November 4, 2022

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: Make Your Voice Heard Request for Information

Dear Administrator Brooks-LaSure,

On behalf of the American Nephrology Nurses Association (ANNA), I write to provide comments on the Make Your Voice Heard Request for Information (RFI). We commend your dedication to collecting stakeholder input on these critical questions. Our comments are below.

ANNA 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 7,000 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.

Question 1: CMS wants to empower all individuals to efficiently navigate the healthcare system and access comprehensive healthcare. We are interested in receiving public comment on personal perspectives and experiences, including narrative anecdotes, describing challenges individuals currently face in understanding, choosing, accessing, paying for, or utilizing healthcare services (including medication) across CMS programs.

Access to quality kidney care remains an ongoing issue in our country. The following are challenges ANNA members have experienced related to individuals accessing kidney care:

- In the End Stage Renal Disease (ESRD) Proposed Rule, CMS acknowledged the kidney care community’s concerns about the current blanket “no new money” policy. This policy restricts any adjustments to the
ESRD PPS system rate when a new drug or biological is introduced to bundle into an existing functional category at the end of a Transitional Drug Add-On Payment Adjustment (TDAPA) period. However, add-on payment adjustments for new drugs and biologicals that fall within existing categories after the TDAPA period ends are necessary to protect access to these innovative products. To resolve this conflict, we urge CMS to add new money to the payment rate for drugs/biologicals that are in functional categories after the TDAPA period ends, which ultimately will increase access to critical medications.

- Actual, direct patient care labor costs associated with providing dialysis services are not currently captured accurately and additional direct patient care labor categories should be explored. Dialysis centers cannot compete with other health care settings such as hospitals due to wage competition. We urge CMS to examine how to accurately capture labor costs to ensure individuals still have timely access to these treatments; anecdotally, providers are reporting having to pay higher wages to attract nurses and technicians into dialysis.

- For some individuals, the lack of access to reliable transportation can greatly affect the quality of care. Limited access to transportation results in missed and delayed appointments, decreased dialysis treatment times, and accessibility issues for those with mobility and physical health challenges. More specifically, the negative health effects related to lack of transportation can fall hardest on our most vulnerable populations in low-income areas, who typically do not own their own vehicles. Many must rely on public transportation, if it is even available, and their health care is restricted to public transportation routes, resulting in inequitable access to necessary health care services and resources.

Additionally, lack of access to the internet greatly affects the quality of care. The use of the internet in health care has grown since the onset of the pandemic. Via the internet you can now participate in telehealth visits, order medication, schedule appointments, access health records and laboratory results, and retrieve information in multiple languages. While telehealth continues to increase in access, the lack of broadband internet results inequitable access to care visits as well as to a broad range of communication resources such as online portals and audio/video enabled tools. Many health care services now require internet access to schedule appointments, complete the registration process, and receive care results for continuity of care between providers.

Question 2: CMS wants to better understand the factors impacting provider well-being and learn more about the distribution of the healthcare workforce. We are particularly interested in understanding the greatest challenges for healthcare workers in meeting the needs of their patients, and the impact of
CMS policies, documentation and reporting requirements, operations, or communications on provider well-being and retention.

ANNA continues to have great concerns about ensuring an adequate, qualified, and resilient nursing workforce. This includes recruiting and retaining qualified nephrology registered 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 its contributions.

We further remain concerned about the increasing shortage of qualified nephrology registered nurses and its contributing factors, which have expanded over time. These 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 need of individuals needing kidney replacement treatments.

Workforce Retention: There is a strong connection between the current work environment and the high number of nephrology nurses leaving their specialty, and in some cases, the nursing profession entirely. There is a lot of pressure on nephrology nurses to perform at a high level with limited staffing support, increasingly high patient caseloads, and an increase in scheduled work time.

Workplace Violence: According to the Bureau of Labor Statistics, in 2019, the incident 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. The danger faced by health care workers is leading nurses to leave the industry which contributes to the ongoing workforce shortage issues. ANNA encourages CMS to be vigilant in efforts to protect nephrology nurses, and all health care providers playing a role in the treatment of Medicare ESRD beneficiaries.

Mental Health of Nephrology Nurses: ANNA is most concerned by the extremely high level of “burnout” impacting nurses across the country, including nephrology nurses. The increased burnout has not merely resulted in registered 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 stated, “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

**Negative Impacts of Replacing Nephrology Nurses with Other Licensed or Unlicensed Professionals:** Given the nature of home dialysis care, it is imperative that nephrology registered 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 registered nurses, so they have the proper skill set to train and educate patients and their caregivers for home therapy, as well as prepare additional registered nurses to be proficient and competent at 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 access to these therapies. However, due to the COVID-19 pandemic and the workforce issues, nephrology registered nurses are leaving the profession in large numbers resulting in growing vacancies, and fewer registered nurses available to train and manage patients on in-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 unlicensed professionals without serious consequence to patients. Nephrology registered nurses regularly assess a patient’s needs, evaluate that data, develop an individualized plan of care, and then educate patients and their caregivers on how to execute the care plan. These skills only fall under the scope of practice of the registered nurse. The consistency and quality of care suffers when these critical activities are split up amongst other licensed or un-licensed professionals without the training or skill set to complete those functions.

**Question 3:** CMS wants to further advance health equity across our programs by identifying and promoting policies, programs, and practices that may help eliminate health disparities. We want to better understand individual and community-level burdens, health-related social needs (such as food insecurity and inadequate or unstable housing), and recommended strategies to address health inequities, including opportunities to address social determinants of health and burdens impairing access to comprehensive quality care.

An estimated 37 million Americans live with chronic kidney disease (CKD), and most are undiagnosed. In fact, 40% of people with severely reduced kidney
function (not on dialysis) are not aware of having CKD. Every 24 hours, 360 people begin dialysis treatment for kidney failure (CDC, Chronic Kidney Disease Initiative, February 28, 2022). These statistics are even more alarming in communities of color. The Centers for Disease Control and Prevention (CDC) reports that 16% of non-Hispanic Black adults and 14% of Hispanic adults in the United States have CKD, compared to only 13% of non-Hispanic White or Asian adults in the United States. The NIH notes that higher risk for CKD among these groups is primarily due to higher risk for other conditions such as diabetes and high blood pressure, both of which are highly prevalent among Black, Latino, and Native American patients in the United States (Stat News Look to nurses to help accelerate the transformation of health care by Lynda Benton, Robyn Begley and Debbie Hatmaker Aug. 20, 2021).

We applaud CMS’s continued work to address health inequity in our country and we are especially pleased at the recognition that racial disparities affect treatment for ESRD. ANNA strongly believes that addressing social determinants of health (SDoH) is a foundational step in achieving health equity. To that end, we submit the following observations for your consideration:

a. While refining payment policy to mitigate health disparities is an important issue, we urge CMS to increase the bundle payment to address underlying SDoHs that contribute to health disparities.

b. The more co-morbidities an individual has, the more complex his or her care plan. These individuals need more time, resources, and money to receive the care they need. We ask that CMS consider a holistic approach to care, so that an individual’s co-morbidities can be appropriately managed alongside their dialysis treatments. CMS should further consider capturing data related to SDoH and using it to prevent co-morbidities. We also urge CMS to invest in educating individuals on CKD. The CDC estimates that 40% of people with severely reduced kidney function (and not on dialysis) are not aware of having CKD (CDC, Chronic Kidney Disease Initiative, February 28, 2022). As CKD progresses in these individuals, the more expensive their treatment becomes. Catching CKD earlier not only benefits the individual and affords them a better quality of life, but also helps curb the cost of treatment for CKD.

c. As CMS is aware, there is an acute lack of data related to specific patient populations. While ANNA members can provide countless anecdotes on factors that affect communities of color, we are not equipped to collect the data in a meaningful way. As CMS proceeds to discuss how to address data collection and analysis, ANNA would appreciate the opportunity to be a part of the discussion to provide the viewpoint of practicing nephrology
registered nurses who can help understand the data and its implications.

d. When deciding what additional data to collect, we recommend collecting data related to food insecurity, shelter insecurity, and access to transportation, as this can greatly affect the quality of patient care.

e. Regarding technology, ANNA supports new and innovative technologies in the dialysis space. However, the technology is not useful for those who do not have internet access. We urge CMS to work with Congress and other regulatory agencies to swiftly address the issue of broadband access to ensure an individual’s care needs are met.

f. When collecting self-identified demographic data, we urge caution as this collection method may perpetuate racial disparities (See White, K., Lawrence, J.A., Tchangalova, N. et al. Socially-assigned race and health: a scoping review with global implications for population health equity. Int J Equity Health 19, 25 (2020) for further details).

g. Additionally, CMS should consider collecting SDoH 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 in-home dialysis adoption.

h. Finally, we recommend:

• Expanding access to CKD screening to be included in the annual wellness benefit;
• Incentivizing medical professionals to specialize in nephrology; and
• Providing CKD treatment and education earlier in the progression of the disease and before an individual’s kidneys fail.

We appreciate the opportunity to comment on these important issues. As always, we are eager and available to be a resource to you and your staff on these and other important health care matters. Please do not hesitate to contact me at (angie.kurosaka@gmail.com) should you have any questions or if we can be of any assistance.

Sincerely,

Dr. Angie Kurosaka

Angie Kurosaka, DNP, RN, CNN, CCM, NEA-BC
President, American Nephrology Nurses Association