March 11, 2022

The Honorable Bruce Westerman
U.S. House of Representatives
202 Cannon House Office Building
Washington, DC 20515

The Honorable Brad Wenstrup
U.S. House of Representatives
2419 Rayburn House Office Building
Washington, DC 20515

The Honorable John Joyce
U.S. House of Representatives
1221 Longworth House Office Building
Washington, DC 20515

Dear Representatives Joyce, Wenstrup, and Westerman:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Healthy Future Task Force Subcommittee on Treatments (Treatment Subcommittee) with comments to the request for information (RFI) soliciting feedback on medical innovation. We thank you for your efforts to promote the availability and development of life-saving treatments, devices, and diagnostics while addressing the rising costs to patients.

The Alliance is a coalition of kidney dialysis stakeholders representing patients, clinicians, providers, and industry. We have come together to promote and advance policies to facilitate treatment choice in dialysis care while addressing systemic barriers that limit access for patients and their families to the many benefits of home dialysis.

We appreciate the Treatments Subcommittee's openness to engage with stakeholders like the Alliance for Home Dialysis on these critical issues. We are eager to serve as a resource as Congress considers policy solutions to create system-wide healthcare improvements and incentivize medical innovation, particularly concerning kidney disease. The Alliance is pleased to offer the following comments in response to this RFI to ensure and expand patient access to innovative treatments, such as home dialysis.

Goal 2, Question 1: *What barriers to innovation in the drug, device, or diagnostic space should Congress address?*

Predictable and Consistent Access to Innovation
The Alliance recognizes the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) program as an essential means for encouraging the development and expanded use of innovative dialysis technologies. TPNIES helps cover the implementation costs of new home dialysis equipment, making the equipment more widely available to the patients who need them. As more patients choose these modalities, it is more important than ever for CMS to ensure that the intent and impact of the TPNIES program are fully realized. As such, we continue to call for the following changes to this program to provide long-term certainty for home dialysis patients.

- Extend the TPNIES adjustment period from two years to at least three years.
- Implement a post-TPNIES payment adjustment to ensure appropriate reimbursement upon the expiration of TPNIES.
- Consider new categories for approval, such as safety innovations.
- Establish a formal process to provide premarket feedback on the data needed to support a TPNIES application and guidance throughout the TPNIES application process.

Access to Phone Evaluation and Management (E&M) Services
The Alliance for Home Dialysis was pleased that CMS granted our request at the beginning of the COVID-19 public health emergency (PHE) to change the Physician Fee Schedule status indicators for telephone consult codes (99441-99443) from "N" for non-covered to "A" for covered. As you may be aware, CMS has not permanently extended the coverage of these codes, which means they will be removed from the covered Medicare telehealth services list after the COVID-19 PHE ends.

We strongly encourage CMS to permanently add codes 99441-99443 to the Medicare telehealth services list. These E&M services will continue to be essential for patients with ESRD or acute kidney injury (AKI), especially as the pandemic continues to provide an obstacle for patients to meet with their physicians. Phone consultation with physicians is an essential lifeline for home dialysis patients in underserved communities with unreliable broadband or access to technology. The Alliance supports continued coverage of these telephone consult codes and believes that these E&M services deserve to be permanently included in the Medicare telehealth services list.

The Alliance understands and stresses that appropriate guardrails should be in place for audio calls, such as:

- Documentation should include that a good faith effort for an audio-video call was inadequate to complete the visit.

- Patients' relevant electronic medical records and dialysis treatment flowsheets were available and reviewed during the call.

We would request that patient participation in an audio-only E&M visit be sufficient for consent and fulfill the patient-initiated requirements. In instances where poor connectivity allows for some, but not all, of a visit to be conducted through video, a provider should use their best judgment as to which billing code most accurately describes the visit.

Originating Site and Geographic Restrictions
The Alliance for Home Dialysis has long supported the designation of a patient's home and dialysis facility as originating sites for home dialysis services, without the rural/urban geographic restrictions. We were pleased to see Congress grant this request in the 2018 Balanced Budget Act, which included the CHRONIC Care Act and its provisions to waive these requirements for home dialysis patients. Our members report that the benefits have redounded to the use of the broader kidney patient community:

- CKD patients need regular care to properly manage their disease, including education on their modality options if and when they enter kidney failure. Allowing some of this care to be remotely delivered can lessen some of the challenges patients face in accessing this care.
- Kidney transplant patients require extensive evaluation and education before and after their transplant surgery, and continued monitoring post-surgery to evaluate organ function, medication adherence, and other vital transplant outcomes. Accessing this care requires regular visits with medical staff at kidney transplant centers, which are often urban institutions requiring patients to travel a long way to seek care. Many of these visits can be conducted via telehealth, saving patients time and expense.
- Providers working in an acute care setting can use telehealth or remote patient monitoring (RPM) capabilities to provide dialysis care to patients in a dialysis center or home.

Goal 2, Question 4: *What are the various categories of Digital Health that need to be recognized from the standpoint of reimbursement to begin exploring the mechanisms for coverage, coding, and payment that may already exist, and to understand where gaps remain under current regulatory and statutory frameworks?*

Access to Digital Health Innovation
The standard of care for Medicare end stage renal disease (ESRD) patients is evolving towards more patient-centered modalities, including digital tools to remotely monitoring patients. 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. Remote patient monitoring digital 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.

The End Stage Renal Disease Prospective Payment System (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. This bundled payment system did not contemplate 21st-century digital health innovations. Under the current system, there is no separate reimbursement for new digital health technology such as RPM, artificial intelligence (AI), wearable technology, and clinical decision support tools. We believe that a more robust incentive would encourage developing, adopting, and using innovative tools that improve ESRD patient experiences and outcomes.

To improve the adoption of innovative care management and treatment technologies for ESRD patients and to increase patient access to these technologies, the Alliance asks policymakers to allow renal dialysis providers to bill separately for digital health innovations. Providing payment for adopting and deploying remote patient monitoring digital tools will enhance treatment care options for ESRD patients. Further, by increasing access to these remote monitoring tools, we can ease the path towards putting more patients on home dialysis, which is consistent with the U.S. Government's stated goals under the Advancing American Kidney Health Initiative (AAKHI).

Further, we support the CY 2020 PFS Final Rule determination that CPT codes for RPM services 99091, 99453, 99454, and 99457 should be billable monthly and ask CMS to allow the use of these codes for ESRD patients.

The Alliance appreciates the opportunity to provide comments to this RFI. Please do not hesitate to reach out to Alliance staff to discuss how we can work together. Should you require further information, please contact Kelly Ferguson at kferguson@homedialysisalliance.org.

Sincerely,

Kelly Ferguson
Policy Director
Alliance for Home Dialysis

American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association*
American Society of Nephrology*
American Society of Pediatric Nephrology
Baxter*
Centers for Dialysis Care
DaVita*
DEKA*
Dialysis Clinic, Inc.*
Dialysis Patient Citizens*
Fresenius Medical Care/NxStage*
Home Dialyzors United
Medical Education Institute
National Kidney Foundation*
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