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September 16, 2019

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-5527-P
P.O. Box 8013
Baltimore, MD 21244-8010

Re: CMS-5527-P; Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures; Fed. Reg. Vol. 84, No. 138 (Thursday, July 18, 2019)

Dear Administrator Verma:

On behalf of the American Nephrology Nurses Association (ANNA), I am writing to provide comments on the proposed rule for the "Specialty Care Models to Improve Quality of Care and Reduce Expenditures (CMS-5527-P; 84 Fed. Reg. 138)."

ANNA applauds the President and U.S. Department of Health and Human Services (HHS) Secretary, and the Administrator of the Centers for Medicare and Medicaid Services (CMS), for taking bold action to propose the ambitious goals in the "Advancing American Kidney Health" Executive Order. ANNA fully supports the initiative's goal of "improving the lives of Americans with kidney disease by expanding treatment options and reducing health care costs."

The enclosed comments speak to the mandatory payment model to move more patients from in-center to home dialysis and increase the number of patients receiving kidney transplants. ANNA supports the stated goals of the initiative: increasing efforts to prevent, detect, and slow the progression of kidney disease; providing patients who have kidney disease with more options for treatment; and increasing the availability of organs for transplant. ANNA would very much like to play an active role in the development of the policies that will be implemented to achieve these objectives.

ANNA views this initiative as an opportunity for nephrology nurses to be strategic and forward-thinking regarding the expertise our profession has to offer. ANNA believes the successful implementation of the initiative will require the active involvement of nephrology nurses who possess the necessary education, training, and clinical skills to provide the most effective care to patients with kidney disease in all settings. Nephrology nurses must not only be at the table, they must have a leading role as full partners with HHS, CMS, and other stakeholders in the process.

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 of more than 8,500 registered nurses in 80 local chapters across the United States. Members practice in all areas of nephrology, including hemodialysis, chronic kidney disease, peritoneal dialysis, acute care, and transplantation. Most of our members work in freestanding dialysis units, hospital outpatient units, outpatient clinics, and hospital inpatient units.

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

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

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

Nephrology Nurses are Essential to Quality Patient Care in all Modalities

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

Nephrology nurses are indispensable in providing individuals with kidney disease with quality care and ensuring, to the extent medically possible, each one experiences successful outcomes in their chosen treatment modality. These dedicated nurses have been on the frontlines during the implementation of every new treatment and payment model change for End-Stage Renal Disease (ESRD) care. 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.

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. The policy and treatment changes outlined in the Agency's proposed rule for the ESRD Treatment Choices (ETC) Model represents a monumental change in the treatment of patients with chronic kidney disease and ESRD. There must be substantial changes made to ensure staffing, training, education, and preparedness of the nephrology-nursing workforce to achieve the desired outcomes in the proposed rule and the overall initiative.

As the professional organization representing this important group of health professionals, we believe it is critical that the Agency consider the perspectives, views, concerns, and recommendations of nephrology nurses on how the ETC model is designed and the policies governing the model implementation.

Overview of ANNA's Comments on ETC Proposed Rule

ANNA is an active member of a number of different formal and informal coalitions, and groups involved in health policy advocacy issues affecting the nursing profession, kidney disease prevention, treatment, and research. We are proud to be a signatory of the comment letters submitted by Kidney Care

Partners (KCP) and the Alliance for Home Dialysis (Alliance). While ANNA has endorsed the various recommendations in the KCP and Alliance letters, the following comments are focused on the role of nephrology nurses in treating their patients safely with the highest quality of care, while ensuring the nurses' voices and concerns are heard, and their roles as health professionals are supported and protected.

ANNA urges CMS to consider how to address and plan for the concerns raised in this letter and to work directly with ANNA, members of the kidney and nursing communities, and other relevant stakeholders to address these issues before implementing the ETC payment model. These are the major topics or categories of ANNA's comments on the proposed rule:

- **Ensuring an Adequate and Qualified Nursing Workforce**
- **Recruiting and Retaining Qualified Nephrology Nurses**
- **Training, Education, and Preparation for Nurses, Patients, and Caregivers**
- **ANNA's Requested Actions on the ETC Model**

Ensuring an Adequate and Qualified Nursing Workforce

The shortage of registered nurses in the United States is a recurring issue. Economic, workforce, and market issues have been the primary drivers of the limited supply of qualified nurses. The shortage of nephrology nurses providing in-center care is an issue ANNA has raised with the Agency in previous comments and remains a great concern under the ETC model proposal. The demands for skills needed to treat the medically complex patient with end-stage renal disease require a robust, educated, and properly trained nursing workforce that is not currently in place.

The factors causing the nephrology nursing shortage are similar to the factors causing nursing shortages in other areas of practice and specialization. These include an aging workforce, the lack of adequate staffing to serve a growing patient population with complex conditions, high registered nurse workloads, an unsupportive dialysis work environment, limited exposure to nephrology nursing during undergraduate nursing programs, and an extremely high level of "burnout" resulting in nephrology nurses leaving the specialty and in some cases, the profession.

The shortage of nephrology nurses is occurring at a time when in-center dialysis clinics have been implementing and adapting to the relatively new Medicare Prospective Payment System (PPS) and Quality Incentive Program

(QIP). ANNA has been a supporter of the ESRD PPS and QIP from its inception. We have provided detailed written comments, met with CMS leaders and career staff on relevant issues, and our members have served on various Technical Expert Panels to assist the agency with key initiatives.

However, the collection of patient data and clinical information for this focus on quality measures has been largely placed upon the limited number of nurses staffing outpatient dialysis facilities. We recognize the importance of the many QIP clinical, reporting, and monitoring measures. However, a shortage of nephrology nurses combined with this increased administrative responsibility, as we mentioned to the Agency in previous comments, has decreased the amount of time nephrology nurses have to devote to direct patient care.

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. ANNA is deeply concerned the ETC model proposed rule does not offer a strategy or plan to address the issue of ensuring sufficient nephrology nurses are available and prepared to make this transition from primarily in-center to primarily home dialysis care.

Recruiting and Retaining Qualified Nephrology Nurses

ANNA supports the Administration's efforts to shine a light on the number of Americans living with chronic kidney disease. However, it is critical that the Agency recognize that the lack of adequate nurse staffing and the shortage of nephrology nurses available to assist may thwart any move towards a new model of care. 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 needs to address directly. Additionally, the United States is facing a shortage of nephrologists entering practice compounded by an increasing number of retiring nephrologists. To address this issue, nephrology nurse practitioners have been hired to fill this void and additional nephrology nurse practitioners will need to be recruited and educated to meet patient demands.

The challenges facing the nephrology-nursing workforce all have a direct impact on the ability to recruit and retain qualified registered nurses in nephrology. The entire nursing workforce, including those in nephrology, is aging and the number of nursing students going into the specialty has not kept pace with increasing demand for their services.

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 profession. ANNA believes the level of nephrology burnout and job dissatisfaction has discouraged other registered nurses from pursuing the specialty as a career option.

ANNA is concerned that these demands and burnout will increase with home dialysis patients requiring a 24-hour, seven-day-a-week resource, via a nurse-staffed hotline or phone system, to address clinical concerns or assist with technical problems with the patient's home dialysis equipment. We agree this would be a role nephrology nurses are qualified and suited to provide; however, without adequate nurse staffing this added responsibility can lead to overload and burnout. ANNA encourages the Agency and the industry to account for the need of registered nurses to manage these types of services when calculating the demand for nursing staff.

Training, Education, and Preparation for Nurses, Patients, and Caregivers

ANNA supports the Agency's efforts to increase home dialysis care and transplantation. However, ANNA is concerned about the absence of a proposed structure or plan for implementing the training and education needed for nurses, nurse practitioners and all providers, as well as patients, caregivers, and others to ensure quality home therapy care. In addition, ANNA believes a standardized training and education process needs to be developed to achieve the desired outcomes for the anticipated large number of patients moving to home dialysis.

Home dialysis care makes it imperative that nephrology nurses and other health providers anticipate and prepare for any complications that may occur, to both smooth the course toward patient independence in home therapy and to prevent therapy failure. There must be an investment in training nephrology nurses so they have the proper skill set to train 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.

It must be understood that moving a registered nurse from a hemodialysis in-center setting into home dialysis training is not a simple process. According to the Medicare Conditions for Coverage for ESRD Facilities (CMS-3818-F), nurses are required to have 12 months' experience as a registered nurse plus 3

months' experience in the modality (i.e. hemodialysis or peritoneal dialysis) and some state ESRD regulations impose more stringent requirements. ANNA urges CMS to give full consideration to this issue during the development of the final rule.

In addition, the skills and training for patient care education and delivery for the in-center and home environments are not interchangeable. Nephrology nurses will require advanced training in home dialysis. The basic level of training is not sufficient for the level of skills and competencies required of nurses who train patients and families in the management of the complexities of home dialysis care. ANNA is concerned that both an insufficient level of nephrology nursing workforce home therapy training and variations in the nurses' home training preparation across dialysis facilities will lead to a lack of standardization in this area. ANNA emphasizes the urgent need for the Agency and key stakeholders to take into consideration the vital role that nephrology nurses serve in the provision of home dialysis education and training to patients, and thus the success of the ETC model. ANNA recommends that a needs assessment be conducted to understand the level of preparedness needed prior to implementation of the proposed rule.

ANNA is extremely concerned that the kidney community and dialysis industry is currently unprepared for the increased number of patients that will transition to home therapy under the proposed rule. ANNA feels strongly that the current staffing model for in-center dialysis care is insufficient for the number of patients who will fail or experience complications requiring them to leave home therapy and return to in-center care at least temporarily. More importantly, ANNA fears that the proposed payment model and incentive for home dialysis therapy may stimulate the encouragement of both incident and prevalent ESRD patients to choose home dialysis when they may not be clinically appropriate or ready for this modality leading to a high failure rate.

ANNA members have expressed concerns about the availability of respite care to provide short-term relief to primary caregivers and patients conducting dialysis in the home environment. ANNA urges the Agency to recognize respite care and to provide resources for it. To sustain patients at home, it is critical that there be a robust support system to provide relief for exhausted patients and/or their caregivers and prevent home therapy failure. We believe an agreed-upon payment mechanism should be established for providing in-center respite treatment without a payment penalty.

ANNA understands the limitations on available space at facilities for home dialysis training. The Agency should consider in the final rule options for

space required, to address the need for both training space and space for scheduled and unscheduled visits. Facilities will need time to secure space and redesign current spaces for home therapy training and clinical appointments.

ANNA's Requested Actions on the ETC Model

ANNA can see pathways to achieving some of the goals and outcomes the Administration listed in the Executive Order. Nephrology nurses are adaptable and forward thinking, and they have historically found a way to provide the highest quality care for their patients regardless of the circumstances or constraints placed upon them. Past experiences have shown that seeking nurses' input and providing a key role for them in the development and implementation of new policies will enhance a timely and cost-efficient execution of policy. We recognize that this policy depends on the nursing workforce for successful achievement of its outcomes; that is, improving the quality of care of patients with kidney disease.

ANNA is hopeful that the Agency will consider the concerns and issues raised in this letter and avoid a decline in patient outcomes, decrease in quality care, and confusion among patients, health professionals, and the Agency. In addition to the comments/recommendations from KCP and the Alliance, the following is a list of actions CMS can take that we believe will be helpful for successful implementation of the ETC model:

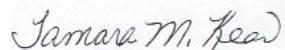
- **Extend the implementation period beyond the proposed April 2020 date to allow patients, nurses, and others impacted by these reforms to properly prepare and address barriers to home therapies and transplants.**
- **Provide a "ramp-up" period at the start of the initiative to allow time to increase the number of qualified home training nurses.**
- **Allow for the training and preparation of an adequate nursing workforce that will be necessary for preparing patients and families for home therapies.**
- **Engage ANNA in the development of strategies that address the need for an adequate nephrology-nursing workforce prior to the implementation of the final rule.**

- **Consider a concurrent pilot project aimed at exploring best practices for the recruitment and retention of an adequate nephrology-nursing workforce to care for Americans living with kidney disease.**
- **Seek out guidance directly from nephrology nurses on the planning and implementation of this and any future reforms to care and treatment of kidney disease patients.**

Conclusion

ANNA greatly appreciates the opportunity to share our views and concerns about the Medicare proposed rule on “Specialty Care Models to Improve Quality of Care and Reduce Expenditures.” As the leading professional association representing nephrology nurses, we look forward to continuing to work with HHS and CMS on these important issues. Should you have any questions, please contact me or ANNA’s Health Policy Representative, Jim Twaddell, at jim.twaddell@dbr.com or 202-230-5130. We thank you for your consideration

Sincerely,



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