



September 6, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
7500 Security Boulevard
Baltimore, MD 21244

Re: *CMS-1770-P* Medicare and Medicaid Programs; CY 2023 Payment Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); and Implementing Requirements for Manufactures of Certain Single-Dose Container for Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amount.

Dear Administrator Brooks-LaSure:

On behalf of the Alliance for Home Dialysis (the Alliance), thank you for the opportunity to provide comments on the proposed FY 2023 Physician Fee Schedule (PFS) rule. The Alliance is a coalition of clinical societies, patient groups, facilities, and innovators who have come together to advocate for policies that will increase access to home dialysis: both peritoneal dialysis and home hemodialysis. We believe that patients deserve to be empowered and able to access the best treatment for them- in partnership with their clinical team- which is very often home therapy. We appreciate all CMS has done in recent years to break down barriers impacting the use of home dialysis and look forward to continuing to work together for years to come.

Our comments are as follows:

Telehealth

As CMS has pointed out, the COVID-19 public health emergency (PHE) has deeply impacted how medical care is delivered, particularly regarding the increased usage of telehealth. For ESRD patients, this has been especially important, as most are immunocompromised, and clinicians have needed to find innovative ways to ensure they can safely distance themselves at home as much as possible. These efforts have led to learnings that can be applied even after the end of this PHE- both during times of relatively normal risk as well as if other infectious diseases (for example, monkeypox and polio) pose a danger to this patient population.

1. The Alliance supports the continued use of telephone-only clinical visits.

The Alliance appreciates CMS's openness to extending telehealth services via phone-only visits after the end of the public health emergency (PHE) and 151-day period after. Overall, we believe that phone-only visits can be a useful and necessary resource for clinicians and patients, but that guardrails should be in place to ensure that patient safety and high-quality care are maintained.

In certain circumstances, phone visits can allow connectivity between patients and clinicians that would otherwise be impossible. For example, some patients do not have access to reliable audio-visual communication, especially those in rural areas with low to no wireless internet access, or elderly patients who are uncomfortable utilizing this technology. Further, phone-only visits can be useful in the instance that an audio-visual visit is interrupted due to internet outage, connectivity issues, etc.; with phone-only as an option, that visit can be finished over the phone, therefore avoiding the need to reschedule and take up more clinical and patient time. In addition, telehealth, including phone visits, can often be used to determine whether a patient is experiencing an acute problem that needs in-person attention; by assessing and triaging via telehealth, clinicians can save valuable staff time and ensure that those patients who truly need in-person care can access it. By allowing phone visits in these and other appropriate circumstances, more patients will be able to access home dialysis modalities- and more importantly- *stay* at home and not have to resort back to in-center therapy due to technological challenges.

Even so, we do believe that the statutorily required quarterly in-person monthly capitated payment visit (MCP) is important and should remain in place- this visit is an irreplaceable opportunity for clinicians to examine patients in person. Specifically, we believe that hands-on assessment of the dialysis access site is important during these quarterly visits.

Should CMS expand the usage of phone-only visits, the Alliance urges CMS to consider a minimum documentation requirement for why an audio-visual visit is not possible or why phone-only is most appropriate. Further, we believe that before phone-only visits are allowed, the patient and clinician should have an existing relationship, with exceptions for urgent/emergency visits or referrals from other clinicians reflecting an immediate need to be seen. And finally, during a phone visit, the clinician should have access to all records, vitals, and nursing support that would be available in-person or over an audio-visual connection to ensure the highest quality of patient care is performed.

2. The Alliance supports home dialysis training via telehealth in certain situations.

During the COVID-19 pandemic, some clinicians began offering certain elements of home dialysis training via telehealth, which would normally be performed by clinicians in person. The Alliance believes that while certain aspects of training, like the teaching of cannulation techniques, are best done in an in-person setting to ensure optimum patient safety, many other aspects can safely be taught during audio-visual telehealth visits.

Training via telehealth could help with challenges clinical offices face due to staff shortages. Patients also often prefer a telehealth option due to its efficiency- they do not have to spend time and resources driving to and from an in-person location while still getting maximum time with their provider. For home dialysis patients, who often maintain employment, telehealth can contribute to the flexibility they need to continue living life as normally as possible. Therefore, offering the potential for telemedicine training to supplement in-person training is something CMS should give regulatory consideration to.

However, training visits with clinicians via telehealth are not currently being reimbursed to clinicians by CMS.

We believe that there are adjustments that CMS can make through the Physician Fee Schedule that will allow reimbursement for home dialysis by nephrologists via telehealth.

Specifically, the Alliance requests that CMS add CPT codes 90989 (dialysis training, patient, including helper where applicable, any mode, complete course) and 90993 (dialysis training, patient, including helper where applicable, any mode, course not completed, per training session) to the approved telehealth list. These are physician codes that allow up to 25 sessions of home dialysis training in person. This change will allow clinicians, in conjunction with the patient through shared decision-making, to determine whether they wish to use telehealth capabilities for home dialysis training.

3. The Alliance supports the expansion of Remote Patient Monitoring (RPM) technologies and services with appropriate reimbursement, including for chronic conditions, including ESRD.

New innovations, like RPM, can often improve patient access to a broader array of kidney care modalities, including home dialysis. As such, the Alliance has long advocated for broad access, and many of our members are particularly invested in expanding RPM technologies and service capabilities that enhance the ability of patients to access care remotely. We have stated before, and continue to believe, that as the standard of care for Medicare ESRD patients evolves toward more patient-centered modalities, coding for RPM technologies and services will be critical to ensuring that providers may properly provide such technologies and services. We also reiterate our agreement with CMS that RPM technologies and services do not create a risk of duplicative payment or overlap with Transitional Care Management (TCM) services; instead, we assert that the provision of medically appropriate RPM technologies and services can *complement* the TCM code sets and that removing billing restrictions will increase utilization of TCM services. We appreciate all that CMS has done in previous rules to ensure that certain CPT codes for RPM technologies and services can be billable monthly.

We understand that before the public health emergency, RPM was only allowable for certain chronic conditions. We would like CMS to be aware that these technologies and services can and should also be used acutely; for example, a patient may come home from the hospital and need extra monitoring for a period of time that is not standard for home dialysis patients. In a situation like this, RPM can be invaluable in helping to ensure that the patient is receiving the highest quality of care possible at home, and ideally avoiding rehospitalization because if a problem is detected, intervention can be immediate.

As always, the Alliance also wants to ensure that any new innovations are utilized responsibly, including RPM technologies and services. In this case, we believe that documentation will be important to ensure that patients have diagnoses that support the use of RPM.

Finally, we understand that ESRD care is paid for uniquely (under a bundled payment to physicians) as compared to other disease states paid for by traditional fee-for-service Medicare. While this structure is different, it should not preclude the usage of RPM and reimbursement for those technologies and services by nephrologists when it appropriate for patients. We urge CMS to consider how RPM can be integrated into the ESRD payment system, rather than allowing nephrologists and other specialists who typically manage these complex patients to lose out on the chance to utilize this important tool.

4. The Alliance appreciates CMS's continued attention to remote therapeutic monitoring and urges consideration of the application to ESRD.

The Alliance thanks CMS for the continued focus on remote therapeutic monitoring (RTM) and was encouraged to see the proposal of four new HCPCS G codes, with one of those aimed at increasing patient access to RTM. As CMS continues to expand RTM services, we encourage you to consider adding codes for use by ESRD patients.

Discarded Drug Refund Policy

While the Alliance understands that the Infrastructure Investment and Jobs Act requires manufacturers to provide a refund to CMS for discarded single source drug amounts from single-dose containers or single-use package drugs, we are concerned that CMS' implementation will inadvertently impact ESRD products, including those used by home dialysis patients.

As a baseline matter, we agree with both Congress and CMS that reducing unnecessary drug waste, especially for expensive or high-demand drugs like oncology products, is a laudable goal. However, we are concerned that the blanket requirements in the rule may be burdensome or even impossible to comply in certain situations. While determining waste amounts of drugs in the hospital setting is likely possible with minimal additional administrative burden, as pharmacists are used to doing these calculations already, we cannot say the same about dialysis facilities- and more importantly, home dialysis patients who are often completing their treatments alone in their homes.

Therefore, we urge CMS to consider an exemption to these requirements for drugs and biologics paid for under the ESRD bundled payment. We believe this is consistent with CMS' overall approach in the proposed rule that proposes a clarification that the policy would not be required for drugs where payment is packaged under the OPPI or ASC payment system or drugs administered in the FQHC or RHC setting.¹ We support the proposed clarification and its extension to the ESRD payment system.

Kidney Disease and Health Equity

The Alliance has long worked to address health equity issues related to home dialysis through policy as well as educational projects, such as a three-year patient-focused project we conducted alongside the NAACP. We remain committed to advocating for patients of all backgrounds to have access to all treatment modalities, including home dialysis. Further, we believe that addressing health equity challenges may make a positive difference in the number of patients who experience so-called "crash" dialysis starts, which typically lead to in-center dialysis.

While access to education about CKD and ESRD are crucial to any patient with kidney disease, research has shown that patients of color, especially Black patients, are shown to be less likely to receive pre-ESRD nephrology care than their white counterparts and are often not exposed to the same opportunities for early education. We believe that disparity in access to these important educational resources can impact not only dialysis modality choices, but also transplants. We believe that there should be a greater focus on ensuring that these populations have access to desperately needed education, especially upstream, meaning before dialysis, so that they are less likely to "crash" into the emergency room.

¹ 87 Fed. Reg. 46057

1. The Alliance urges CMS to consider additional data analysis related to equity.

While we are glad that CMS already collects a large amount of data related to health equity, we believe that additional analysis could be helpful. Specifically, we urge CMS to consider ways in which data based on race and data based on socioeconomic status can be combined and compared to any patterns that may currently be missed.

Should this data show any trends about home dialysis rates, we could then work on interventions specific to the barriers at play. For example, dialyzing at home requires sufficient water and electric infrastructure that some patients do not currently have- however, data tracking these populations of patients is currently lacking but could benefit entities in a position to help with modifications.

In addition, data on patient retention and loss rate could be very helpful as we try to monitor the overall increase in home dialysis penetration both broadly across the country and at a community level. Should CMS develop a standardized way to measure this, data could be compared across regions in the US, which could be used to develop targeted interventions and diagnose opportunities for improvement.

Finally, we believe that it could be helpful for CMS to gather data on patients who express interest in going home, but ultimately choose in-center dialysis. A gap currently exists as to *why* those patients make the choices that they do. Knowing why patients elect not to go home could help stakeholders and CMS to address any institutional barriers in play.

Kidney Disease Education

The Alliance has advocated for changes to the KDE benefit that we believe would increase uptake; we appreciate CMS's attention to this issue, particularly through finalizing expansions of KDE within the ESRD Treatment Choices Model. We believe that there are additional steps CMS can take to make KDE more accessible to patients.

1. CMS should waive the coinsurance requirement for KDE.

Currently, Medicare beneficiaries are responsible for the 20% copay associated with KDE as a Part B benefit. For some beneficiaries, the 20% coinsurance is prohibitive to accessing these important educational services. We recommend that CMS waive the coinsurance requirement that would otherwise be applicable under section 1833(a)(1) of the Social Security Act concerning KDE services for beneficiaries.

2. CMS should designate KDE as a preventive service.

As stated above, the Alliance is concerned that the coinsurance associated with KDE disincentivizes both providers and patients from taking advantage of this education. Providers are reluctant to bill patients for a service that was provided for free in the past, and patients may not have the resources to pay the coinsurance.

However, CMS has the authority to add full coverage for preventive services in Medicare through the National Coverage Determination process if the new service meets certain criteria. We believe that KDE meets these criteria and encourage CMS to support the inclusion of KDE as a preventive service.

3. CMS should allow dialysis facilities to bill for KDE.

Dialysis facilities are well-equipped to provide KDE. They typically employ the interdisciplinary teams necessary for effective KDE, and patients are often present already in dialysis clinics- even home dialysis patients who sometimes see their nephrologist in person. Yet, dialysis clinics are currently excluded from the reimbursement for KDE provided at their facilities. We urge CMS to allow these clinics to provide and bill for KDE.

Peritoneal Dialysis Catheter Placement

1. The Alliance supports allowing reimbursement for CPT code 49436 in office but agrees with the RUC recommended 5 minutes of clinical time.

To begin peritoneal dialysis (PD), the most commonly utilized home dialysis modality in the US, insertion of a PD catheter is required, as opposed to a fistula, which is placed in hemodialysis patients. The Alliance has identified systemic barriers associated with the timely placement of PD catheters to CMS. In the FY 2022 Physician Fee Schedule final rule, CMS finalized CPT code 49436, Delayed Creation Exit Site from Embedded Catheter, as potentially misvalued. The code was then found to be appropriate to value for the non-facility/office setting, and the RUC reviewed it in January 2022. The Alliance agrees that the office setting would be appropriate for this code and that expanding the site of care to include a non-facility could positively address the current barrier related to operating room availability. Many of our clinician members continue to report inadequate operating room access and lack of ability to schedule time in available operating rooms as reasons why PD catheter placement is delayed. While certain kinds of PD catheter placement procedures can be done bedside, most are placed in the operating room at the hospital or ambulatory surgical center.

The RUC recommended 5 minutes for Clinical Activity Code CA013, as related to this procedure in the office, and the Alliance is concerned that CMS is proposing to reduce that recommendation to the standard time of 2 minutes in this year's proposed rule. We urge CMS to reevaluate and finalize the RUC recommended 5 minutes.

In addition, we believe that percutaneous technique (image guided) PD catheter placement² should be payable in all sites of service, including the office setting, as well. We urge CMS to consider adding CPT code 49418 to allowable for reimbursement in all settings.

Proposed MVP

1. The Alliance supports the proposed MVP "Optimal Care for Kidney Health."

We were pleased to see the proposal of an MVP related to managing kidney disease. The Alliance has long advocated for quality measures that will enhance the patient experience and help to ensure that CKD and ESRD patients are getting the highest quality care. While our work typically focuses on home dialysis, we believe that by aiming a new measure at conditions that contribute to or result from kidney disease, clinicians will be able to better serve this population of patients. Specifically, we support the inclusion of the proposed quality measures into the MVP, as well as the improvement activities laid out

² CPT code 49418

in the proposal. We appreciate that those improvement activities focus on patient engagement, health equity, shared decision-making, and care coordination, all of which are important for achieving good patient outcomes. We urge CMS to finalize this MVP.

2. KDE should be included in MIPS as an MVP or part of an MVP.

As explained above, the Alliance strongly believes that incentivizing KDE usage is key to ensuring that patients receive the information they need to make informed decisions about dialysis modalities. Further, we know that patients who are educated earlier in the diagnosis process tend to have a smoother transition to dialysis care, as opposed to a “crash start” in the emergency room. In order to increase KDE usage, we suggest that CMS consider incentivizing utilization of the KDE benefit through MIPS, perhaps through an MVP.

Thank you for your consideration of this comment. We look forward to continuing to work with CMS to increase access to home dialysis across the country. For any questions, please reach out to Michelle Seger at mseger@vennstrategies.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Michelle Seger', with a long horizontal flourish extending to the right.

Michelle Seger
Managing Director
Alliance for Home Dialysis



American Association of Kidney Patients
American Kidney Fund
American Nephrology Nurses Association
American Society of Nephrology
Baxter
Centers for Dialysis Care
DeVita
DEKA
Dialysis Clinic, Inc.
Dialysis Patient Citizens
Fresenius Medical Care/NxStage
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