

September 25, 2019

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Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1713-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CMS-1713-P; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program; Fed. Reg. Vol. 84, No. 151 (August 6, 2019)

Dear Administrator Verma:

On behalf of the American Nephrology Nurses Association (ANNA), I am writing to provide comments on the proposed rule for the "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program"; CMS-1713-P; Fed. Reg. Vol. 84, No. 151 (August 6, 2019).

ANNA is the professional association representing nurses who work in all areas of nephrology. Established as a nonprofit organization in 1969, ANNA has a membership of more than 8,500 registered nurses in 80 local chapters across the United States. Members practice in all areas of nephrology, including hemodialysis, chronic kidney disease, peritoneal dialysis, acute care, and transplantation. Care of patients with chronic kidney disease (CKD) is complicated and complex and requires the advanced education and training in the disease processes and treatment modalities for kidney disease.

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

ANNA is an active member of Kidney Care Partners (KCP) and the Alliance for Home Dialysis (Alliance). We are proud to have joined their comment letters to the Agency on the ESRD PPS and QIP proposed rule.

ANNA has endorsed the recommendations in the KCP and Alliance letters and reiterated many of those recommendations in this letter. However, ANNA urges CMS in reviewing these comments, to consider the important role nephrology nurses play in providing safe, high quality care to Medicare ESRD beneficiaries. In addition, we encourage the Agency to work directly with ANNA to ensure the concerns of the nephrology nursing workforce are heard, and their roles as health professionals are supported and protected.

Advancing American Kidney Health

ANNA was pleased to see the release of the “Advancing American Kidney Health” Executive Order in July. We applauded the Administration’s ambitious goals to improve the lives of Americans with kidney disease. Nephrology nurses have been on the frontlines during the implementation of every new treatment and payment model change for End-Stage Renal Disease (ESRD) care.

ANNA believes the successful implementation of the initiative will require the active involvement of nephrology nurses who possess the necessary education, training, and clinical skills to provide the most effective care to patients with kidney disease. The following is a summary of the issues ANNA has raised with the Agency in previous comment letters and in-person meetings. These concerns were included in ANNA’s written comments in response to the CMS proposed rule on a new mandatory payment model included in the Executive Order.

Nephrology Nurses Role in Delivering Quality Patient Care

Nursing is the largest health profession in the United States and nephrology nurses spend more time on direct patient care than any other health care provider treating chronic kidney disease. Nephrology nurses’ work goes far beyond simply treating patients at in-center dialysis clinics. Nephrology nurses are employed in dialysis units, home therapy settings, transplant centers, colleges and universities, research organizations, clinics, and acute/critical care environments.

Nephrology nurses are indispensable to ensuring kidney disease patients receive the highest quality of care and to the extent medically possible, each person experiences successful outcomes in their chosen treatment modality. Nephrology nurses work diligently to ensure that this vulnerable patient population with complex needs is cared for and protected, even when the nurses’ guidance, suggestions, and opinions on the implementation of policy have not been sought out or in many cases simply ignored.

ANNA believes that the demand for quality nephrology patient care will continue to grow in the future, especially with the many changes occurring within health care and specifically, within the specialty of nephrology due to an increase in health conditions such as diabetes and hypertension that often lead to kidney disease. Our nurses are in a unique position to enhance the quality of care delivered to individuals with kidney disease in a variety of settings.

We know continued education has a positive impact on the quality of care delivered to patients with kidney disease. We believe that a sound educational program is necessary to develop, maintain, and augment competence in practice and the continuance of high-quality care delivery. We actively support research to both develop evidence-based practice, as well as advance nursing science. We believe in the team approach to patient care and support interdisciplinary collaboration as essential to the delivery of cost-effective, high-quality patient care. Nephrology nurses are integral members of this patient care team.

ESRD Treatment Choices (ETC) Model

ANNA recently submitted comments on the ETC payment model proposed rule. The comment letter focused on ensuring an adequate and qualified nursing workforce, recruiting and retaining qualified nephrology nurses, and properly training, educating, and preparing nurses, patients, and caregivers for changes in dialysis treatment modalities.

ANNA will play an active role with the Agency in the implementation of the ETC payment model and the other key elements of the Advancing American Kidney Health initiative. We view the new policy objectives set forth in the Executive Order as an opportunity for nephrology nurses to utilize the expertise our profession has to offer in providing strategic and forward-thinking ideas and policy recommendations to the Agency.

Calendar Year (2020) ESRD Prospective Payment System (PPS)

The Agency has proposed \$240.27 as the base rate for the ESRD PPS payments in CY 2020. ANNA and our colleagues in the kidney community wish to emphasize to CMS the importance of having an adequate and stable reimbursement to system for facilities providing care to Medicare ESRD beneficiaries.

KCP's comment letter on the PPS section of the 2019 proposed rule references a recent Medicare Advisory Payment Commission (MedPAC) report stating that the costs associated with providing services to ESRD patients exceeds the Medicare payments. One of the important benefits of a stable and adequately funded Medicare ESRD system is ensuring facilities can provide the proper level of nurse staffing to ensure quality care and patient safety.

Transitional Drug Add-on Payment Adjustment (TDAPA)

ANNA supports policy proposals to encourage the adoption of new and innovative products into the ESRD PPS and the establishment of a long-term pathway that adjusts the payment to reimburse for the item when added to the bundle. In addition, we continue to support a policy to evaluate innovative products, regardless of their functional category.

We continue to join KCP in expressing concerns about a broad policy that does not provide any new funding for the development and evaluation of innovative new products. As ANNA stated in their 2018 comment letter to the Agency, we support the recommendation from KCP that CMS adopt "guardrails" to define when a drug or biological product is truly innovative and if the product meets the qualifications under "guardrails", it should receive the payment adjustment.

ANNA has been a leader in the kidney and nursing communities as well as among other advocacy groups in supporting increased funding at the National Institutes of Health. These efforts include advocating for increased research funding in the areas of CKD and ESRD. In addition, ANNA joins with other members of the kidney community to urge Congress and the Agency to expand the Kidney Disease Education benefit and develop new similar initiatives.

Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES)

ANNA supports KCP's recommendation that CMS continue to apply TPNIES in order to obtain two full calendar years of data about the utilization and cost of the products.

In addition, we encourage CMS to modify the base payment rate to include funds for the difference in the cost of the new device.

Calcimimetics

ANNA continues to support extending TDAPA for calcimimetics in order to obtain two full years of claims data. It is our understanding that this number of claims data is necessary to determine the appropriate reimbursement rate following the end of the transitional period for calcimimetics. In addition, we are concerned about the Agency's proposal to reduce the basis for the calcimimetic TDAPA to the Average Sales Price (ASP) +0 percent. As mentioned in previous comment letters, ASP does not reflect the costs of purchasing products well above ASP. We encourage CMS to finalize ASP+6 percent as the basis for the calcimimetic TDAPA.

Case-Mix and Facility Level Adjusters

ANNA supports the elimination of the co-morbid case-mix adjusters for pericarditis, gastrointestinal tract bleeding with hemorrhage, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome. The documentation of these conditions can be burdensome, and we have found there is limited benefit to the use of information collected. Returning the funding to the base rate will benefit patient care. In addition, we encourage CMS to review the age, weight, low-volume, and rural adjusters. These adjusters add a data collection burden without helping to eliminate the disincentives to provide care to more costly patients by increasing rates.

Outlier Policy

ANNA agrees with the concerns expressed by KCP on the Agency's decision to include the TDAPA costs for calcimimetics in the outlier calculation, even though the drugs are not eligible for an outlier payment.

Wage Index

ANNA continues to support CMS's process for determining the wage indices. We join with KCP in requesting that CMS consider modifying the policy used to adjust wage index values given new laws requiring wage increases. The current policy creates delays of over one year until the wage index accounts for these changes.

ESA Monitoring Policy (EMP)

ANNA supports eliminating the application of the EMP to the outlier. We agree with statements in the proposed rule that since ESAs have been added

to the ESRD PPS, the EMP is no longer necessary. In addition, ANNA supports the continued collection of patient hemoglobin levels.

Payment for Dialysis Services for Acute Kidney Injury (AKI)

ANNA supports the proposed AKI payment rate for CY 2020. We support KCP's request that CMS publish details on the development of a formal monitoring program. We find it helpful to understand how CMS is monitoring the AKI benefit. ANNA wishes to continue emphasizing the critical role of nephrology nurses and the increased responsibilities that are placed on them when managing the complex nursing and care needs of patients with AKI. The unique and distinct characteristics of the ESRD and AKI patient populations require critical differences in treatment protocols.

For example, AKI patients require more vigilant monitoring, particularly in infection prevention, blood pressure management, more frequent laboratory testing, additional medication administration, and increased educational needs. The care of an AKI patient often requires more care coordination of the interdisciplinary team. These are not patient care responsibilities that can be delegated to technicians or other staff; only specialized nephrology nurses can provide the type of highly intensive and coordinated care that is necessary for these patients to achieve improved health outcomes.

Given the increased nursing time required to provide high-quality care to AKI patients, ANNA strongly urges CMS to recognize the specialized high-quality nursing care that nephrology nurses offer as it continues to modify the AKI payment policy.

End Stage Renal Disease Quality Incentive Program (QIP)

ANNA appreciates CMS' Measures that Matter initiative stated objective of "focusing on core issues that are essential to providing high quality care and improving patient outcomes while reducing the cost and burden associated with quality measurement." ANNA supports the comments of the kidney community on the importance of the QIP measures being valid and reliable and we encourage the Agency to re-evaluate existing measures when the data shows problems with validity and reliability.

ANNA's comment on the QIP measures in this letter are consistent with our previous recommendations and aligned with KCP and our other coalition partners. However, beyond our comments on existing quality measures, ANNA would like to reemphasize the importance of collaborating with us, in the development of nursing sensitive outcome measures.

There have been numerous empirical studies published that have evaluated the importance of the role nurses play in ensuring quality healthcare. This evidence-based research has demonstrated that nursing care has a significant impact on the quality of care provided to patients. As the health professionals responsible for providing the majority of hands-on care for Medicare ESRD beneficiaries, ANNA believes the Agency should consider ways to recognize and measure the value of the nurse/patient relationship in the QIP.

Standardized Transfusion Ratio (STrR) measure

We understand the challenges to ensuring the validity of the STrR as a clinical measure without being able to have a sufficient percentage of blood transfusions. ANNA agrees with KCP's expression of appreciation to the Agency on the decision to convert the STrR to a reporting measure while working to fix these problems. In addition, ANNA supports KCP's recommendation that CMS should replace the STrR with a hemoglobin (Hgb) threshold measure, such as the Hgb < 10 g/dL measure.

NHSN Blood Stream Infection (BSI)

ANNA continues to support the removal of the NHSN BSI clinical measure and using the Dialysis Event Reporting Measure. As mentioned in KCP's comments, the CY 2019 ESRD proposed rule stated that as many as 60-80 percent of dialysis events may be underreported with the measure. ANNA members have expressed frustration with the use of the measure, when it inaccurately reports the number of blood stream infections at their facility.

ICH-CAHPS

ANNA continues to support the ICH-CAHPS measure but remains concerned with the low number of responses and the response from patients about "survey fatigue." We agree with others in the kidney community who have expressed the importance of the patient's perspective in considering certain health care choices, but the current method does not encourage or assist the patients in completing the survey. In addition, ANNA supports the recommendation that CMS only survey patients once a year and provide the results of the survey to facilities and patients in order to respond to patient concerns.

Hypercalcemia

ANNA supports the discontinuation of the Hypercalcemia measure and the use of the serum phosphorous as a reporting measure for bone mineral metabolism measurement.

Support for Rate Measures

Based reports from ANNA members, we understand that nephrology nurses prefer the use of rate measures to ratios measures. ANNA agrees with KCP's comments on the importance of patients understanding how to apply the data from the measures to allow for informed decisions. We believe the use of rate measures would be more effective in achieving this objective than using ratio measures.

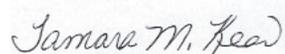
Alignment of Quality Programs

ANNA continues to join with KCP in our commitment to work with the Agency to improve the Medicare ESRD quality programs. We continue to support the recommendation that CMS align the DFC and ESRD QIP programs by ensuring that the measures have the same specifications and the same scoring mechanism. We believe this change will provide patients with two programs for decision-making that are not providing conflicting information.

Conclusion

ANNA greatly appreciates the opportunity to share our views and concerns about the Medicare proposed rule on "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program" (CMS-1713-P). Should you have any questions, please contact me or ANNA's Health Policy Representative, Jim Twaddell, at jim.twaddell@dbr.com or 202-230-5130. We thank you for your consideration

Sincerely,



Tamara M. Kear, PhD, RN, CNS, CNN
ANNA President