AdvaMed
Advanced Medical Technology Association

701 Pennsylvania Avenue, NW
Suite 800
Washington, D.C. 20004–2654
P :: 202.783.8700
F :: 202.783.8750
W:: AdvaMed.org

March 8, 2022

Carol Blackford
Director, Hospital and Ambulatory Policy Group

Jason Bennett
Director, Technology, Coding, and Pricing Group

Jana Lindquist
Director, Division of Chronic Care Management

David Wright
Director, Quality, Safety, and Oversight Group

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments in Advance of Calendar Year (CY) 2023 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Notice of Proposed Rulemaking (NPRM)

Dear Ms. Blackford, Mr. Bennett, Ms. Lindquist, and Ms. Oviatt,

On behalf of the Advanced Medical Technology Association (AdvaMed), we are writing to urge the Centers for Medicare and Medicaid Services (CMS) to consider several important issues as the Agency begins to develop its CY 2023 ESRD PPS 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.

In advance of the proposed rule, AdvaMed is submitting comments on the following:

- Addressing Barriers to Dialysis Modality Choice
- Increasing Use of Telehealth and Remote Monitoring Technology
- Modernizing the ESRD Conditions for Coverage
- Requiring Transparency and Reducing Conflicts in Joint Venture Arrangements and Medical Directorship Agreements
- Refining the TPNIES Program

Addressing 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

[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

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. 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.

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-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

---

[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/

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 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.

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.

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.

Requiring Transparency and Reducing Conflicts in Joint Venture Agreements and Medical Directorship Agreements

Certain joint ventures and other ownership arrangements may create conflicts and barriers to access for dialysis patients. 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 as part of updating the CfCs 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

[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

[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.

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

Refining the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Program

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. 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. We believe 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 will be necessary to allow time to collect claims and cost data that align more closely with typical patterns of care for patients utilizing these technologies. We therefore request 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

[11] *See* CY 2021 ESRD PPS Final Rule at 60650.

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. We therefore urge CMS to provide additional guidance on the type and level of evidence required to support a successful TPNIES application, taking into consideration the unique challenges associated with studies in the ESRD setting.

Expand TPNIES to Dialysis Facilities that Acquire Home Dialysis Devices Through Operating Leases

In the CY 2021 ESRD PPS Final Rule, CMS finalized its decision to expand TPNIES to capital-related assets that are home dialysis machines when used in the home for a single patient. However, in doing so, CMS explicitly excluded home dialysis equipment obtained by an ESRD facility through an operating lease from the definition of "capital-related asset". While we understand CMS' position that equipment obtained through an operating lease is not subject to depreciation in the same manner as equipment owned outright, we believe this definition places undue restrictions on TPNIES payments for small and medium-size facilities. Smaller ESRD facilities, unlike large dialysis organizations, may lack the financial reserves required to purchase these new devices outright, and exclusion from TPNIES may further disincentivize these smaller facilities from investing in new home dialysis technologies. This, in turn, may reduce patient access to home dialysis. We therefore urge CMS to extend TPNIES for home dialysis machines to those obtained through operating leases.

Remove Offset to the Capital Equipment Payment Calculation

In the CY 2021 ESRD PPS Final Rule, CMS finalized a payment policy for capital-related assets that are home dialysis machines when used in the home under which CMS would pay the 65 percent fraction of the MAC-determined preadjusted treatment amount, minus an additional per treatment offset amount. The combined effect of these policies may undervalue an innovative technology that

[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.

meets the TPNIES criteria to a maximum of 26 percent of the cost of the device paid over two years. Limiting the incentive associated with TPNIES in this manner is unlikely to drive the innovation CMS seeks to promote, particularly in the home dialysis space. We therefore urge CMS to remove the offset policy from the payment calculation for capital-related assets that are home dialysis machines.

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, 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, we believe CMS should align with the NTAP policy and allow for an additional year of TPNIES.

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. We believe that 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.

We appreciate this opportunity to share our recommendations for your consideration in preparation for the CY 2023 ESRD PPS 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