AdvaMed
Advanced Medical Technology Association

February 1, 2022

Via Electronic Mail
Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3409-NC
7500 Security Blvd
Baltimore, MD 21244-1850

Re: Request for Information: Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities

Dear Administrator Brooks-LaSure,

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide responses to the Request for Information regarding Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities. 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.

We appreciate that this RFI takes the first step of acknowledging the need to develop and align policies across all providers who provide services to patients with kidney disease. However, we urge CMS to address the additional payment and legal barriers that must be eliminated to ensure these patients have greater choice in dialysis modality and improved access to innovative technologies to improve patient outcomes and engagement in their care.

Our comments below address several topics covered in this RFI:

- Patient Barriers to Dialysis Modality Choice
- Modernizing the ESRD Conditions for Coverage
- Use of Telehealth and Remote Monitoring Technology
- Transparency in Joint Venture Arrangements and Medical Directorship Agreements
- Aligning Incentives for New and Innovative Care Models

I. Patient Barriers to Dialysis Modality Choice

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 clinic. HHD is a safe and effective modality for incident "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.

Currently, PD is the dominant home modality in the US,[4] and a choice patients should have when considering modalities. We believe CMS should address removing existing barriers to PD catheter placement as part of its larger effort to increase home dialysis access and uptake.

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[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
[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

As CMS notes, 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 for 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.

II. Modernizing the ESRD Conditions for Coverage

The ESRD Conditions for Coverage (CfCs) have not been holistically updated in over 15 years. Modernizing the CfCs to create distinct and separate regulation for home dialysis programs will provide flexibility and accessibility to home options for more patients. Allowing flexibility in where patients can begin home dialysis training and by whom the training can be delivered could allow for more successful transitions from acute dialysis to home for patients that experience an unplanned dialysis start.

In addition, these regulations need to be updated to account for innovation in technology and care delivery. Surveyors and facilities need regulations and guidance specific to home dialysis that allows providers the flexibility needed to support, improve, and innovate care in the wide variety of home environments that exist. Current regulations apply in-center regulations to home dialysis through exceptions set forth in various guidance documents, creating confusion among potential new home providers and surveyors and resulting in discouragement to providers and delays in certification.

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[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/

Furthermore, ambiguity in CMS guidance leads to policies that adopt the most stringent interpretation to avoid risk. This results in policies that inadvertently rob patients of the largest benefits of self-care at home – patient autonomy and increased independence. In addition, unnecessary and burdensome requirements can increase costs, making it less enticing for providers to establish home services. Reducing regulations generally and ensuring regulations appropriately reflect the care setting for home patients can help lower operational costs and remove barriers to access for home dialysis.

Most importantly, updating and modernizing the CfCs can help address the ongoing nephrology nurse shortage. The COVID-19 public health emergency has only exacerbated a preexisting staffing shortage, with current projections suggesting there will be fewer nephrology nurses at a time of steadily increasing need.[9] This shortage is most acutely felt in the home dialysis space, where a severe home dialysis nursing shortage has significantly restricted patient access to home dialysis care options. We therefore recommend the CfCs regarding care at home and personnel qualifications be revisited to balance the need for nurses and need for trained nurses.

III. 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-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

[9] Boyle SM, Washington R, McCann P, Koul S, McLarney B, Gadegbeku CA. The Nephrology Nursing Shortage: Insights from a Pandemic. American Journal of Kidney Disease. 2022;79(1):113-116. Published 16 August 2021. https://doi.org/10.1053/j.ajkd.2021.07.007

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 dialyzing at home while 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.

IV. Transparency in Joint Venture Arrangements and Medical Directorship Agreements

While there is some evidence to suggest that joint ventures may have an impact on patient care, resource use, and choice of modality, substantially more information is needed to fully understand the scope of the impact of these relationships.[10] We therefore recommend CMS require qualified dialysis facilities to disclose to CMS all individuals and entities with a financial interest in the facility, facility subsidiary and joint venture partnerships that it or its subsidiaries are a party to. This reporting to CMS should include the national provider identifier (NPI) number of such individuals, and the NPI for providers that are party to such an entity. We further recommend CMS require physicians who make self-referrals to dialysis facilities where they have a financial interest to disclose this to their patients, consistent with the requirements of the American Medical Association Code of Medical Ethics, Physician Self-Referral, 9.6.9, adopted in 2008.

We further recommend CMS clearly define the Medical Director role in the CfCs as a purely clinical and quality oversight position, and not a business strategy role and prohibit facilities from requiring nephrologists to sign non-compete agreements in order to serve as a Medical Director. Often times, these non-compete agreements extend beyond the duration of the Medical Director's employment with a facility, thereby harming nephrologists who want to explore opportunities as a Medical Director elsewhere. These agreements also harm patients by limiting options to receive care, as new programs can be stalled from opening if they are unable to find a Medical Director. Finally, patients should know the Medical Director in charge of the clinical and quality care delivered in the facilities. We therefore recommend CMS require

[10] *See e.g.*, Glickman A, Lin E, Berns JS. Conflicts of interest in dialysis: A barrier to policy reforms. *Semin Dial*. 2020;33(1):83-89. doi:10.1111/sdi.12848.

facilities to post this information in clinics and put this information on the Dialysis Facility Compare website.

V. Aligning Incentives for New and Innovative Care Models

We applaud CMS' efforts to date to remove barriers to adopting innovative technologies and services for ESRD treatment. We believe 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. For this reason, we continue to advocate for improvements to TPNIES, including:

- Providing additional guidance on the "substantial clinical improvement" criteria, including the type and level of evidence required to support a successful TPNIES application;
- Removing the offset to the capital equipment payment calculation for capital-related assets that are home dialysis machines;
- Expanding TPNIES to dialysis facilities that acquire home dialysis devices through operating leases;
- Extending the TPNIES adjustment period to three years as further incentive for ESRD providers to adopt new and innovative equipment and supplies; and
- Adopting a post-TPNIES payment adjustment to the ESRD PPS base rate as part of a larger reevaluation of the ESRD bundle
- Provide an additional year of TPNIES payments for devices receiving payment due to ongoing PHE.

As stated in previous comment letters, we continue to advocate for improvements to the ESRD PPS as a whole. The bundle's current structure presents a major impediment to innovation in the ESRD space, as a lack of adequate, ongoing reimbursement for new technologies reduces the incentive to innovate. We therefore urge CMS to modernize the ESRD PPS in a manner that recognizes the importance of technological innovation to improving patient outcomes, increasing patients' treatment options, and pursuing new payment models that may reduce total cost of care for these patients.

AdvaMed appreciates the opportunity to provide industry insights under this Request for Information. If you have any questions, please contact Kirsten Tullia at ktullia@advamed.org.

Sincerely,

Chandra Branham
Department Head and Senior Vice President, Payment and Health Care Delivery Policy