

**BOARD OF
DIRECTORS**

OFFICERS

President
David Walz

President-Elect
Angela Kurosaka

Immediate Past President
Lillian Pryor

Secretary
Tanya Scott

Treasurer
Sara Kennedy

Director
Elizabeth St. John

Director
Nancy Colobong Smith

Director
Lucy Todd

Executive Director
Tamara Kear

August 31, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Humans Services
Attention: CMS-1749-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CMS-1749-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, and End-Stage Renal Disease Treatment Choices Model” (July 9, 2021)

Dear Administrator Brooks-LaSure:

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-1749-P). ANNA is providing comments on the PPS, AKI, QIP, ETC, and RFI sections of the proposed rule; in addition, we have highlighted important issues facing nephrology nurses.

ANNA believes that the demand for quality nephrology care will continue to grow, particularly considering the impact of COVID-19 on patients experiencing acute kidney injury (AKI) and chronic kidney disease (CKD).¹ Nephrology nurses are in a unique position to enhance the quality of care delivered to individuals with kidney disease in a variety of settings. The challenging yet determined work of nephrology nurses

¹ Nugent J, Aklilu A, Yamamoto Y, et al. Assessment of Acute Kidney Injury and Longitudinal Kidney Function After Hospital Discharge Among Patients With and Without COVID-19. JAMA Netw Open. 2021;4(3):e211095. doi:10.1001/jamanetworkopen.2021.1095

during the COVID-19 pandemic, whether in-center, acute care settings, or preparing patients for home therapies, only underscores the importance and value they bring to the care of End Stage Renal Disease (ESRD) beneficiaries.

ANNA continues to have great concerns about ensuring an adequate, qualified, and resilient nursing workforce. This includes recruiting and retaining qualified nephrology nurses, and appropriately training, educating, and preparing nurses, patients, and caregivers for changes in dialysis treatment modalities directed by the Advancing American Kidney Health Initiative. It also includes the need for essential resources from stakeholders in building a nursing workforce that is supported and valued for their contributions. 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 and equitable care to the growing number of patients diagnosed with kidney disease.

ANNA continues to urge the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) to take coordinated action to address these important issues. The U.S. Bureau of Labor and Statistics projects a seven (7) percent increase in employment needs from 2019 to 2029. The average growth rate for all occupations is four (4) percent.² Additionally, the supply and demand of registered nurses (RNs) will have substantial variation and impact on access to care across the nation. As we have stated in previous letters to CMS, a lack of a substantive response on these workforce challenges will result in the loss of a generation of nurses who are leaving the specialty due to the impact of the mental and physical health strain that has been significantly exacerbated by the COVID-19 pandemic. This exodus of nurses from all practice specialties, including nephrology nursing, is occurring and the impact will be felt over the next decade.

Simply stated, since the onset of the pandemic, the nursing workforce shortage has worsened. Based on evidence, this will harm the quality of care and mortality rates for all patients, including those suffering from kidney disease.³ These results are opposite to the objectives outlined in the Administration's goals for the Advancing American

² Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Registered Nurses, at <https://www.bls.gov/ooh/healthcare/registered-nurses.htm> (visited August 23, 2021).

³ American Association of Colleges of Nursing. (2020, September). Fact Sheet: Nursing Shortage. American Association of Colleges of Nursing, About the Nursing Shortage. <https://www.aacnnursing.org/Portals/42/News/Factsheets/Nursing-Shortage-Factsheet.pdf>

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. ANNA is ready to work with the Agency to outline and address the issues affecting the nephrology nursing profession.

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 8,000 registered nurses and nearly 78 local chapters across the United States. Members practice in all areas of nephrology, such as conservative management of kidney function, peritoneal dialysis, in-center and home hemodialysis, continuous kidney replacement therapies, transplant, industry, research, education, and government/regulatory agencies. Persons with CKD have complex care needs. To meet the needs of these individuals, nephrology nurses must have the requisite advanced education and training in the disease processes and treatment modalities for kidney disease.

ANNA develops and updates standards of clinical practice, educates practitioners, conducts, and supports research, and disseminates knowledge and new ideas and participates in healthcare policy. 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 continued delivery of high-quality care. We actively support research to both advance nursing science and to generate research-based evidence for translation into practice. We believe in a cross-disciplinary team approach to patient care and support interdisciplinary collaboration as essential to the delivery of cost-effective, high-quality patient care.

A Critical Time for the Nephrology Nursing Profession

As the leading professional organization representing nephrology nursing, we believe CMS and other federal agencies must understand the critical issues occurring within

our nursing specialty. ANNA has previously commented on these challenges to HHS, the Health Resources and Services Administration, CMS, and Congress. These are not new issues, nor are these issues that have emerged due to COVID-19. Rather, they are exacerbated by the pandemic.

A recent New York Times opinion editorial by a highly respected nurse researcher noted that nursing is the largest health profession with over 4,000,000 nurses in the country. These frontline caregivers have the highest level of trust among the American public. The op-ed said, “Let’s prioritize, preserve, and accelerate nurse-led advancement which, in turn, will support outcomes, drive new care models, and help build a more equitable health care system as we work toward a “new normal.””⁴

ANNA believes this is a time to listen to the voices of our nurse leaders, invest in this important profession, and take bold action to protect these essential frontline healthcare caregivers. Nurses are too busy providing patient care and saving lives, and they need help saving themselves and the profession of nursing. We are calling on the federal government to provide this support to nurses, so they can continue their essential work providing high quality patient care.

Restoring the Nursing Workforce

Several nurse leaders recently published an opinion editorial about the challenges facing America’s nurses since the pandemic. “One clear takeaway from the pandemic so far is that it has unlocked new momentum in the delivery of care to patients, with notable advancements powered by nurses. Examples include nurse-led command centers that deploy health system resources to treat patients more effectively, creative partnerships that connect homebound individuals to highly trained health practitioners, tighter collaborations between points of care and the academic institutions that prepare nurses to practice, and more.”⁵ This expanded care demand requires a workforce to meet these patients’ needs and preferences.

According to a previously mentioned opinion editorial addressing the nursing shortage, it will require strategies to, “Grow the pipeline of new nurses. Building a nursing

⁴ Stat News Look to nurses to help accelerate the transformation of health care by Lynda Benton, Robyn Begley and Debbie Hatmaker Aug. 20, 2021

⁵ New York Times, August 21, 2021 ‘Nursing Is in Crisis’: Staff Shortages Put Patients at Risk, Andrew Jacobs

workforce for tomorrow's needs should involve planning at the national level. Broader educational opportunities outside of traditional acute-care settings, as well as diversified continuing education, will help create more professional pathways for nurses, fill the expanding roles nurses will play across the health care continuum, bolster their skills, and reduce attrition. Nurses of many backgrounds, demographic identities, and skill sets are increasingly essential to meet the dynamic health needs of the U.S., now and into the future.”⁵ ANNA strongly agrees with these comments, the following areas need critical support from the federal government to help rebuild the nursing workforce.

Work Environment

ANNA remains concerned about the shortage of qualified nephrology nurses. The factors contributing to the nephrology nursing shortage have only expanded over time. These include an aging workforce, a lack of adequate training, unsupportive work environments, limited exposure to nephrology in undergraduate nursing programs, and a significant increase in patients with acute kidney injury needing treatment because of COVID-19.

ANNA has commented previously about the connection between the work environment and the pressure on nephrology nurses to perform with limited staffing support, while managing increasingly high patient caseloads, and working an extraordinary number of hours. The result of these work conditions is a high number of nephrology nurses leaving the specialty and, in some cases, leaving the nursing profession entirely.

The New York Times Opinion Editorial previously mentioned also noted “We celebrate nurses now. We call them heroes. But if we value their sacrifices and want them to be there when we need them, we must prevent a return to the poor pre-pandemic working conditions that led to high nurse burnout and turnover rates even before COVID-19.”⁶ The focus of nephrology nurses will always be on the health and safety of their patients, but according to the Code of Ethics for Nurses, nurses owe a duty to their own health, well-being and safety.⁷

⁶ Linda H. Aiken, New York Times, August 12, 2021, Nurses Deserve Better. So do their patients.

⁷ American Nurses Association. (2015, January). Code of Ethics PDF. ANA.

<https://www.nursingworld.org/practice-policy/nursing-excellence/ethics/code-of-ethics-for-nurses/coe-view-only/>

Mental Health and Nurse Suicide

ANNA is most concerned by the extremely high level of “burnout” impacting nurses across the country, including nephrology nurses. The high level of burnout has not merely resulted in nurses leaving the specialty or the profession, but it has dramatically affected their mental health and in some cases has led to an increase in nurse suicide. When mental health is not protected, and the overall well-being of nurses is strained this not only put nurses in danger but can also jeopardize patient care. From a 2020 issue of the Nephrology Nursing Journal, an article on nurse burnout shared, “In the outpatient dialysis unit, reducing nurse burnout is vital to retaining nurses and ensuring patients receive the quality of care essential to their needs (O’Brien, 2011). Burnout compromises job performance and patient safety (Gutsan et al., 2018).”

Burnout is not only a phenomenon of professional fatigue resulting in emotional, physical, and mental exhaustion. The Nephrology Nursing Journal article further explains, “there are many potential contributors to burnout in nurses, including lack of control, unclear expectations, dysfunctional work dynamics, extremes of activity, lack of social support, and work life imbalance.”⁸ However, what is most striking from the journal article is the following:

“Further, suicide may be a severe consequence of clinician burnout (Davidson et al., 2018; National Academy of Medicine, 2019). Davidson and colleagues (2020), in a long-term study on nurse suicide in the United States, found that nurses are at a higher risk for suicide than the general population. In addition, while dealing with a pandemic from COVID-19, nurses are also dealing with a public health epidemic of nurse burnout, depression, and suicide.”⁸

The nursing profession is in overdrive to serve patients during this public health emergency and the full impact to the nursing profession is yet to be seen. Based on this early information, ANNA strongly recommends policymakers consider initiatives and reforms to support and stabilize the nursing profession.

⁸ Prevention Strategies to Cope with Nurse Burnout (Nephrology Nursing Journal, November –December 2020- Vol. 47, No. 6)

Workplace Violence

According to the Bureau of Labor Statistics in 2019, the incidence rate for violence and other injuries by persons in the health care and social assistance industry was 14.7 for every 10,000 full-time workers. The total rate for all industries was 4.4. ANNA supports the House-passed *Workplace Violence Prevention for Health Care and Social Service Workers Act*. The bill requires the Department of Labor (DOL) to address workplace violence in health care, social service, and other sectors. Specifically, the Agency should issue an interim occupational safety and health standard that requires certain employers to take actions to protect workers and other personnel from workplace violence. Nephrology nurses spend a great deal of time with patients and therefore face these challenges regularly. ANNA encourages CMS to be vigilant in efforts to protect nephrology nurses, and all members of the healthcare team playing a role in the treatment of Medicare ESRD beneficiaries.

Health Disparities

An estimated 37 million Americans live with chronic kidney disease, which can lead to kidney failure or ESRD. Nearly half of those are undiagnosed. ESRD is 3.7 times greater in African Americans, 1.4 times greater in Native Americans, and 1.5 times greater in Asian Americans than white Americans.⁹ Fixing health disparities begins with acknowledging their existence and understanding how the various disparities influence an individual's health. It requires a knowledge of the social determinants of health and how they can affect each individual/patient and populations of people. To know our patients, care for them, and advocate for them, we must look beyond their blood pressures, glomerular filtration rates, and weight gains between dialysis procedures to understand the social determinants of health that preceded their kidney disease and its manifestations."¹⁰ We stand with CMS in their commitment to health equity and recommend the agency take swift action from the feedback received in this proposed rulemaking to address health disparities in ESRD patients.

⁹ *Kidney Disease Statistics for the United States*. (2016, December). National Institute of Diabetes and Digestive and Kidney Diseases. <https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease>

¹⁰ Stat News Look to nurses to help accelerate the transformation of health care by Lynda Benton, Robyn Begley and Debbie Hatmaker Aug. 20, 2021

Equity and Diversity

In June 2020, the ANNA Board of Directors released a statement that read in part, “ANNA stands in solidarity with our members and the patients for whom we provide care, whose health and well-being are threatened by long-standing inequality stemming from racism and injustice. ANNA recognizes that patient populations impacted by racism and injustice often are also the same populations at an increased risk of developing kidney disease. Despite these challenges, and recently in the face of a pandemic, nephrology nurses show up to provide compassionate and respectful care to all patients, acknowledging the inherent dignity, worth, and unique attributes of every person without prejudice.”

To commit to the call to action, ANNA created a Diversity, Equity, and Inclusion Committee with the purpose of “influencing kidney health by engaging within the communities we serve to address healthcare equity and advocate for improved access to nephrology health care and education for all.” The committee works to “build a diverse and inclusive association that will ensure that our practices and policies do not allow, condone, or result in discrimination and create an ongoing educational process to build diversity, equity, and inclusion competencies.”

In addition, ANNA supports the July 6 comments from KCP in their letter to the OMB on “Methods and Leading Practices for Advancing Equity and Support for Underserved Communities through Government Request for Information.” The letter recommends to “Collect social determinant of health data using Z-codes to account for and report on the most common non-clinical barriers to home dialysis, including housing or financial insecurity, minimal caregiver support, other mental and certain physical illnesses, or advanced age to provide information about these barriers and develop policies to overcome them and to be able to set target rates of home dialysis adoption.”

ANNA works as a leading member of patient care for kidney disease and our nursing communities are committed to advocating for equity and inclusion on behalf of our patients and fellow nurses. We strongly encourage CMS to continue and expand efforts to consider the nursing work environment, mental health, equity, and diversity issues in the development of policy and regulations. Addressing these inequities and improving patient outcomes are at the center of health care. We recognize the

multifaceted needs of the nephrology patient population, but as you can see from our comments, we must support the nursing workforce so they can adequately support kidney patients and their individual needs and choices, and effect positive change and outcomes.

I. Calendar Year 2022 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? Or CMS in reviewing the following comments, to consider the important role nephrology nurses play in providing safe, high-quality care to Medicare ESRD beneficiaries.

Proposed Impacts to the CY 2022 ESRD PPS Base Rate

ANNA supports the Agency's proposed \$255.55 for the ESRD PPS base rate for CY 2022. 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 as detailed in the following comments. ANNA appreciates the Agency's discretion to utilize the most recent data, if available before the publication of the final rule, to determine the final CY 2022 market basket update and productivity adjustment.

The Proposed CY 2022 ESRD PPS Wage Indices

ANNA joins KCP in recognizing the end of the phase-in for the wage index adjustment and supports the final phase-in of the wage index. Additionally, ANNA recommends CMS to consider using additional data beyond the hospital wage data as ESRD patients receive care in various settings such as dialysis centers, skilled nursing facilities, and at home.

Proposed CY 2022 Update to the Outlier Policy

ANNA agrees with KCP to adjust the Outlier Pool and continues to recommend that CMS address the systemic under-payment created by the current policy. We

recommend CMS to reduce the outlier percentage to better match the use of the outlier pool. Historic data show that it regularly pays out between 0.5 and 0.6 percent, which supports using this percent for the withhold rather than a full 1.0 percent. For any year in which the outlier pool funds are not used, CMS should return the remaining amount to the base rate or make the funds available to address health disparities or address other payment policy priorities.

Update to the Offset Amount for TPNIES

ANNA strongly supports the advancement of technology and innovation in the treatment of kidney disease, as it is essential to expanding patient choice, but we believe the structure of the Medicare ESRD payment system does not encourage the development of new treatment options. As mentioned in KCP's comment letter, individuals living with kidney disease, especially kidney failure, have not experienced the same level of medical innovation that others living with conditions like cardiac disease or cancer have been able to access during the last 30 years. 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 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.

Case-Mix and Facility-Level Adjusters

ANNA continues to encourage CMS to address problems with certain case-mix adjusters as they create a data collection burden and add costs without a clear and justifiable benefit. ANNA joins with KCP in encouraging the Agency to eliminate the co-morbid case-mix adjuster. In addition, ANNA supports KCP's proposal to expand the scope of the low volume payment adjustment to help direct needed funds towards rural and urban patients and facilities.

II. Payment for Services for Acute Kidney Injury (AKI)

ANNA supports the proposed CY 2022 AKI payment rate of \$255.55 for AKI, which is the same as the base rate proposed under the ESRD PPS for CY 2022. 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 have in managing the complex nursing and care needs of patients with AKI. The most recent data from The United States Renal Data System (USRDS) shows in 2017, roughly 800 Medicare fee-for-service beneficiaries-initiated outpatient dialysis for treatment of AKI; in 2018, that number increased to roughly 1000 beneficiaries. 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. As mentioned previously, COVID-19 has led to an increase in the number of individuals afflicted with AKI, and the role of nephrology nurses in managing the care of this population has never been so important.

There is a critical opportunity for nephrology nurses to improve health outcomes in the high-risk population of AKI patients through more vigilant monitoring, particularly in infection prevention, blood pressure and volume management, more frequent laboratory testing, and medication adherence measures. ANNA strongly encourages CMS to recognize how only specialized nephrology nurses can provide the high intensity and coordinated care needed by these medically complex patients and modify the AKI payment policy accordingly.

AKI patients seek care in a variety of settings and payment is needed to invest and innovate nursing care for our patients. Among patients who were hospitalized with AKI in 2018, approximately 52% were discharged to home, 31% were discharged to a skilled nursing facility, 6.7% were discharged to hospice, and 8.4% died in the hospital (USRDS, 2020). To support the demand for care at home the right equipment, training and resources are needed.

III. ESRD Quality Incentive Program (QIP)

The QIP should continue to focus on a small number of meaningful measures that report outcomes where there are gaps in care. We strongly encourage CMS to reduce the number of measures in the ESRD QIP and modify some of them to address

problems with the current measures. With fewer measures, the ESRD QIP comprise a more meaningful and parsimonious set of indicators that would allow caregivers to better focus on health care quality. Narrowing the program would ensure that each measure has substantial weight to avoid any individual measure being diluted by the others. Measures for which there are significant gaps in outcomes, or which are priorities that can subsequently and positively impact other quality outcomes, such as reducing catheter placement, should be weighted more than other measures.

Extraordinary Circumstances Exception (ECE), Flexibilities for the ESRD QIP, and Measure Suppression Policy in Response to the COVID-19 PHE

ANNA appreciates CMS' recognition of the impact of COVID-19 on the ESRD QIP. ANNA supports the Extension of the Extraordinary Circumstances Exception (ECE) previously granted for the ESRD QIP and notification of ECE due to ESRD Quality Reporting System challenges. ANNA also supports the proposed flexibilities for the ESRD QIP in response to the COVID-19 PHE. 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 as the pandemic continues to affect kidney care delivery. Particularly, its effect on AKI, and the progression to CKD. Additionally, ANNA fully supports the proposed Measure Suppression Policy for the Duration of the COVID-19 PHE. We agree with the concern that the data will be distorted and skew results as hot spots emerge and fluctuate around the country.

Proposals to Suppress Four ESRD QIP Measures for PY 2022

ANNA agrees with the Agency's proposal to suppress the four ESRD QIP Measures including the Standardized Hospitalization Measure, Standardized Readmissions Ratio Measure, In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) Survey Administration Measure, and Long-Term Catheter Rate Measure. In addition, ANNA supports KCP's suggestion to suppress the Hemodialysis Vascular Access, Standardized Fistula Rate Measure, and the Percentage of Prevalent Patients Waitlisted clinical measure.

IV. End Stage Renal Disease Treatment Choices (ETC) Model

ANNA has supported and remains optimistic about the goals of the “Advancing American Kidney Health Initiative” and the ETC payment model. However, we remain concerned about having an adequate, trained, and educated nursing workforce to meet the ambitious goals and objectives of the Executive Order including the ETC model. According to *The Future of Nursing 2020-2030: Charting a Path to Achieve Health Equity* report, “Healthcare systems enable and support nurses to tailor care to meet the specific medical and social needs of diverse patients to optimize their health.”¹¹ Barriers of working to the full extent of nurses’ education and training must be removed so that nurses’ contributions, which we have seen during the pandemic, can have a positive effect on the care delivery to patients with kidney disease.

ANNA joins with KCP in expressing appreciation to the Agency for issuing a proposed rule with recommended improvements to the ETC model and we concur with their recommendations. Specifically, encouraging the ETC model to support patients’ abilities to select the modality that works best for them and ensuring quality performance data is made available on an annual basis. Moreover, if nurses who focus on person-centered care are allowed to practice to the full extent of their education and training, we can have an important impact on patients’ selection of treatment modality and the quality of care these individuals receive.

¹¹ National Academies of Sciences, Engineering, and Medicine. 2021. *The Future of Nursing 2020-2030: Charting a Path to Achieve Health Equity*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25982>.

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-1749-P).

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

Sincerely,



David F. Walz, MBA BSN RN CNN FACHE
ANNA President