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September 4, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1732-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” (July 13, 2020)

Dear Administrator Verma:

On behalf of the American Nephrology Nurses Association (ANNA), I am writing to provide comments on the proposed rule for the “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” (CMS-1732-P).

ANNA believes that the demand for quality nephrology care will continue to grow in the future, due to both general changes in health care and, more specifically, due to an increase in health conditions such as diabetes and hypertension that often lead to kidney disease. The unfortunate incidence of acute kidney injury related to COVID-19 is another reason that the demand for quality nephrology care is growing. Our nurses are in a unique position to enhance the quality of care delivered to individuals with kidney disease in a variety of settings.

ANNA is providing comments on the PPS, AKI, and QIP sections of the proposed rule; in addition, we have highlighted important issues facing nephrology nurses during the COVID-19 pandemic. ANNA has raised many of these issues in previous Medicare ESRD PPS and QIP comment letters, including in our comments on the ESRD Treatment Care (ETC) payment model rule proposed in September 2019.

ANNA urges the Department of Health and Human Services and CMS to work with other federal agencies, such as the Health Resources and Services Administration (HRSA), to take collective and coordinated action to address these issues. A lack of substantive responses and action on these issues will

result in the loss of essential healthcare providers who are currently treating patients, and the loss of a generation of nurses who will be leaving the specialty for retirement or due to the impact of COVID-19 on the mental and physical health of the nursing workforce. If we are not able to recruit and retain nephrology nurses, a nursing workforce shortage will continue to worsen which, based on research, will have an impact on the quality of care for all patients, including those suffering from kidney disease. These results are opposite to the objectives outlined in the Administration’s goals for the Advancing American Kidney Health initiative. We urge 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.

Background and Mission of ANNA

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 base of more than 8,400 registered nurses and 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, complex and requires 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, and disseminates knowledge and new ideas. Our professional association promotes interdisciplinary communication and collaboration, and monitors and addresses issues encompassing the breadth of nephrology nursing practice.

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 delivery of high-quality care. We actively support research to both develop evidence-based practice and 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.

Continued Support of the Advancing American Kidney Health Initiative

ANNA continues to support the “Advancing American Kidney Health” Executive Order. ANNA has provided comments to the Agency on several key elements of the initiative. We remain optimistic on the initiative’s goals for improving the lives of Americans with kidney disease. However, ANNA has many concerns about the

nephrology nursing practice that need addressing to achieve the ambitious objectives outlined in the initiative.

ANNA provided the Agency with recommendations in response to the ETC payment model proposed rule in September 2019. Our comment letter focused on ensuring an adequate and qualified nursing workforce, recruiting and retaining qualified nephrology nurses, and appropriately training, educating, and preparing nurses, patients, and caregivers for changes in dialysis treatment modalities. The COVID-19 pandemic has further demonstrated that nephrology nurses serving on the frontlines of this pandemic must possess the necessary education, training, and clinical skills to provide the most effective care to the growing number of patients being diagnosed with kidney disease. We still await the release of the ETC final rule, and we encourage the Agency to engage ANNA and use the expertise of our members to provide guidance and policy recommendations during the implementation of those regulations.

Nephrology Nursing Shortage: A Critical Issue Requiring Action

Nursing is the largest health profession in the United States (U.S.) and nephrology nurses spend more time on direct patient care than any other health care provider treating chronic kidney disease. As the professional organization representing this important group of health professionals, we believe that in the course of its decision-making, the Agency must understand and fully consider the feedback and recommendations of nephrology nurses on the clinical issues we are facing.

The shortage of nephrology nurses is an issue that has needed attention from the Agency for many years. ANNA consistently expressed its concerns and provided examples and available data on the importance of addressing this issue. While ANNA supports many of the efforts to strengthen the Medicare ESRD program, we remain extremely concerned about the shortage of nephrology nurses to meet the current demand. This was our concern before the COVID-19 pandemic and, with the significant increase in AKI patients needing treatment due to COVID-19, our concerns related to a shortage of qualified nephrology nurses are heightened.

The factors contributing to the nephrology nursing shortage are similar to the factors that contribute to shortages in other nurse specialties. These include an aging workforce, a lack of adequate training, unsupportive work environments, limited exposure to nephrology in undergraduate nursing programs, and an extremely high level of “burnout” resulting in nurses leaving the specialty. These factors have only been exacerbated by the COVID-19 pandemic.

Adequate Nurse Staffing

The U.S. nursing workforce is aging, and RN retirements are accelerating. Compounding this problem is the fact that nursing schools across the country are struggling to expand the capacity for students entering nursing programs. Thus, the number of new nurses entering the profession and the nephrology specialty has not kept pace with the increasing demand for their services. The need to recruit new registered nurses and retain the nurses currently working in nephrology is an important issue, one we believe the Agency and the industry must address directly. In its 2019 comments to the Agency, ANNA said the following:

“At minimum, adequate nurse staffing at in-center dialysis facilities, home dialysis programs, and transplant centers is the key to positive patient outcomes, decreased hospitalizations, and reduced overall costs.”

According to studies on RN staffing and patient safety, low registered nurse staffing and high workloads were significantly associated with low safety ratings. The finding of the study resulted in the following statement, “As RNs’ contributions to patient safety in clinical settings are increasingly quantified, it has become even more apparent that a sufficient supply of RNs in all areas of practice, including hemodialysis units, is essential to ensuring quality and safe patient care.”¹

Work Environment and Burnout

ANNA’s research indicates that nephrology nursing burnout and job dissatisfaction has discouraged many registered nurses from pursuing the specialty as a career option or remaining in the profession long term. The work environment and pressure on nephrology nurses to perform with limited staffing support, while managing increasingly high patient caseloads and working an extraordinary number of hours, has pushed many nephrology nurses out of the specialty and, in some cases, out of the profession.

Moreover, the challenges that nurses, including those working in nephrology settings, face in caring for patients with COVID-19 cannot be ignored. According to a Hastings Center Report from May/June 2020, *COVID-19: Ethical Challenges for Nurses*, the pandemic confronts nurses and other healthcare workers with unique risks and ethical and emotional strains. The article explains how staffing and supply shortages, the emotional strain of caring for and supporting extremely sick and dying patients, and constant worry and concern for themselves and their families are likely to have long-lasting effects on the health and well-being of nurses and other health care workers, including nurses who work in nephrology settings. ANNA agrees with the article’s “urging policymakers” to ensure that nurses’ perspectives and experiences are

¹ *Registered Nurse Staffing, Workload, and Nursing Care Left Undone, and Their Relationships to Patient Safety in Hemodialysis Units* Nephrology Nursing Journal, Volume 47, Issue 2 (July/August 2020)
<https://search.proquest.com/docview/2395882111?pq-origsite=gscholar&fromopenview=true>

integrated into both local and federal decision-making to address the increasing demand for nurses and to minimize the unique risks and emotional strain many nurses face throughout this pandemic.²

Mental Health

On May 19, 2020, ANNA joined a letter with several national nursing organizations to the Administration requesting support for nurses serving on the frontlines of the COVID-19 pandemic. The letter expressed the grave concern of the nursing groups about the psychological health and well-being of nurses. The letter requests that the Administration take concrete steps to provide psychological first aid.

The American Nurses Foundation, the philanthropic arm of the American Nurses Association, conducted a mental health and wellness survey of nearly 10,000 U.S. nurses in July 2020. According to the findings, half of the nurses surveyed continue to feel overwhelmed, and nearly 30% say they are experiencing feelings of depression. Three out of four (72.8%) nurses who responded say they are suffering from challenges with sleep (either excessive sleep or sleeplessness).

ANNA is conducting a large survey-based, cross-sectional study investigating the mental health and well-being of nephrology nurses. While this study's planning commenced before the COVID-19 pandemic, some of the 37 items on the survey were selected to allow for an assessment of the impact of COVID-19 on the mental health and well-being of nephrology nurses. Data collection commenced in July 2020, with preliminary results available and to be presented at ANNA's Nephrology Nursing Practice, Management, & Leadership Conference in November 2020. We will share those results with Agency when they are final.

Long-Term Solutions Are Needed

While we cannot provide definitive projections on the number of nephrology nurses leaving the specialty or the profession at this time, ANNA is leading an effort to collect this data and information and we look forward to providing our findings to the Agency shortly. Sadly, it is all too likely this information will be consistent with national projections with regard to the U.S. nursing workforce. That is, nephrology nursing is experiencing a shortage of registered nurses that is expected to intensify as these nurses age and retire. Compounding the nephrology nursing shortage is that the supply of nurses entering the specialty will not be sufficient to meet the demand for nephrology nursing care and services.

² COVID-19: Ethical Challenges for Nurses
Hastings Center Report, Volume 50, Issue 3 (May/ June 2020)
<https://onlinelibrary.wiley.com/doi/10.1002/hast.1110>

In our 2019 ETC comment letter, we stated the following:

“History and experience have shown that the active involvement of nurses on the front end of planning and executing any health policy reform is the linchpin to a successful result. Nephrology nurses have worked 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.”

This is not a time to ignore the ideas, concerns, or voices of these essential frontline healthcare providers. Regardless of circumstances, conditions, or challenges, their only focus has always been and will always be on the health and safety of their patients.

Calendar Year 2021 ESRD Prospective Payment System (PPS)

ANNA is an active member of and a leading organization within Kidney Care Partners (KCP) and the Alliance for Home Dialysis (Alliance). ANNA has joined both of their comment letters to the Agency on the proposed rule, and we endorse their recommendations; we have reiterated a number of those recommendations in this letter. However, ANNA encourages the agency in reviewing the following comments to consider the important role nephrology nurses play in providing safe, high-quality care to Medicare ESRD beneficiaries.

ANNA appreciates and supports the Agency’s proposed \$255.59 or 2.2 percent increase for the ESRD PPS base rate for CY 2021. ANNA joins with KCP and others in the kidney community in stressing the importance of stability and sustainability in the Medicare ESRD payment system, and in the agency’s work to advance new technology and treatment innovations. ANNA continues to have concerns about certain case-mix and facility-level adjustors, however, as detailed in the following comments.

TDAPA and TPNIES

ANNA strongly supports the advancement of technology and innovation in the treatment of kidney disease, but we believe the structure of the Medicare ESRD payment system does not encourage the development of new treatment options. We support the Transitional Drug Add-on Payment Adjustment (TDAPA) and the Transitional Add-on Payment for New and Innovative Equipment and Supplies (TPNIES) to address this issue. However, we continue to share the concerns of KCP and other organizations about the long-term stability of the ESRD payment system, because the current policies do not sufficiently adjust the base payment rate when the agency adds new products to the bundle.

Calcimimetic

ANNA appreciates that CMS used a three-year transitional add-on period before adding calcimimetics to the ESRD PPS bundle. As mentioned in the ANNA 2019 comment letter and detailed in KCP's 2020 comment letter, this transitional period allowed accumulation of accurate claims data for these products. We agree with KCP's recommendation that the Agency use the most recent publicly available data in establishing the utilization rate for calcimimetics. As explained by KCP, using the most recent 12 months of data aligns with the Agency's proposed use of the most recent Annual Sale Price data in establishing the price for calcimimetics, and would be consistent with the approach used in other Medicare payment systems.

Case-Mix and Facility-Level Adjusters

As referenced in past comment letters, ANNA encourages CMS to address problems with certain case-mix and facility-level adjusters. The recommendations include eliminating the co-morbid case-mix adjusters for pericarditis, gastrointestinal tract bleeding with hemorrhage, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome. As we stated in our previous comment letters, these adjusters create a data collection burden and add costs without a clear and justifiable benefit.

ANNA is encouraged by the increased flexibility provided by the Agency in the application of the low-volume payment adjustment (LVPA). ANNA supports KCP's recommendation of a single low-volume facility adjuster that would better target payments for facilities providing fewer than 4,000 treatments per year. The revised adjuster would resolve the issues created by the overlap between the LVPA and rural adjusters, by replacing them with the single low-volume facility adjuster recommended by KCP.

Payment for Services for Acute Kidney Injury (AKI)

ANNA supports the proposed CY 2021 AKI payment rate of \$255.59 for AKI, which is the same as the base rate proposed under the ESRD PPS for CY 2021. We continue to request that the Agency provide stakeholders with information on the AKI monitoring program. We believe researchers and clinicians would benefit from knowing what the agency is monitoring and what the agency is learning from the analysis of the results from monitoring efforts.

Over the past several years, ANNA has shared with the Agency in our written comments, the vital role nephrology nurses play in managing the complex nursing and care needs of patients with AKI. The unique characteristics of AKI patients require vastly different treatment protocols from ESRD patients, with focused efforts to preserve residual renal function, resulting in additional complex clinical responsibilities

for the nephrology nurse. There is a critical opportunity for nephrology nurses to improve outcomes in the high-risk population of AKI patients through more vigilant monitoring, particularly in infection prevention, blood pressure management, more frequent laboratory testing, and additional medication administration. Only specialized nephrology nurses can provide the high intensity and coordinated care needed by these medically complex patients, and ANNA has urged CMS to recognize this fact and modify the AKI payment policy accordingly.

COVID-19 and AKI

According to a news report, “At Mount Sinai Hospital in New York, 46% of patients admitted to the hospital with COVID-19 since the beginning of the pandemic had some form of acute kidney injury; of those, 17% required urgent dialysis.”³ Surprisingly, 82% of these AKI patients had no history of kidney issues; only 18% did. More than a third of these patients who survived did not recover the same level of kidney function they had before contracting the virus.

According to Dr. Steven Coca, Associate Professor of Nephrology at Mount Sinai Health System, “The next epidemic will be chronic kidney disease in the U.S. among those who recovered from the coronavirus. Since the start of the coronavirus pandemic, we have seen the highest rate of kidney failure in our lifetimes. It’s a long-term health burden for patients, the medical community, and the U.S. economy.”³

ESRD Quality Incentive Program (QIP)

ANNA has been a consistent and longtime supporter of the QIP, and we were pleased to see the proposals detailed in the QIP section of the rule. The following comments reflect ANNA’s suggestions for improving upon what CMS has proposed in the rule, and are consistent with previous ANNA comments. As always, we offer to work with CMS and others in the kidney community to ensure the QIP measures accurately and reliably assess the care provided to ESRD patients at outpatient dialysis facilities.

Reevaluation of Reporting Measures

We join with KCP in supporting the Agency’s plan to re-evaluate reporting measures to align them more closely with National Quality Forum (NQF) measure specifications. In addition, we support many of the principles included in KCP’s comment letter for CMS’s review of the existing QIP measures.

Measure Reliability and Quality Program Alignment

³ High odds severe COVID-19 can lead to kidney injury or failure, medical studies reveal
CNBC.com by Lori Louannou (Aug. 3, 2020)

<https://www.cnbc.com/2020/08/03/severe-covid-19-can-lead-to-kidney-failure-medical-studies-reveal.html>

ANNA encourages the Agency to use valid and reliable measures as established through NQF endorsement, and adopt endorsed measures when they are available over measures without endorsement. In addition, ANNA joins with KCP in requesting that CMS review previous recommendations submitted by the community for strengthening the ESRD QIP and Dialysis Facility Compare, to allow these programs to achieve their independent goals.

Ultrafiltration Rate and Medication Reconciliation

ANNA supports CMS's proposals to modify the Ultrafiltration Rate and Medication Reconciliation reporting measures to a "patient-months" model, to improve alignment with the NQF-endorsed measures.

NHSN Validation Study

ANNA supports the CMS proposal to reduce the submission requirement for facilities selected to participate in the NHSN validation study from 40 to 20 patient records from any two quarters during the applicable calendar year.

NHSN Dialysis Event and Bloodstream Infection Measures

ANNA continues to join with others in the kidney community in requesting that the Agency eliminate the NHSN Blood Stream Infection (BSI) measure and use of the Dialysis Event Reporting Measure alone. We support transparency and efforts to reduce bloodstream infections, but we concur with KCP's statement that a measure inadequately representing a facility's performance limits the ability of patients to make informed decisions regarding their care. In addition, the use of these measures penalizes facilities pursuing and reporting hospital infection data needed to provide a complete picture of infection rates.

Standardized Transfusion Ratio

ANNA supports the Agency's decision to convert the Standardized Transfusion Ratio (STrR) to a reporting measure. We continue to recommend that CMS replace the STrR with a low hemoglobin (Hgb) measure.

Hypercalcemia Measure

ANNA continues to support the retirement of the Hypercalcemia Measure from use in the ESRD QIP. KCP reiterates that it would be appropriate, for purposes of having a bone mineral metabolism measure, to use the NQF serum phosphorus measure as a

reporting measure in the QIP. Physicians rely upon the serum phosphorus measure, more so than the serum calcium measure, to make clinical decisions.

Adequacy Comprehensive Measure

ANNA agrees with KCP's concerns that a pooled measure is not a reliable way to measure quality, and we support the removal of the Dialysis Adequacy Comprehensive Measure from the QIP.

ICH-CAHPS Measure

ANNA supports patient satisfaction measures, but the low response rates for the ICH-CAHPS has created problems with the validity of the measure. We continue to recommend that CMS help reduce the burden placed on patients by surveying patients only once a year.

Medicare Advantage

ANNA agrees with the view of KCP that greater transparency is needed to update relevant QIP measures, as an increasing number of Medicare Advantage (MA) patients enter the ESRD program.

Impact of COVID-19 on the QIP

As previously mentioned, COVID-19 has affected all areas of patient care. ANNA agrees with the views expressed by KCP and encourages the Agency to address the impact of COVID-19 on performance measures for the current year and coming years if the pandemic continues to affect kidney care delivery.

Nursing- Sensitive Outcome Measures

ANNA has commented several times on the importance and relevance to the nephrology nursing profession of nursing-sensitive outcome measures. As ANNA has mentioned previously, there have been numerous studies demonstrating the significant impact nursing care has on quality of care and positive patient outcomes. The continuing work of nephrology nurses during the COVID-19 pandemic only underscores the importance and value they bring to the care of ESRD beneficiaries. ANNA believes the Agency should consider ways to recognize and measure the value of nurses by including nursing-sensitive performance and outcome indicators in the QIP.

Conclusion

ANNA appreciates having the opportunity to provide written comments concerning the proposed rule for the “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” (CMS-1732-P).

Should you have any questions, please contact myself, or ANNA’s Health Policy Representative Jim Twaddell, at jim.twaddell@faegrewalker.com or 202-230-5130. We thank you for your consideration.

Sincerely,



Lillian A. Pryor, MSN, RN, CNN
ANNA President