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August 22, 2022

Via Electronic Mail
Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Attn: CMS-1768-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator Brooks-LaSure,

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the proposed Calendar Year (CY) 2023 End Stage Renal Disease Prospective Payment System proposed rule. AdvaMed member companies produce the medical devices and technologies that play a crucial role in allowing Medicare beneficiaries to lead healthy, productive, and independent lives in their homes and communities, thereby fulfilling the intent of Congress when it created benefits to assist persons with serious kidney disease. We strongly support policies that improve treatment choices for patients with ESRD and address systemic barriers that may limit access to the full range of treatment options available for the approximately 400,000 Medicare beneficiaries with kidney failure.

Our comments below address several topics:

- Addressing Barriers to Patient Modality Choice
- Increasing Use of Telehealth and Remote Monitoring Technology

- Refining the Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Program
- End Stage Renal Disease Quality Incentive Program (ESRD QIP)
- ESRD Treatment Choices (ETC) Model

Addressing Barriers to Patient Modality Choice

Treatment Modality Choice for Patients with ESRD

As stated in previous comment letters, we support CMS' efforts to increase patient options for dialysis treatment beyond in-center hemodialysis and empower these patients to make decisions about their care. We further support CMS' efforts to identify barriers to patient access and choice in home dialysis (i.e., home hemodialysis (HHD) and peritoneal dialysis (PD)). There is a disproportionate lack of home dialysis access for low-income communities and communities of color. Nationally, Black patients are 30.1% less likely, and Hispanic patients are 7.6% less likely than white patients to start PD. Similarly, for HHD, Hispanic patients are on average 42.1% less likely, and Black patients are 9.8% less likely, to receive HHD.[1] Non-white patients are also more likely to start dialysis urgently and most patients who start dialysis in a hospital are immediately referred for in-center dialysis upon discharge making urgent start solutions for "crash" patients to access PD and HHD critical to achieving near-term equity in home dialysis access.[2]

Hemodialysis is the modality most often initiated by hospital staff for urgent start patients, but often the patient is discharged to an in-center hemodialysis clinic. HHD is a safe and effective modality for patients not previously diagnosed with chronic kidney disease or ESRD who initiate dialysis as emergency treatment (incident or "crash" start patients). There has been a long-missed opportunity for educating these patients about their option for conducting HHD while in the hospital. In addition, studies have shown that HHD, when received more than three times per week, has similar patient survival rates as a kidney transplant.[3] Solutions that would encourage and facilitate initiation of home education and training in the hospital by nephrologists, dialysis nurses and hospital social workers, could significantly increase the adoption of HHD for incident patients, but would require changes to the ESRD Conditions for Coverage interpretive guidance to allow for this early approach.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4926974/
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4926974/
[3] Nishio-Lucar AG, Bose S, Lyons G, Awuah KT, Ma JZ, Lockridge RS Jr. Intensive Home Hemodialysis Survival Comparable to Deceased Donor Kidney Transplantation. Kidney Int Rep. 2020;5(3):296-306. Published 2020 Jan 9. doi:10.1016/j.ekir.2019.12.019

Currently, PD is the dominant home modality in the US,[4] and a choice patients should have when considering modalities. CMS should address removing existing barriers to PD catheter placement as part of its larger effort to increase home dialysis access and uptake. As CMS has previously noted, there are several significant barriers impacting PD catheter placement, including:

- Lack of dedicated hospital-based catheter insertion teams for unplanned peritoneal dialysis starts;[5] instead, these patients are often given a central venous catheter[6] and reflexively shuttled to in-center hemodialysis, even if home dialysis would be a better option;
- Inadequate training of surgeons and interventional radiologists on PD catheter insertion methodology;[7] and
- Obstacles related to scheduling of operating room time.[8]

However, the most striking barrier, and the one CMS has the most ability to correct in the immediate term, is the low reimbursement for PD catheter placement. We therefore believe that if CMS wants to increase PD uptake, the Agency must incentivize increasing PD catheter insertions.

AdvaMed therefore requests CMS:

- ***Collaborate across payment systems to incentivize increasing PD catheter insertions by increasing reimbursement for PD catheter placement.***

Treatment Modality Choice for Patients with Acute Kidney Injury (AKI)

Under current Medicare payment policy, patients with AKI are limited to receiving in-center hemodialysis, regardless of their individual prognosis or course of treatment prior to hospital discharge. As a result, these patients are often subject to the standardized treatment durations and schedules intended to treat patients with ESRD, not patients with dialysis-dependent AKI, who could potentially avoid long-term dialysis through recovery of function. This current policy restricting access to home dialysis modalities for AKI patients also perpetuates the current inequity in the use of home dialysis among people of color. Black Americans are more likely than White Americans to experience AKI;[9] as a result, this policy

[4] "At the end of 2018, there were nearly 69,000 patients performing dialysis in the home, or 12.5% of all patients undergoing dialysis. Nearly 85% of patients on home dialysis performed peritoneal dialysis." https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4658397/
[6] There is broad agreement in the kidney disease clinical community that CVC is a suboptimal dialysis access, therefore we decided to deal only with best practices (either PD catheter or fistula) in this letter. There is no desire to increase placement of CVCs.
[7] https://kidney360.asnjournals.org/content/1/10/1165
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4114666/
[9] Grams ME, Matsushita K, Sang Y, Estrella MM, Foster MC, Tin A, et al. "Explaining the racial difference in AKI incidence." 25 J Am Soc Nephrol 1834-41. (2014).

expands the existing gap in the ability of Black Americans with kidney failure to select their preferred treatment modality.

Since Congress expanded treatment options for those living with AKI to include dialysis facilities, clinical understanding of AKI has advanced. Initially, CMS expressed concern about AKI patients receiving dialysis at home, particularly PD. However, during the COVID-19 public health emergency (PHE), many patients who developed AKI received home dialysis successfully. The initial safety concerns that underly the current policy have been shown to be unwarranted.

Both professional nephrologist societies, the Renal Physicians Association and the American Society of Nephrology, agree AKI patients can safely receive dialysis at home via PD or HHD. The Renal Physicians Association has long supported access to all dialysis modalities for AKI patients, stating, "In light of the increased emphasis on expanding access to home dialysis in general and the increasing number of programs utilizing emergent or urgent peritoneal dialysis as opposed to hemodialysis as rescue therapy for patients presenting in urgent need, excluding such patients from coverage seems counter to the shared goal."[10]

While CMS has not proposed an allowance for dialysis-dependent AKI patients to receive care at home in this rule, CMS could establish a waiver now that extends to outpatient AKI dialysis under the current PHE. Longer-term, CMS should permanently allow for AKI dialysis at home to be reimbursed, include an adjuster to the PPS for dialysis-dependent AKI patients to receive staff-assisted dialysis at home, and reimburse for home training for these patients.

AdvaMed therefore requests CMS:

- ***In the short term, establish a waiver enabling AKI patients to access home dialysis modalities for the duration of the current PHE; and***
- ***In the long term, eliminate the payment policy limiting AKI patients access to home dialysis modalities.***

Increasing Use of Telehealth and Remote Monitoring Technology

The standard of care for Medicare ESRD patients is evolving towards more patient-centered modalities, including the use of remote patient monitoring (RPM) tools and services. Increased use of digital tools and online applications often empower patients to take a more active role in their healthcare decisions alongside their care providers. RPM tools enable providers to track the progress of disease and empower dialysis patients with the option to have their physiologic and therapeutic information monitored remotely, reducing the need for in-person visits.

However, a lack of clear payment pathways for these tools creates a barrier to the use of these tools by physicians and patients alike. The ESRD PPS provides a case-

[10] Renal Physicians Association. "RPA Comments on the 2017 ESRD PPS Proposed Rule Including AKI Policy" http://www.renalmed.org/page/ESRDPPSRuleComments? (2016).

mix- and facility-adjusted, per treatment bundled payment for dialysis, including drugs, laboratory services, equipment and supplies, and capital related costs. Under the current system though, there is no separate reimbursement for new digital health technology, resulting in little incentive to adopt and use innovative tools that improve ESRD patient experiences and outcomes.

To improve adoption of innovative care management and treatment technologies for ESRD patients and to increase patient access to these technologies, AdvaMed asks CMS to allow renal dialysis facilities to bill separately for remote patient monitoring tools. Providing payment for adopting and deploying remote patient monitoring tools will enhance treatment care options for ESRD patients.

Further, we support the determination in the CY 2020 PFS Final Rule that CPT codes for RPM services 99091, 99453, 99454, and 99457 should be billable monthly. In addition to our belief that CMS should allow the use of these codes for ESRD patients, we would suggest that CMS allow these codes to apply for patients with acute kidney injury (AKI) who may still be recovering their kidney function. Such patients can benefit significantly from the option to have their physiologic information monitored remotely, negating the need for frequent in-person visits.

AdvaMed therefore requests CMS:

- ***Allow renal dialysis facilities to bill separately for remote patient monitoring tools; and***
- ***Extend CPT codes for RPM services to patients with AKI.***

Refining the TPNIES Program

We applaud CMS' efforts to date to remove barriers to adopting innovative technologies and services for ESRD treatment. The Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) is a critical pathway for patients to access innovative and novel dialysis equipment that can improve patient care, particularly for dialysis care outside of the dialysis facility. However, we remain concerned that overly restrictive requirements may blunt the intent of this new incentive to encourage innovation in the delivery of dialysis care. We are therefore writing to recommend specific modifications to the TPNIES program to further improve this important lever in driving innovation for ESRD patients.

Provide an Additional Year of TPNIES Payments for Devices Receiving Payment Due to the Ongoing Public Health Emergency (PHE)

During the FY/CY 2022 rulemaking cycle, CMS exercised its equitable adjustment authority to provide for one-year extensions to devices receiving payment under the New Technology Add-On Payment (NTAP) and Transitional Pass-Through (TPT) payment programs. AdvaMed applauded this decision to extend NTAP and TPT payments, and request CMS provide a similar extension for devices receiving

TPNIES. The PHE continues to have a major impact on providers' ability to adopt new innovative technologies, as demands associated with the PHE have created a direct burden on resources and utilization of new technologies due to the unordinary treatment patterns for patients. Due to these ongoing resource constraints, we believe an additional year of TPNIES is necessary to allow time to collect claims and cost data that align more closely with typical patterns of care for patients utilizing these technologies.

AdvaMed therefore requests CMS:

- ***Provide technologies that have been approved for TPNIES an additional year of payments due to the ongoing PHE.***

Provide Guidance on the Substantial Clinical Improvement Criteria Specific to the ESRD Setting

In adopting TPNIES, CMS outlined that applicants would need to demonstrate that they are "innovative" by meeting substantial clinical improvement (SCI) criteria. The Agency then adopted the standard for SCI based on the Inpatient Prospective Payment System (IPPS) regulations at 42 CFR 412.87(b)(1) and related guidance.[11] While we understand and agree with the goal of promoting consistency and across the different payment systems, we remain concerned application of the TPNIES criteria to applications to date fails to consider the unique challenges of testing new ESRD technologies and treatments. The ESRD population is diverse and complex, making it difficult to test interventions within the framework of a traditional randomized controlled trial design. Difficult recruitment and high dropout rates are also common in clinical trials involving ESRD patients, with high illness burden as one possible factor.[12,13,14] Furthermore, we believe the need for evidence must be balanced against the costs and time involved in collecting data, and how that process can delay the availability of novel technologies addressing important unmet clinical needs.

AdvaMed therefore requests CMS:

- ***Provide additional guidance on the type and level of evidence required to support a successful TPNIES application, taking into***

[11] *See* CY 2021 ESRD PPS Final Rule at 60650.
[12] Kovesday, C., Clinical trials in end-stage renal disease –priorities and challenges. Nephrol Dial Transplant (2019) 34:1084-1089. Doi: 10.1093/ndt/gfz088.
[13] Farragher, J.F., Thomas, C., Ravani, P., Manns, B., Elliott, M. J., & Hemmelgarn, B. R. Protocol for a pilot randomised controlled trial of an educational programme for adults on chronic haemodialysis with fatigue (Fatigue-HD). BMJ open, (2019) 9(7), e030333. https://doi.org/10.1136/bmjopen-2019-030333.
[14] Israni, A.K., Halpern, S.D., McFadden, C., Israni, R.K., Wasserstein, A., Kobrin, S., Berns, J.S. Willingness of dialysis patients to participate in a randomized controlled trial of daily dialysis. (2004) 65(3):990-998. https://doi.org/10.1111/j.1523-1755.2004.00460.

consideration the unique challenges associated with studies in the ESRD setting.

Extend TPNIES Adjustment Period to Three Years

We continue to recommend CMS extend the TPNIES adjustment period from two years to three years. CMS has expressly stated the basis for the TPNIES payment adjustment is to enable and support the adoption of new technologies in the ESRD continuum of care, and we wholeheartedly agree. In its current form, the ESRD PPS Final Rule requires providers to cover the incremental cost of using new technologies under the existing ESRD PPS bundled rate at the conclusion of the two-year TPNIES period. This differs from the Transitional Drug Add-on Payment Adjuster (TDAPA) used to collect data to inform incorporating the costs of new drugs into the bundled payment. TPNIES instead, is an incentive for providers to adopt new and innovative equipment and supplies through an off-set to the cost. Furthermore, companies that frequently bring new and innovative equipment and supplies to market are smaller; and they tend to lack the type of distribution and support infrastructure that their larger, more established counterparts may feature. Staffing constraints of smaller manufacturers mean that most ESRD facilities would only have several months of TPNIES coverage by the time a smaller company could make the technology available to them. Accordingly, a two-year runway still leaves a level of risk that could discourage smaller start-up companies from pursuing the development of new and innovative equipment and supplies. Extending the coverage period would help small innovators take full advantage of the TPNIES program.

The NTAP for the IPPS allows for technologies to qualify for the add-on up to three years to account for the lag time in data collection to be reflected in updated diagnosis-related groups (DRGs). This is most analogous to TPNIES because while CMS is not proposing to increase the bundle for TPNIES products, the ESRD market basket update will likely take three years, if not more, to reflect the updated costs of equipment. Given that it takes significantly longer for devices, particularly home dialysis machines to achieve significant adoption, CMS should align with the NTAP policy and allow for an additional year of TPNIES.

AdvaMed therefore requests CMS:

- ***Extend the TPNIES coverage period to three years to allow sufficient time for innovative technology uptake and account for the lag time in data collection to reflect updated equipment costs.***

Adopt a Post-TPNIES Payment Adjustment

Lastly, in its current form, the ESRD PPS Final Rule requires providers to cover the incremental cost of using new technologies under the existing ESRD PPS bundled rate at the conclusion of the current two-year TPNIES period. This assumes sufficient data will be collected and the bundled rate will be updated in a timely

fashion cover any additional costs for the new equipment and supplies. Failure to positively adjust the ESRD PPS base rate after the transitional adjustment period would result in a situation where providers must absorb the costs of new devices after the expiration of the new device add-on payment. This could discourage providers from adopting the new device at the outset or from using the device for the long-term. Both outcomes would hinder innovation and stall improvements in patient care. Until a methodology for incorporating the costs of these TPNIES technologies is properly included in the ESRD PPS, we recommend CMS consider a post-TPNIES payment adjustment to ensure appropriate reimbursement to providers.

AdvaMed therefore requests CMS:

- ***Consider adoption of a post-TPNIES payment adjustment to ensure appropriate reimbursement to providers adopting new and innovative technologies in the ESRD setting.***

End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

Request for Information on Quality Indicators for Home Dialysis Patients

A critical measure of success for home dialysis is avoiding drop-out and permanent conversion to in-center dialysis. Retention is jointly rated as a top priority amongst home dialysis patients and clinicians.[15] As CMS also notes in this proposed rule, "… increasing rates of home dialysis has the potential to not only reduce Medicare expenditures, but also to preserve or enhance the quality of care for ESRD beneficiaries." Measuring annual home dialysis retention rates that exclude transplant (a desired outcome) and mortality (which is already separately measured in the ESRD QIP) are important to ensuring that patients are appropriately supported at home and that known barriers such as treatment burden for patients and care partner fatigue, technical challenges operating a dialysis machine, and supplies management are addressed.[16]

We also encourage CMS to expeditiously pursue and incorporate patient-reported home dialysis experience into an ESRD QIP measure.[17] As CMS works to grow the home dialysis patient population, measuring patient experience and being able to compare that experience to that of in-center patients will become increasingly important. The Home Dialysis Care Experience instrument (a 26-item patient-

[15] Manera KE, et al. Establishing a Core Outcome Set for Peritoneal Dialysis: Report of the SONG-PD (Standardized Outcomes in Nephrology–Peritoneal Dialysis) Consensus Workshop, American Journal of Kidney Diseases, Volume 75, Issue 3, Pages 404-412, 2020.
[16] Chan CT, et al. Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference Outcomes Report American Journal of Kidney Diseases, Volume 73, Issue 3, 363 – 371.
[17] Rivara MB, Edwards T, Patrick D, Anderson L, Himmelfarb J, Mehrotra R. Development and Content Validity of a Patient-Reported Experience Measure for Home Dialysis. Clin J Am Soc Nephrol. 2021 Apr 7;16(4):588-598.

reported experience measure that assesses patient experience of care for patients receiving PD and HHD) was developed in collaboration with 21 home patients, three patient care partners, 33 home dialysis nurses, and eight nephrologists. CMS should implement its use in the ESRD QIP as a reporting measure for home patient experience and as results and familiarity with the survey tool are gained, develop an appropriate outcomes measure for future years.

AdvaMed therefore recommends CMS:

- ***Consider adoption of a home dialysis retention rate measure, with appropriate exclusionary criteria; and***
- ***Pursue development of a patient-reported home dialysis experience of care for use in the ESRD QIP.***

ESRD Treatment Choices (ETC) Model

Measuring the home dialysis rate and creating incentives for home and transplant referrals in low-income populations was a laudable payment policy change that CMS has undertaken over the past few years through the establishment and recent enhancements to the ESRD Treatment Choices (ETC) Model. However, as a function of creating a comparison group, CMS has potentially created a disincentive in some areas of the country to grow home. This, coupled with the challenge to recruit home dialysis nurses, could create a scenario of haves and have nots where the national companies, that serve the majority of dialysis patients, divert resources to growing home dialysis in ETC regions and patients in non-participating regions face continued or potentially worsened access to home. Despite challenges, the ETC Model has had success in growing adoption of home dialysis. To ensure there are no geographical disparities in home dialysis access, we strongly encourage CMS to launch national implementation of the model.

AdvaMed therefore recommends CMS:

- ***Consider national implementation of the ETC Model at the conclusion of the model testing period.***

We appreciate this opportunity to comment on the proposed rule. If you have any questions, please contact Kirsten Tullia (ktullia@advamed.org).

Sincerely,

Chandra N. Branham, J.D.

Senior Vice President and Head of Payment & Healthcare Delivery Policy