



February 1, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3409-NC
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CMS-3409-NC: Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities

Dear Administrator Brooks-LaSure:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments to the request for information (RFI) soliciting feedback on potential changes to the requirements that transplant programs, organ procurement organizations, and end-stage renal disease (ESRD) facilities must meet to participate in the Medicare and Medicaid programs.

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 CMS'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 the Biden administration considers policy solutions to create system-wide healthcare improvements, particularly regarding kidney disease. The Alliance is pleased to offer the following comments in response to this RFI related to expanding access to home dialysis.

- 1. What are patient barriers to dialysis modality choice? How can we overcome obstacles to ensure patients understand their options and have the freedom to choose their treatment modality?**

Patients facing kidney failure experience barriers to choosing the best modality for themselves and their families, often beginning in the chronic kidney disease (CKD) state and continuing into the ESRD phase.

Early Barriers

Kidney Disease Education (KDE)

Improving health care for ESRD patients calls for policy changes to help patients surmount common and often prohibitive barriers to home therapy. Many of these barriers stem from a lack of knowledge about treatment options, as nearly half of all new dialysis patients begin treatment without previous access to a nephrologist.¹ Access to education about ESRD and available dialysis treatment options is crucial to any patient with kidney disease. However, patients experience barriers to receiving pre-ESRD nephrology care and are often not exposed to opportunities for early education. Further, patient comments suggest that conventional education sources cannot reach some patients, especially those in underserved communities and that more creative, patient-centered approaches may be needed.² Finally, patients testify all too often that they are unaware that they could dialyze at home because a physician steered the patient away from the home modality, even though the physician and patient may not even have had a comprehensive discussion about that option.³

One critical resource is the Kidney Disease Education (KDE) Medicare benefit, covering up to six kidney disease education sessions for pre-dialysis patients up to Stage 4 Chronic Kidney Disease (CKD). Doctors, physician assistants, nurse practitioners, and clinical nurse specialists can offer these services, as well as certain rural healthcare facilities. Beneficiaries can use this benefit to learn about various CKD-related topics, such as managing health conditions and potential treatment options.⁴ The KDE benefit has been shown to improve informed dialysis selection, patient awareness of chronic kidney disease, and utilization of home dialysis.⁵ However, the KDE benefit is severely underutilized. According to a survey of 369,968 qualifying incident ESRD Medicare beneficiaries, only 3469 (0.9%) received KDE services before dialysis initiation.⁶ The Government Accountability Office (GAO) similarly found that few Medicare beneficiaries have used the KDE benefit. The low utilization may result from statutory payment limitations on the types of providers permitted to furnish the benefit and the Medicare patients eligible to receive

¹ <https://www.beckershospitalreview.com/quality/earlier-diagnosis-patient-education-and-integrated-care-can-help-reduce-the-prevalence-of-dialysis-crash-starts.html>

² <https://homedialysisalliance.org/wp-content/uploads/2021/10/AHD-Roundtable-Summary-3.29.2021.pdf>

³ Ibid

⁴ <https://www.medicare.gov/coverage/kidney-disease-education>

⁵ Shukla AM, Bozorgmehri S, Ruchi R, Mohandas R, Hale-Gallardo JL, Ozrazgat-Baslanti T, Orozco T, Segal MS, Jia H. Utilization of CMS pre-ESRD Kidney Disease Education services and its associations with the home dialysis therapies. *Perit Dial Int.* 2021 Sep;41(5):453-462. DOI: 10.1177/0896860820975586. Epub 2020 Dec 1. PMID: 33258420.

⁶ Ibid

it.⁷ The KDE benefit, as a Part B service, is also subject to a 20% coinsurance payment which may be prohibitive for low-income patients.

In 2019, the ESRD Treatment Choices (ETC) Model made certain waivers for the provision of KDE. An ETC Managing Clinician can supervise a clinical nurse specialist, licensed clinical social worker, nurse practitioner, physician assistant, and registered dietician/nutrition professional in the delivery of KDE, and model participants are eligible for KDE beyond Stage 4 – into Stage 5, and for the 6 months of their dialysis treatment. However, CMS estimates that only 30% of kidney care providers in the U.S. are included in this model, leaving most ESRD patients out of these important waivers. We encourage CMS to expand these waivers to all ESRD patients and allow for dialysis facilities to be reimbursed for providing KDE.

The Alliance has long advocated for CMS to waive the coinsurance requirement for KDE.⁸ Given the relationship between poverty and CKD prevalence, we believe that for some beneficiaries, the 20% coinsurance is prohibitive to accessing the services, and eliminating it would allow more beneficiaries to access KDE services. We appreciate that in the calendar year (CY) 2022 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule, CMS decided to allow ETC participants to reduce or waive the beneficiary coinsurance for KDE services, subject to specific requirements. However, we are concerned that CMS is precluding interested patients from accessing this beneficial service by limiting the coinsurance waiver to only ETC participants. The Alliance, therefore, asks that the coinsurance waiver be extended beyond the ETC model to all ESRD beneficiaries to ensure that the greatest possible number of beneficiaries utilizes KDE services.

The Alliance has also suggested that KDE be designated as a preventive service to improve earlier awareness of kidney disease.⁹ To ensure that pre-ESRD patients can earlier detect their kidney disease, we believe U.S. Preventive Services Task Force (USPSTF) should evaluate the fitness of KDE services for an "A" or "B" grade. Such a determination by the USPSTF would facilitate uptake amongst private insurers and increase the overall coverage of KDE services. Doing so would allow more beneficiaries to access KDE services. Beyond these changes to improve access, the Medicare program should consider a uniform curriculum for KDE provision to address disparities in the quality of KDE programs from one community to another.

Increasing Uptake of Home Dialysis Options

Incident "Crash" Patients

A product of inadequate pre-nephrology care is the prevalence of unplanned or "crash" dialysis starts, which may negatively impact the choice set for a patient at the beginning of their dialysis journey.¹⁰ These unplanned starts are associated with increased patient morbidity and

⁷ <https://www.gao.gov/assets/gao-16-125.pdf>

⁸ https://homedialysisalliance.org/wp-content/uploads/2021/10/CY-2021-Alliance-PFS_October-5th-8.pdf

⁹ <http://homedialysisalliance.org/wp-content/uploads/2018/09/Alliance-ESRD-PPS-CY19-FINAL.pdf>

¹⁰ <https://www.kidneyfund.org/kidney-today/kidney-disease-is-in-the-national-spotlight.html>

mortality and lower quality of life scores.^{11,12} Patients who crash into dialysis are less likely to dialyze at home for multiple reasons:

- When patients crash into dialysis, they are called upon to make life-altering decisions under adverse conditions (e.g. in an emergency room, under distress, in a short amount of time). Many patients enter this setting unaware of the choices they have for their dialysis.
- Crash patients often suffer a lack of cognitive function due to high uremia, limiting their ability to take in information and make decisions.
- The emergent hospital setting for dialysis patients strongly lends itself to an in-center approach. Too many clinicians and hospitals are unfamiliar with the benefits that can accrue to appropriate patients on home dialysis. Thus, they may be less likely to prescribe it to crash patients. Furthermore, as we detail later in this document, PD catheter insertion is challenging to access in-hospital, due to lack of qualified surgeons and operating room space.

Not only are unplanned starts more costly and dangerous for patients, but they may also lead to pressured and uninformed decisions that will negatively affect patients throughout their lives. As such, we believe hospitals should make patients aware of opportunities to train and transition to home dialysis immediately following a hospital crash. A patient who begins on an in-center modality is less likely to transition to home as they have become accustomed to the in-center treatment environment. As discussed further in this document, hospitals often lack trained surgeons and ample operating room space for placing peritoneal catheters, creating profound barriers to access for crash patients who might otherwise benefit from this home dialysis modality. Patients may be sent home initially with a catheter for hemodialysis, and a permanent dialysis access can subsequently be placed and matured during this transitional period.

Hemodialysis is the modality most often initiated by hospital staff for crash patients, but often the patient is discharged to an in-center clinic. Home hemodialysis (HHD) and peritoneal dialysis (PD) are safe and effective modalities for incident “crash” start patients. There has been a long-missed opportunity for educating these patients about their options for conducting HHD and PD while in the hospital. Solutions that would encourage and facilitate the initiation of home education and training in the hospital by nephrologists, dialysis nurses, and hospital social workers, could significantly increase the adoption of home dialysis for incident patients.

Peritoneal dialysis is one type of dialysis treatment for kidney failure. PD treatment requires a patient to fill their abdominal cavity with a solution to filter blood and remove waste. This process occurs several times every 24 hours and can be done at home, the workplace, or other non-medical settings. Individuals treated with PD can also use a machine known as a cycler to

¹¹<https://www.beckershospitalreview.com/quality/earlier-diagnosis-patient-education-and-integrated-care-can-help-reduce-the-prevalence-of-dialysis-crash-starts.html>

¹² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4950106/>

perform these exchanges while they are sleeping.¹³ At the end of 2018, there were nearly 69,000 patients performing dialysis in the home, or 12.5% of all dialysis patients. Almost 85% of patients on home dialysis performed peritoneal dialysis.¹⁴

Due to PD's current prevalence in the U.S., we believe that to help move the needle on home dialysis access and uptake, CMS should prioritize removing existing barriers to PD catheter placement.¹⁵ However, several significant barriers exist to PD catheter placement which CMS should prioritize addressing. These include:

- Lack of dedicated hospital-based catheter insertion teams for unplanned peritoneal dialysis starts.
- Inadequate training of surgeons and interventional radiologists on PD catheter insertion methodology.
- Obstacles related to scheduling of operating room time.^{16,17,18}

However, the most striking barrier, which CMS can correct for in the immediate term, is the low reimbursement for PD catheter placement.

CMS should encourage PD uptake by incentivizing PD catheter insertions. The Agency must incentivize increasing PD catheter insertions. One way to achieve this would be through equalizing reimbursements for PD catheters and vascular access procedures in a model setting where the Agency could measure the impact of such a reimbursement change. Such incentive would entail creating a voluntary track or option where participants receive a payment increase per PD placement to equalize the reimbursement between PD catheter insertion and vascular placement within the model. Such a track could incentivize access specialists to partner with ETC managing clinicians to place PD catheters, thereby addressing a critical barrier to home dialysis access for patients.

To implement, CMS could make it known that if surgeons or other access specialists create partnerships with ETC managing clinicians, they will be eligible for a reimbursement bump for each PD catheter placed as part of the model. Such incentive payments would be consistent with the ETC Model's structure, which establishes initial incentives for participants to achieve

¹³ <https://www.mayoclinic.org/tests-procedures/peritoneal-dialysis/about/pac-20384725>

¹⁴ <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

¹⁵ United States Renal System (USRDS). "Incidence, Prevalence, Patient Characteristics, and Treatment Modalities," United States Renal Data System (USRDS), 2020, <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidenceprevalence-patient-characteristics-and-treatment-modalities>.

¹⁶ Pajek J. Overcoming the Underutilisation of Peritoneal Dialysis. *Biomed Res Int.* 2015; 2015:431092. doi:10.1155/2015/431092.

¹⁷ Rajora N, Shastri S, Pirwani G, Saxena R. How To Build a Successful Urgent-Start Peritoneal Dialysis Program. *Kidney* 360. 2020 October 1 (10) 1165-1177; <https://doi.org/10.34067/KID.0002392020>.

¹⁸ Abdel-Aal AK, Dybbro P, Hathaway P, Guest S, Neuwirth M, Krishnamurthy V. Best practices consensus protocol for peritoneal dialysis catheter placement by interventional radiologists. *Perit Dial Int.* 2014;34(5):481-493. doi:10.3747/pdi.2013.00029.

the model's focus on increasing home dialysis. CMS should also consider tracking the success rates of participants in these voluntary arrangements and adding a quality component to ensure a high standard for patient care.

For further detail, we have attached a copy of our submission in response to the ESRD PPS Proposed Rule as an appendix to this comment.

Barriers to Home Patient Retention

Roughly 40% of existing home patients leave home therapies every year in favor of in-center treatments.¹⁹ The reasons for this are varied and include both clinical and non-clinical issues. For example, PD patients may experience catheter failure or peritoneal infection, complicating their peritoneal dialysis treatment.²⁰ More broadly, a worsening of their condition – be it ESRD or another comorbidity – can lead a patient to be unable to dialyze at home or force a hospitalization in a facility that may not be adequately equipped or willing to continue PD treatment.

Psychosocial barriers, and challenges around socioeconomic determinants of health, can hinder patients who seek to dialyze at home. Patients may burn out, their caregivers may change or become too sick themselves to continue their duties, or home situations may be unstable or unsuitable for home treatments.²¹

2. *What are the reasons for differing rates of home dialysis by race/ethnicity? How can we address any barriers in access to home dialysis to improve equity in access to home dialysis?*

While the portion of dialysis patients performing home dialysis in the United States is slowly increasing, the U.S. lags many other industrialized countries.²² Relatively low utilization of home dialysis in the U.S. is partially attributable to the disproportionate lack of home dialysis access for low-income communities and communities of color, which make up a significant portion of dialysis patients. Data make clear that, in the United States, people of color have less access to home dialysis therapy. Nationally, Black patients are 30.1% less likely, and Hispanic patients are 7.6% less likely than white patients to start peritoneal dialysis (PD). Similarly, for home hemodialysis (HHD), Hispanic patients are on average 42.1% less likely, and Black patients are 9.8% less likely, to receive HHD.²³

¹⁹ Li, Li MMA,b; Pei, Hualian MMc; Liu, Zhenhui MMd; Zhang, Jingjing MDa,* Analysis of risk factors and construction of prediction model of drop out from peritoneal dialysis, *Medicine*: January 22, 2021 - Volume 100 - Issue 3 - p e24195

²⁰ <https://pubmed.ncbi.nlm.nih.gov/31932094/>

²¹ Torres H, Naljayan M, Frontini M, Aguilar E, Barry S, Reisin E. Evaluating Factors Contributing to Dropout in a Large Peritoneal Dialysis Program. *Am J Med Sci*. 2020 Jul 1:S0002-9629(20)30290-1.

²² <https://www.healio.com/news/nephrology/20200219/home-dialysis-use-varies-by-race-largely-due-to-socioeconomic-factors#>

²³ Ibid.

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.

Access to Primary Care

Access to pre-dialysis nephrology care – and, indeed, access to insurance – are less prevalent among minority patients.²⁴ As a result, too many “crash” into dialysis in the emergency room, where traditional hemodialysis is the most seamless option.²⁵ A relative lack of health insurance partially causes this lack of access compared to whites.²⁶ 2018 data shows that Blacks are 1.5 times more likely to be uninsured than whites, while the Hispanic uninsured rate was almost 2.5 higher than the rate of whites.²⁷ More broadly, a report by the Agency for Healthcare Research and Quality found that Blacks and Hispanics had worse access to care when compared with whites.²⁸ Unsurprisingly, a recent survey of patients with ESRD showed that a more significant proportion of Black patients (57%) than white patients (44%) had an emergent start or “crash” dialysis start.²⁹ We encourage policymakers to focus on shifting this paradigm for all patients – particularly patients of color – who face a “crash” start to dialysis. Policy action can help provide needed support before and after kidney failure and empower patients to participate in healthcare decision-making.

Disparate Access to Education

As previously noted, chronic kidney disease patients often do not receive adequate education about their treatment options in stages of their kidney disease, during which they can make plans for the type of dialysis modality that best suits them. In fact, limited health literacy, which disproportionately affects people of color, was found to impact 25% of patients with CKD.³⁰ Black patients are less likely to receive pre-ESRD nephrology care than their white counterparts and often are not exposed to the same opportunities for early education.³¹ Further, research has found that socioeconomic factors impact the awareness and utilization of treatment options, such as home dialysis or kidney transplant.³²

Stakeholders in the kidney community are learning that impactful patient education requires meeting patients where they are. For example, a kidney technology company recently paired

²⁴ Ibid.

²⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4950106/#:~:text=There%20are%20varying%20definitions%2C%20but,catheter%20or%20during%20a%20hospitalization>

²⁶ <https://www.kff.org/racial-equity-and-health-policy/issue-brief/changes-in-health-coverage-by-race-and-ethnicity-since-the-aca-2010-2018/>

²⁷ Ibid.

²⁸ <https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrd/2019qdr.pdf>

²⁹ <https://www.renalandurologynews.com/home/news/black-white-race-health-disparities-kidney-dialysis-care-survey-results/>

³⁰ <https://academic.oup.com/ndt/article/33/9/1545/4643002>

³¹ <https://www.outsetmedical.com/perspective/nkf-survey-eskd-patients-racial-health-disparities-home-dialysis/>

³² Ibid.

with the National Kidney Foundation to survey dialysis patients and found that a lack of education and socioeconomic factors, rather than an inherent racial difference, contribute to the lower rate of home dialysis uptake in communities of color. These results led the two organizations to develop a pilot treatment-focused curriculum for patients at risk for kidney failure delivered in their communities.³³ Approaches like these should be studied and potentially emulated, with policies to support and expand those that work.

Access to Caregiver Support

Patients who do choose home dialysis need, and often lack, assistance and moral support when beginning dialysis. *Dialysis care partners* are trusted friends or family members who play a critical role, assisting patients with essential tasks such as setting up the home dialysis equipment, cooking meals, and running errands. Care partners also provide patients with support and encouragement. Unfortunately, all too many patients lack care partners entirely. Furthermore, where these caregivers exist, they are highly vulnerable to burnout. When support is lacking, particularly at the beginning of a home dialysis journey, adverse health outcomes may force patients to revert to in-center treatment. Compared with white patients, the risk of transferring from the home dialysis modality to in-center hemodialysis was higher in Black ESRD patients.³⁴ In recognition of the further need for robust caregiver support, particularly in underserved communities, we ask that policymakers consider more broadly applicable funding, such as grants for childcare, replacement of lost income, or compensation. Doing so may help alleviate the economic burden currently shouldered by caregivers and provide more flexibility for these individuals.

4. If more patients choose home dialysis, would there be systems and infrastructure in place to support this? Were more patients to choose home dialysis, what other supports, systems, or infrastructure might be necessary?

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 important means for encouraging the development and expanded use of innovative dialysis technologies. The TPNIES add-on payment helps cover the implementation costs of new home dialysis equipment, making them 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.

³³ <https://www.outsetmedical.com/perspective/nkf-survey-eskd-patients-racial-health-disparities-home-dialysis/>

³⁴ <https://www.newswise.com/articles/study-examines-differences-over-time-in-home-dialysis-initiation-by-race-and-ethnicity>

- 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.

PD Catheter Access and Hospital Resources

As alluded to elsewhere in this document, critical barriers to PD catheter access – and therefore to optimal uptake of home dialysis – exist in the hospital setting; these include, but are not limited to, lack of trained staff and inadequate operating room space. These challenges are only made more acute by the ongoing COVID-19 pandemic and the strains placed on hospitals. CMS should consider measures to encourage PD catheter placement outside the emergency room, for example, at a patient bedside or in another sterile clinic room. Accordingly, as part of the Alliance's submission to the CY22 ESRD PPS proposed rule, we outlined a demo proposal to improve PD catheter placement, including codes (49418, 49421, 49324) that are already payable outside the operating room.³⁵ The benefit of following this framework would be that it improves access to PD treatment without requiring significant infrastructure investments or creating new codes.

6. To what degree does telehealth and remote monitoring technology impact decisions of home dialysis use? Would allowing physicians to leverage evolving telehealth and remote monitoring technology for their patients increase the selection of and uptake of home dialysis as a modality? What are best practices in this area that would facilitate the delivery of safe and quality care?

As you know, home dialysis patients have had access to telehealth for their monthly clinical visits since the passage of the CHRONIC Act in 2018. This capability has proven a wonderful tool to increase patient flexibility. The Alliance firmly believes that remote patient visits can help preserve resources, promote social distancing, and provide more convenience for patients. As new technologies – like telehealth and Remote Patient Monitoring (RPM) – have emerged to help improve a patient's quality of, and access to, a more comprehensive array of kidney care modalities, the Alliance has advocated for broader access to these innovations. Alliance members have stressed that the importance of telehealth will continue to grow, especially as it relates to educating pre-dialysis patients and ensuring competent, continuous care for beneficiaries that may not necessarily be able to travel to the clinic. Many of our member organizations have already invested in new telehealth and RPM capabilities because we know that patients can benefit from the option to receive some of their dialysis care remotely. However, underserved patients living in urban and rural communities alike continue to experience poor access to necessary technologies and cannot fully benefit from new digital tools or expanded access to telehealth. For example, lack of access to high-speed internet or appropriate communication devices keeps some of our member organizations' patients from

³⁵ https://homedialysisalliance.org/wp-content/uploads/2021/09/CY2022_PPS_AllianceforHomeDialysis_8.31.21.pdf

leveraging the benefits of certain telehealth and RPM technology. Unfortunately, the pandemic has only intensified these challenges.³⁶

The COVID-19 pandemic required, and CMS delivered rapid and necessary changes to allow dialysis patients to stay in their homes as much as possible during the public health emergency (PHE). First and foremost, we applaud the Coronavirus Aid, Relief, and Economic Security (CARES) Act provisions that allowed for flexibility across all dialysis modalities in times of a PHE.³⁷ In addition, we appreciate that CMS relaxed the barriers to providing telehealth services over rural state lines, waived the once-a-quarter in-person visit requirement for home dialysis patients, and allowed for the use of non-Health Insurance Portability and Accountability Act (HIPAA)-complaint platforms, such as Skype and FaceTime.³⁸ Furthermore, we appreciate that HHS sent a letter to state governors seeking to remove other barriers to telemedicine, including state licensing requirements and scope of practice laws during the PHE.³⁹

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 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 are aware, the 2022 Physician Fee Schedule (PFS) Final Rule did not extend the coverage of these codes, so they will be removed from the Medicare telehealth services list as of the date that the COVID-19 PHE ends.

We strongly encourage CMS to grant codes 99441-99443 a Category 3 status. 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. Furthermore, covering these services aligns with President Biden's *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*. Phone consultation with physicians is an essential lifeline for home dialysis patients in underserved communities with unreliable broadband or access to technology. The Alliance believes that this category 3 designation and the continued coverage of these telephone consult codes will ultimately demonstrate that these E&M services deserve to be permanently included in the Medicare telehealth 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.

³⁶ Tummalapalli SL, Warnock N, Mendu ML. The COVID-19 Pandemic Converges With Kidney Policy Transformation: Implications for CKD Population Health. *Am J Kidney Dis*. 2021;77(2):268-271. DOI: 10.1053/j.ajkd.2020.10.004

³⁷ Coronavirus Aid, Relief, and Economic Security Act" or the "CARES Act, Pub. L. No. 116-136 § 3705.

³⁸ CMS. COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers. May 24, 2021. <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>

³⁹ Azar A. HHS Secretary Letter to States Licensing Waivers. March 24, 2020. https://www.ncsbn.org/HHS_Secretary_Letter_to_States_Licensing_Waivers.pdf

- 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 to 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.

Disparate access to Broadband and Technology

For example, not all patients have adequate internet access or devices. The Alliance has heard from physicians that a lack of access to new technologies (e.g., smart tablets) and the requisite technical literacy present issues for their patients. Similarly, patients have shared that other infrastructure-related impediments – such as poor access to the necessary technology to conduct telehealth visits and connectivity/broadband issues – have negatively impacted their ability to utilize home dialysis.

Access to Digital Health Innovation

The standard of care for Medicare ESRD patients is evolving towards more patient-centered modalities, including remote patient monitoring 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.

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. 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 the development, adoption and use of innovative tools that improve ESRD patient experiences and outcomes.

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

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 would ask CMS to allow the use of these codes for ESRD patients.

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. We thank CMS for temporarily allowing both these venues to serve as originating sites for all dialysis patients regardless of modality during the COVID-19 public health emergency. 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 by telehealth, saving patients time and expense.
- Providers working in an acute care setting can use telehealth or RPM capabilities to provide dialysis care to patients in a dialysis center or home.

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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



**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*
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**Denotes Steering Committee member*