August 25, 2023

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

Re: Medicare Program; 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, and End-Stage Renal Disease Treatment Choices Model (Proposed Rule)

Dear Administrator Brooks-LaSure:

On behalf of the American Nephrology Nurses Association (ANNA), I write 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, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model (proposed rule). Please note that ANNA fully supports the comments made by both the Kidney Care Partners (KCP) and the Alliance for Home Dialysis (AHD). In addition to our comments on the proposed rule, we have also highlighted important issues facing nephrology nurses to provide context.

About ANNA

The American Nephrology Nurses Association improves members' lives through education, advocacy, networking, and science. Since it was established as a nonprofit organization in 1969, ANNA has been serving members who span the nephrology nursing spectrum. ANNA has a membership of over 8,000 registered nurses and other health care professionals at all levels of practice. Members work in areas such as conservative management, peritoneal dialysis, hemodialysis, continuous renal replacement therapies, transplantation, industry, and government/regulatory agencies. ANNA is committed to advancing the nephrology nursing specialty and nurturing every ANNA member. We achieve these goals by providing the highest quality educational products, programs, and services. Our members are leaders who advocate for patients, mentor each other, and lobby legislators, all to inspire excellence.

ANNA Comments to ESRD Proposed Rule

1. ***ESRD Prospective Payment System (PPS)***

As we have stated in the past, ANNA continues to believe that the best way to address changes in the mix of goods and services in the market basket is to rebase with a more accurate forecast error. This year, CMS is not proposing any update to the data used to determine the current mix of goods and services and will continue to use 2020 data. We have a number of issues with not updating the methodology and submit the following comments for CMS's consideration.

Inflation

The proposed market basket updated in the proposed rule fails to account for the substantial and continued increase in cost faced by dialysis facilities, including inflation and workforce shortages. For inflation, the Medicare annual inflationary update has not kept pace with actual inflation. As Kidney Care Partners (KCP) note in their letter, data shows that Medicare spending for outpatient dialysis services has decreased by nearly 10% between 2010 and 2020 while the total number of individuals needing dialysis has continued to grow.[1] Furthermore, research demonstrates that heath care costs will rise 7% in 2024 as providers face higher expenses, and those expenses must be passed on to the patients.

Workforce

The issues with inflation bleed into the workforce shortages as serious gaps in the health care workforce drive wages higher, and ultimately lead to access to care issues, site of care closures, and increased wait times.[2] For example, due to workforce shortages, ANNA members report patients having to drive lengthy distances to receive care because facilities nearby have closed, which is significantly more difficult for those without reliable transportation and poor social determinants of health. Furthermore, with the dialysis facilities reducing shifts, ANNA members have observed this as a barrier for patients to continue to work or maintain a productive life. Relatedly, there have also been reports of unnecessary and extended hospital stays as dialysis facilities are unable to accommodate new patients.

ANNA continues to have great concerns about ensuring an adequate, qualified, and resilient nursing workforce, and this problem must be addressed to ensure better care for individuals with kidney disease. With the lack of sustainable

[1] USRDS. Annual Report 2022. Figure 9.6a.

[2] The gathering storm: The transformative impact of inflation on the healthcare sector, Sept. 19, 2022, *available at* https://www.mckinsey.com/industries/healthcare/our-insights/the-gathering-storm-the-transformative-impact-of-inflation-on-the-healthcare-sector. Last visited August 25, 2023.

reimbursement, dialysis units are unable to compete with salaries for a qualified workforce. 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* are of particular concern. Furthermore, workforce issues also include the need for essential resources from stakeholders in building a nursing workforce that is supported and valued for its contributions. These resources include but are not limited to ample personal protective equipment, reasonable lengths of shifts, safe nurse-patient caseloads, and an overall healthy work environment that allows for personal time off, breaks during work shifts, and is free of verbal and physical abuse from patients and other staff.

Specifically, there is a shortage of qualified nephrology nurses, and the factors contributing to the nephrology nursing shortage and position vacancies have expanded over time. These contributing factors include an aging workforce, a lack of adequate training, unsupportive and unsafe work environments, limited exposure to nephrology in undergraduate and graduate nursing programs, and the ongoing and increasing need of individuals needing kidney replacement treatments.

To address the nursing shortage and resulting position vacancies, strategies to grow the pipeline of registered and advanced practice nurses and build a "nursing 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."[3] As such, ANNA urges HHS and CMS to coordinate action to address these important issues.

Potential CMS Actions

Given these alarming statistics, we are profoundly concerned that the market basket increase is only 1.7% for 2024. As such, we, in agreement with KCP, urge CMS to work with kidney care stakeholders to get a better understanding of how the market basket has, over the last decade, neglected to reflect the increases in cost for kidney care. We recognize that addressing the issue with the current market basket will be a multi-year process, negatively impacting patients who are already experiencing reduced access to dialysis.

[3] Linda H. Aiken, Nurses Deserve Better. So do their patients, New York Times, August 21, 2021.

One solution that will provide a stop gap as the market basket is updated is for CMS to adopt the forecast error adjustment in the final rule for 2024, as is already used in the skilled nursing facility prospective payment system. As we did in last year's comments, we request CMS again consider adopting the forecast error adjustment to address the rising costs of these lifesaving services.

Additionally, due to the present reimbursement structure, there is currently very little innovation for individuals on dialysis to ensure they have access to the best care they need. As such, we urge CMS to consider broadening the Transitional Drug Add-On Payment Adjustment (TDAPA) initiative. Specifically, we recommend CMS increases payment for innovation post TDAPA, adopt a process where the reimbursement follows the patient and the amount of the increased reimbursement adjuster is offset by an amount correlated to the reduction in other costs. If there is no reduction in other costs, then the adjustment should be determined accordingly. For example, ANNA's advanced practice registered nurses (APRNs) are not prescribing available innovation treatments, as they will not be reimbursed when the TDAPA period ends next April. Furthermore, Medicare Advantage plans do not have access to TDAPA reimbursement. These barriers result in a different standard of care between patients.

2. ***Proposed Transitional Pediatric ESRD Add-On Payment Adjustment for Pediatric Patients with ESRD Receiving Kidney Dialysis Services***

ANNA greatly appreciates CMS's efforts in the CY 2024 ESRD proposed rule to tackle the unique challenges facing pediatric patients with ESRD who are receiving dialysis services. In particular, ANNA is strongly supportive of the Proposed Transitional Pediatric ESRD Add-On Payment Adjustment of 30%, which will bring payments up to better align with the cost of care for this population and is in line with our response to the RFI that age be used as a proxy for composite care rates. This will especially benefit underserved and disadvantaged communities by improving access to care and helping facilities located in these areas better absorb the costs of providing dialysis services to pediatric patients with ESRD. As noted in the proposed rule, treating pediatric patients with ESRD is costlier than treating adult patients. Furthermore, ANNA is encouraged to see CMS's commitment to health equity and improving data collection on pediatric patients, which we know has historically been a barrier to finding targeted solutions.

We do, however, ask CMS not to apply this policy in a budget neutral manner. Due to budget neutrality, this increase in funding on the pediatric side will inevitably take away funding from adult dialysis patients. As KCP cites in their letter, add-on payment adjustments of this nature are not statutorily required to be budget neutral. To ensure that adult and pediatric individuals who need dialysis

are both able to access services, we urge CMS to implement the pediatric ESRD add-on in a non-budget neutral manner.

We also submit the following recommendations to further reduce costs, improve health equity, and expand access to care in the pediatric population:

- CMS should promote a shift away from hospital-based kidney dialysis for pediatric patients and instead move towards care furnished in a home-based setting. Home dialysis is much less disruptive to school schedules and is associated with a sizable reduction in side effects. Home-based dialysis is also cheaper relative to hospital care and limits the patient load hospital providers must manage.

- Investments must be made to grow the pediatric nephrology workforce. Currently, two states in the U.S. are entirely without a single pediatric nephrologist, and most states have a rate of one pediatric nephrologist per 100,000 children.[4] The massive shortage of pediatric nephrologists restricts access to care from experts in the field, overburdens the limited number of providers in the field, and raises cost. To that end, we recommend CMS include pediatric nurse practitioners, who can assist in meeting the needs of the youngest and most vulnerable individuals on dialysis. ANNA is grateful that CMS recognizes this pressing matter in the proposed rule and hopes CMS will continue its efforts to expand the pediatric nephrologist workforce.

- CMS should consider direct patient labor categories when determining costs to provide dialysis services to pediatric patients because the care team for a pediatric patient requires additional training.

ANNA is committed to supporting dialysis services for pediatric patients with ESRD and any efforts taken by CMS to alleviate the problems faced by this vulnerable population, including issues of access, cost concerns, and health equity. We appreciate the opportunity to comment, and we stand ready to work with you to ensure that pediatric patients receive the care they need and deserve.

3. Quality Incentive Program (QIP)

ANNA remains strongly in support of the ESRD QIP as it provides the strong foundation for expanding value-based purchasing in Medicare. However, as

[4] Pediatric Physicians Workforce Data Book, 2020-2021, available at https://www.abp.org/sites/public/files/pdf/workforcedata2020-2021.pdf. Last visited August 10, 2023.

presented by KCP in their comment letter, we agree that CMS takes the opportunity to work with stakeholders on an ongoing basis to ensure that QIP remains a meaningful program that ultimately betters dialysis outcomes for individuals with kidney disease. Specifically, we urge CMS to focus on measures that reflect the care provided and are actionable by dialysis facilities as well as demonstrate scientific reliability, including measures related to vaccination coverage. We believe a concentrated focus on measures that matter will ultimately lead to better care for individuals on dialysis. Furthermore, it is prudent to note that not much action has been taken to ensure that "home only" programs are not negatively impacted by the fact that only a few of the QIP measures apply to services provided in the home.

4. Time on Machine

In the proposed rule, CMS suggests requiring patient level reporting on resources used to furnish in-center hemodialysis treatment which would be used to apportion composite rates in the case-mix adjustment. While we understand that CMS believes that additional data may be beneficial in determining the appropriate use of resources, we have concerns with this proposal. Specifically, as cited in the KCP letter, based on analyses performed by The Moran Company, "reporting of the number of minutes of hemodialysis treatment a beneficiary receives…while the patient is connected to the dialysis machine"[5] will not provide the type of information CMS anticipates[6] to create more accurate adjusters as time on machine data does not equate to an increased cost in dialysis. In fact, this proposed policy will increase the burden on providers, particularly nephrology nurses. Given the administrative burdens already faced by nephrology nurses, coupled with questions about the usefulness of such data, we ask CMS to reassess the burden it will place on health care professions and the negative impact on direct patient care time.

We also support KCP's suggestions to work with the kidney care community to minimize the burdensome mandate and its impact on patient care. Additionally, if finalized, CMS must provide additional clarifications on the implementation of the policy as well as allow stakeholders sufficient time to adopt the policy.

5. ESRD Treatment Choices (ETC) Model

ANNA, along with the kidney care community, supports the clarifications of the ETC Model policies related to review determinations. We applaud CMS for these proposed provisions and agree that the clarifications will "ensure accountability"

[5] *See* Display Copy 131.
[6] *See* Display Copy 124.

and increase awareness about the availability of administrative review among ETC participants.

Other Issues for Consideration

1. ***Mental Health of Nephrology Nurses***

ANNA remains concerned by the extremely high level of "burnout" impacting nurses across the country, including nephrology nurses. The increased 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, not only is the nurse in danger but patient care can also be jeopardized. 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." 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."

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 information, ANNA strongly recommends policymakers consider initiatives and reforms to support and stabilize the nursing profession.

2. *Negative Impacts of Replacing Nephrology Nurses with Other Licensed or Un-licensed Professionals*

Since the release of HHS's Advancing American Kidney Health Initiative in July 2019, ANNA has supported efforts to increase home dialysis care and services. In fact, we have routinely emphasized the essential role nephrology nurses have in

providing home dialysis care and education to ensure long-term therapy success and patient safety. Given the nature of home dialysis care, it is imperative that nephrology nurses and other health providers anticipate and prepare for complications that may occur to both allow patient independence in-home dialysis therapy and to prevent failure in therapy. This requires a significant investment in educating nephrology nurses, so they have the proper skill set to train and educate patients and their caregivers for home therapy, as well as prepare additional nurses to be proficient and competent in-home dialysis training and therapy management. In addition, nephrology nurse practitioners will require additional training and education to transition in-center patients to home therapies, provide adequate dialysis prescriptions, and troubleshoot complications. ANNA has actively educated nurses about home dialysis therapies to increase patient access to these therapies. However, due to the COVID-19 pandemic and the workforce issues, nephrology nurses are leaving the profession in large numbers, and it is impacting the number of nurses available to train and manage patients on home dialysis therapy.

One solution to this nursing shortage has been to try to fill the gap with other health care and non-health care providers. Nephrology registered nurses are uniquely situated to provide dialysis care and this type of replacement strategy may ultimately cause serious harm to the patients we serve. Additionally, we stress that the scope of practice for nephrology registered nurses cannot be transferred to other licensed or un-licensed professionals without serious consequence to patients. Nephrology registered nurses regularly assess a patient's needs, evaluate that data, and then educate patients and their caregivers on how to execute the care plan. These functions are only within the scope of practice of a registered nurse. The consistency and quality of care suffers when these critical activities are split up amongst other licensed or un-licensed professionals.

It is imperative that the nephrology registered nurse is involved at the inception of a patient's care as this fosters trust, familiarity, and communication between the nurse and patient. Additionally, these registered nurses are trained to quickly identify and troubleshoot a patient's therapy challenges; early identification of challenges and learning patient's needs is imperative to long-term therapy success

and sustainability.

As such, ANNA believes the best path forward is to work in collaboration with nephrology nurses and not 'around' nephrology nurses. The expertise of registered nurses should be considered when making policy decisions about a role which they have expert knowledge and will therefore lead to the best patient outcomes. ANNA will continue to invest in the efforts to advance home dialysis therapies and remain an active member of the nephrology community in this effort. ANNA established a Dialysis Home Therapies Task Force and conducted a Think Tank which clarified the nephrology registered nurse's role in home therapies in the environment of a nephrology health care worker shortage in the effort to ensure the patient's safe and informed transition to home dialysis. We welcome the opportunity to work with HHS and CMS on this important issue.

Conclusion

ANNA appreciates the opportunity to comment on this proposed rule. If you have any questions about ANNA's comments to the proposed provisions, please contact Jim Twaddell at JWTwaddell@venable.com. We stand ready to work with CMS on these important policy changes to ensure individuals in need receive the best care possible for kidney related issues.

Sincerely,

Jennifer Payton

Jennifer Payton MHCA, BSN, RN, CNN
President