of time they are able to provide to direct and individualized patient care. If nephrology nurses are spending valuable clinical time collecting data for quality measures that are not reliable and validated, then they are collecting data merely for the sake of collecting data. Considering the nephrology nurse shortage and the challenges to recruiting, hiring, and retaining qualified Registered Nurses reported by our members, this data collection takes away important time that should be spent on focused patient care.

**Meaningful Measures Initiative**

ANNA joins with the kidney community in supporting the meaningful measures initiative. We very much appreciate the Agency’s interest in focusing on measures that are meaningful, improve quality care, drive improved patient health outcomes, and reduce administrative burdens on providers. We encourage CMS to continue to work with the stakeholder community to refine existing measures and ensure the development of any new measures are valid, reliable, and NQF-endorsed. In addition, ANNA would like to emphasize the importance to patients in being able to fully understand the measures and why they matter in their care.

Nephrology nurses spend more time with patients than any other member of the clinical team and they aim to provide the highest quality care to Medicare beneficiaries. As stated in the previous section, when a nephrology nurse’s limited time is spent collecting data on measures that are not directly related to the patient’s quality of care, that time does not contribute to the improvement of patient outcomes.

ANNA is concerned with the overlap and inconsistencies of the Five Star program and Dialysis Facility Compare (DFC). We join with KCP in recommending that CMS streamline the ESRD QIP and help reduce the administrative burden and promote transparency. The misalignment of the measures across programs creates confusion among patients and an unnecessary burden on nephrology nurses.

ANNA supports KCP’s recommendation about the measures being placed in QIP or DFC and those measures that should not be used in either QIP or DFC. ANNA would
like to comment specifically on the following measures that we believe belong in the QIP:

_Catheter > 90 Days Clinical Measure_

Maintain the catheter > than 90 days measure, but eliminate the Vascular Access Type (VAT) topic. ANNA agrees with the clinical research and the broader kidney community opinion that removing a catheter after 90 days is an extremely important factor in positive outcomes for dialysis patients. ANNA believes that though a fistula in many cases is the optimal choice, it is not the best option for all patients. Therefore, ANNA agrees with KCP’s recommendation of emphasizing the importance of removing catheters.

_Bloodstream Infection Measures_

As in past comment letters, ANNA and KCP encourage CMS to combine the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure and NHSN Bloodstream Infection Clinical Measure into a single clinically reliable outcomes measure.

_In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Clinical Measure_

ANNA has previously shared support of the ICH CAHPS as a reporting measure, but we remain concerned about the burden the survey places on patients and concern with the inability for them to complete the entire survey.

_Standardized Transfusion Ratio (STrR)_

ANNA is concerned about the proposal for the STrR measure to account for 22 percent of the facility’s total performance score, the highest weighting of any measure. We support a reduction in the weighting of this measure to reflect the problems associated with its validity.

_Serum Phosphorus_

Physicians and nephrology nurses use the serum phosphorus measure to make clinical decisions, and ANNA supports this measure in the QIP. In addition, ANNA is in favor of eliminating the hypercalcemia measure.

_Transplant Measure_
ANNA agrees with KCP that a reliable, valid, and actionable transplant measure is important for the QIP. However, we continue to believe it is important for the measures to be endorsed by the NQF. The Percentage of Prevalent Patients Waitlist and Standardized First Kidney Transplant Waitlist have not been endorsed by NQF.

As previously stated, ANNA supports the measures identified by KCP to be included in the DFC. ANNA provides additional comments on the following measures:

**KCQA Ultrafiltration Rate (UFR) Measure**

ANNA has been supportive of the UFR measure and we participated in the development of the KCQA NQF-endorsed measure. We appreciate that CMS included it in the QIP, but we support KCP’s position that the Agency should use the NQF-endorsed specifications for the measure and not make other modifications.

**KCQA Medication Reconciliation Measure**

Nurses are often the first point of care, learning about the patient’s care history and making critical decisions on the patient’s needs. While physicians, dietitians, and other medical staff are involved in medication reconciliation, it is the nephrology nurse who plays the key role in this important patient safety issue. In addition, ANNA supports the recommendation of KCP for the measure to be placed in the Care Coordination domain, rather than the Safety domain, since it more aligns with Meaningful Measures Initiative priorities.

**NHSN Healthcare Personnel Influenza Vaccination Reporting Measure**

ANNA has been a longtime supporter of the NHSN Healthcare Personnel Influenza Vaccination Reporting Measure. However, we remain concerned that the dates of vaccine availability do not coincide with the dates for the measure. ANNA encourages CMS to modify the measure to align with the Centers for Disease Control’s guidelines for immunization, which define the performance period as October 1 or “whenever the vaccine became available.”

**Vascular Access Type (VAT) Measure Topic – Arteriovenous Fistula (AVF) Clinical Measure/Standardized Fistula Measure**

ANNA has long believed in the clinical benefits of eliminating catheters. ANNA agrees with the Agency’s goal to decrease the use of catheters, but support KCP’s recommendation that the VAT Topic and AVF measure should not be included in the QIP.
Accounting for Social Risk Factors

ANNA has previously provided CMS with comments about the unique treatment needs of beneficiaries with socioeconomic demographic factors (social risk factors). We are committed to working with the Agency and the kidney community to account for social risk factors in the QIP through the use of appropriate adjusters and to help reduce health disparities in the Medicare ESRD program.

ANNA supports KCP’s recommendations on the existing QIP measures that should be assessed, establishing social risk factors adjustments and the measures that should not have these factors applied. ANNA also encourages the Agency to work with the KCQA and KCP on this issue and to implement their recommendations in the final rule.

Proposed Requirements for the PYs 2021 and 2022

ANNA would also like to provide our support for KCP’s recommendations on the structure and weighting of measures in the QIP for future payment years. In particular, ANNA supports KCP’s recommendation that CMS not finalize the weighting of measures until they have worked with the stakeholder community to ensure their clinical significance.

ANNA supports KCP’s recommendation that CMS adopt criteria for assessing the weights of QIP measures and emphasizing the measures with the most benefit to dialysis patients. Suggested criteria include the strength of the clinical evidence, the opportunity for improvement, and clinical significance.

Conclusion

ANNA greatly appreciates the opportunity to share our comments on CMS’ proposed rule for the CY 2019 ESRD PPS, AKI payment, and QIP. As the leading professional association representing nephrology nurses, we look forward to continuing to work with the Agency on these important issues to advance the care of patients with kidney disease. Should you have any questions, please contact me or have your staff contact our Health Policy Representative, Jim Twaddell, at jim.twaddell@dbr.com or 202-230-5130. We thank you for your consideration of our recommendations.

Sincerely,

Lynda K. Ball MSN, RN, CNN
ANNA President, 2018-2019