August 26, 2024

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

Subject: Comments on Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

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, Conditions for Coverage for End-Stage Renal Disease Facilities, 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 you additional 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)**

ANNA continues to reinforce that the best way to address changes in the market basket's mix of goods and services is to rebase with a more accurate forecast error. This year, like last year, CMS is again using 2020 data to determine the current mix of goods and services, leading to only a 1.8% increase in reimbursement. This marginal increase is not nearly enough to ensure adequate reimbursement for ESRD services. In fact, in its March 2024 report to Congress, the Medicare Payment Advisory Commission (MedPAC) estimated a margin of zero for 2024,[1] indicating that there are many facilities below zero as well. As KCP states, given the significant increasing costs, it is impossible for many facilities to be able to adjust to unexpected events when they occur or continue providing services as usual to individuals. Additionally, we urge CMS to consider the following related to the proposed PPS changes:

Inflation

The market basket update in the proposed rule fails to account for the substantial and continued increase in costs faced by dialysis facilities, such as inflation. The Medicare annual inflationary update has not kept pace with actual inflation. As KCP notes 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. Furthermore, research demonstrates that health care costs will rise 7% in 2024 as providers face higher expenses, and those expenses must be passed on to the beneficiaries.

[1]MedPAC. *Report to the Congress: Outpatient Dialysis Services* (Mar. 2024).

Workforce

Inflation-related issues overlap workforce shortages as serious gaps in the health care workforce drive wages higher, leading to access to care challenges, site of care closures, and increased wait times. For example, due to workforce shortages, ANNA members have expressed frustration in maintaining patient schedules, starting treatments in a timely fashion, and ensuring they obtain their prescribed treatment times. Additionally, individuals continue 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 significant barrier for those who need to schedule around work and to ultimately maintain a productive life. Relatedly, there have also been reports of unnecessary and extended hospital stays as dialysis facilities are unable to accommodate new beneficiaries.

Unfortunately, due to inadequate reimbursement, dialysis units are unable to compete with salaries for a qualified workforce. Recruiting and retaining qualified nephrology registered nurses, and appropriately training, educating, and preparing nurses, are of particular concern. The shortage of nephrology nurses is further exacerbated by the loss of experienced staff (which may be due to retirement or nurses leaving the profession altogether), which leads to a loss of mentors to develop new staff. Additionally, limited exposure to nephrology in undergraduate and graduate nursing programs, and the ongoing and increasing number of individuals needing kidney replacement treatments also impact the availability of nephrology nurses. Furthermore, workforce issues require essential resources from stakeholders to build a nursing workforce including but not limited to: reasonable lengths of shifts, safe registered 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. These changes are necessary to demonstrate to nephrology nurses that they are supported and valued for their contributions, which will help turn the tide on the workforce shortage in this critical service area.

Oral Bundle

This year, CMS is proposing to incorporate oral-only drugs and biologics in the ESRD PPS using the transitional drug add-on payment adjustment (TDAPA), as previously introduced in the 2016 final rule. ANNA has long supported any policies that allow greater access to care. However, as KCP states in their letter, there is

concern around adding phosphate binders and phosphate lowering drugs to the bundle because such medications must be taken outside of the facility during a time when the patient eats. As you are aware, the doses can vary due to the amount of food eaten by the patient, which makes the regulation of these medications difficult. While the intention to incorporate these medications into the bundle is sound, the implementation will prove to be difficult and much of the process will fall to registered nurses, who are already in short supply. Registered nurses already will likely be responsible for taking on the burden of tracking and dispensing medications, which ultimately means less time with the patient. As such, we urge CMS to rethink the proposed strategy related to adding phosphate binders and phosphate lowering drugs to the bundle.

Furthermore, there is some concern with patients in skilled nursing facilities who received their medications under the Part D program. We agree with KCP, that additional guidance is necessary for a smooth transition for this patient population.

2. Quality Incentive Program (QIP)

CMS proposes changes to the QIP in significant ways, including replacing the Kt/V Dialysis Adequacy measure as described below. As the agency considers adjustments to the QIP, we strongly urge CMS to ensure that new policies do not unintentionally disrupt patient care and are paired with clear guidance and thoughtful support that enable nephrology nurses to continue to do what they do best.

Kt/V Dialysis Adequacy Comprehensive Clinical Measure

ANNA supports replacing the Kt/V Dialysis Adequacy Comprehensive clinical measure with multiple measures to maximize patient-centered outcomes. We appreciate that CMS has considered stakeholder perspectives in recognizing how the comprehensive measure lacks the clinical specificity needed to fully assess the quality of care for specific patient populations or dialysis modality. Furthermore, a single measure impedes understanding of how social determinants of health (SDOH) intersect with dialysis adequacy.

As CMS works to finalize the individual measures, it is crucial that any new changes do not inadvertently impose excessive administrative duties on nephrology nurses, such as new reporting burdens that divert time away from patient care. As KCP highlights in its letter, we similarly concur with CMS's

rationale that "[b]y replacing the current Kt/V Dialysis Adequacy Comprehensive clinical measure with four separate measures, [CMS] would be able to assess Kt/V performance more accurately based on whether the patient is an adult or child and what type of dialysis the patient is receiving."

To further promote quality of care, we also agree with KCP that CMS should utilize the original QIP reporting requirements, which outlined performance at the individual measure level on the posted certificate rather than a composite, aggregated approach. This delineation is crucial to ensuring that the ESRD QIP program is implemented as intended by Congress and that those needing ESRD services, caregivers, providers, and health systems are provided with transparency on the individual facility performance to guide informed decision-making.

Lastly, ANNA joins KCP in supporting weighting the Kt/V measures in total at 11%. We believe that this amount is both appropriate and balanced with respect to statutory requirements and allowing for weighting flexibility for other measures.

Reducing the Number of Measures

ANNA urges CMS to comprehensively evaluate the remaining measures to ensure that the agency is prioritizing quality rather than quantity. Currently, the ESRD QIP is composed of nearly 20 performance measures for a single disease state. While we commend the agency for incorporating a multi-factorial approach to kidney care, we remain concerned that the existence of too many measures may dilute the significance of each single measure and ultimately hinder the accurate measurement of patient outcomes. As a starting point, we join with KCP in supporting the agency's removal of the National Healthcare Safety Network (NHSN) Dialysis Event report measure beginning with PY 2027. We also concur with the concerns identified by KCP regarding the specifications of many of the remaining measures in the ESRD QIP and urge CMS to adopt KCP's proposed recommendations.

Ensuring Measure Alignment with ESRD QIP Value-Based Purchasing Program and Dialysis Facility Compare

To avoid inconsistencies, duplicate efforts, and ensure meaningful measures, CMS must precisely tailor the intended goals of each measure to the stated goals of the Value-Based Purchasing Program and Dialysis Compare. To that end, we support KCP's recommendations regarding which measures should be included in the ESRD QIP value-based purchasing program and which measures should be available

through Dialysis Facility Compare. We believe this reconfiguration is essential to transparency, syncing the measures with their appropriate program to better promote patient decision making and harmonizing their inclusion in the QIP penalty program.

Revaluating Existing Weighting of Domains and Individual Measures

As conveyed above, we strongly believe that the existence of 20 individual measures diminishes the value of each measure due to the weighting system. Although CMS has taken steps to group measures that allocate more weight to certain groups (i.e., domains), we believe this does not go far enough. Therefore, we request that CMS further assess the specifications of each measure, as proposed by KCP, and once the set of measures are refined, recalibrate weighting accordingly. We also urge CMS to meet with ANNA and other kidney care partners prior to the next rulemaking cycle to further discuss weighting.

Continued Application of the ESRD Methodology

ANNA is supportive of the QIP methodology and supports the proposal outlined in the Proposed Rule.

Updating the Data Validation Program

We agree that the success of the ESRD QIP depends on "ensuring that the data submitted to calculate measure scores and [Total Performance Scores] are accurate."[2] We believe CMS must make changes to the current data validation policy to facilitate accurate and comprehensive reporting of ESRD QIP data. These changes should include revising the data validation system both for the EQRS and the NHSN; providing greater transparency on the results of data validation surveys; and implementing a comprehensive due process policy that ensures providers reporting to the ESRD QIP are afforded the same protections as those of other CMS audit programs. Similar to KCP, ANNA would also support bonus payments to facilities that exceed data reporting and accuracy requirements so long as money for these awards is new money and is not subject to budget neutrality requirements; funds should not be diverted from payments made to ESRD facilities.

[2]CMS. "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model." 89 *Fed. Reg.* 55760, 55822 (July 5, 2024).

3. Health Equity Adjustment

In 2021, 18.9% of those with ESRD were dually eligible for Medicare and Medicaid.[3] It is well-documented that reported dual-eligibility status is inextricably linked to negative health outcomes and many dual-eligible beneficiaries have more complex health care needs than their counterparts.[4] As KCP notes, CMS has recognized that providers who care for dually-eligible individuals in skilled nursing facilities (SNF) and inpatient settings often have difficulty achieving quality improvement benchmarks. CMS has also previously recognized the impact of dual-eligible status in the ESRD Treatment Choices (ETC) model. In response to both situations, CMS has adopted a health equity adjustment (HEA) to support providers who serve a greater proportion of dually eligible individuals. While we support CMS's efforts to ensure access to quality care, ANNA believes it is prudent for CMS to consider designing an HEA specific to the ESRD QIP program to ensure that underserved, rural, and otherwise hard-to-reach communities receive high-quality care.

HEA Adds Value to ESRD QIP

We agree that adopting a health equity adjustment helps promote and incentivize equitable, high-quality care and addresses the impacts of non-medical drivers of health. A lack of an HEA for ESRD QIP further exacerbates care inequities and, therefore, disparities in ESRD treatment. As KCP notes, in the inpatient hospital setting, the HEA has resulted in safety-net hospitals receiving payment adjustment increases. As such, ANNA encourages CMS to implement a HEA-specific to the ESRD QIP program to help keep parity for facilities that serve dual-eligible beneficiaries, which can be used to advance equitable care and outcomes across the nation. Furthermore, ANNA joins KCP in encouraging CMS to work with the kidney community to develop a health equity adjustment for the QIP program.

Drawing Upon the Hospital Inpatient PPS (IPPS) HEA

As KCP explains in their comments, CMS can reference the IPPS HEA as a model framework for developing a HEA unique to the ESRD QIP program. We believe that

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[3]USRDS. Annual Data Report. Ch. 9 "Healthcare Expenditures for Persons with ESRD." (2023). Available at: https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd.

[4]Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based- purchasing-programs*.

the bonus-scoring system underpinning the IPPS policy, which awards additional payments to providers who serve larger populations of dual-eligible, is compatible with the design of ESRD QIP and a flexible structure to support individuals with ESRD and facilities. ANNA concurs with KCP that the 60-day comment window for a health equity scoring policy is too soon given the implications of the adjustment for patients and providers alike. Before a potential policy is proposed, ANNA urges CMS to actively consult the ESRD care and clinical community over the next few months to ensure that the adjustment comprehensively reflects the full continuum of ESRD care. To that end, we are committed to serving as a resource to the agency in this area to ensure that nephrology nurses' perspectives are adequately reflected in the proposed policy.

4. **Transitional Period for End-Stage Renal Disease Alternative Payment Model (TPEAPA)**

The continuation of the TPEAPA for pediatric ESRD patients at 30% is beneficial. We urge CMS to consider extending similar support to adult nephrology services, recognizing the unique challenges faced by nurses managing complex adult cases, particularly those involving new and innovative therapies.

5. **End-Stage Renal Disease Treatment Choices (ETC) Model**

The ETC Model's focus on increasing home dialysis and kidney transplant rates is commendable. ANNA joins KCP in supporting the proposed modification to the definition of ESRD beneficiary. Additionally, we echo KCP's comments to the ETC RFI. Specifically, we agree that individuals should have the opportunity to select the dialysis modality that meets their needs and support policies that allow flexibility for home dialysis or in-center dialysis. We also agree with KCP's comments urging CMS to reduce barriers to support patient access. KCP cites the following examples to demonstrate barriers: "For example, dialysis facilities employ dieticians, social workers, and other professionals as part of their care for patients and to help develop each patient's individualized plan of care. These professionals should be allowed to engage with each patient's physician and care teams outside of the facility as well. Yet, current law prohibits the coordination, because physicians are also referring patients to the facilities that employee these professionals. Another example relates to encouraging more home dialysis options for patients. Facilities could provide training, equipment, and/or space to physicians to help them educate their patients prior to starting dialysis about their modality options. But, again, current law blocks this type of coordination."

6. **Home Dialysis Access for Individuals with AKI**

KCP supports extending coverage and reimbursement for home dialysis modalities to individuals with acute kidney injury (AKI) but opposes an additional budget neutrality adjustment for the training add-on. The current ESRD base rate already includes this adjustment, and there is no evidence that utilization of home dialysis will differ significantly between AKI and ESRD populations. Implementing an $8.50 per treatment cut would create a substantial barrier to accessing home dialysis for AKI patients and contradicts CMS's efforts to promote home dialysis. Therefore, KCP urges CMS not to adopt the proposed adjustment.

Additional Consideration

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

One solution to this nursing shortage has been to try to fill the gap with other health care and non-licensed health care providers. While on the surface this seems like a simple solution to the workforce shortage, the unintended consequences cannot be ignored. 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, develop a care plan, then educate patients and their caregivers on how to execute the plan, and then follow up with evaluating the success of 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 divided 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 patients' 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 to circumvent them while making policy decisions that

ultimately impact patient safety. The expertise of registered nurses should be considered when making policy decisions about a role for which they have expert knowledge and will therefore lead to the best patient outcomes.

In recent years, CMS and Congress have explored avenues to move care for Medicare beneficiaries into the home. 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 serve 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 registered nurses 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, the impacts of the COVID-19 pandemic and ongoing workforce issues are causing nephrology nurses to leave the profession in large numbers, which in turn impacts the number of nurses available to train and manage patients on home dialysis therapy.

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 Home Dialysis 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. ANNA also established the Home Dialysis for Nursing Home Residents Task Force to determine the role of the registered nurse in home therapies in nursing homes/skilled nursing facilities. 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,

Nancy Colobong Smith, MN, ARNP, ANP-BC, CNN
President, ANNA