



August 31, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1749-P
P.O. Box 8016
Baltimore, MD 21244-8010

Re: CMS-1749-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

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 on the proposed rule that updates and revises the End Stage Renal Disease (ESRD) prospective payment system (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI); the ESRD Quality Incentive Program (QIP); and the End-Stage Renal Disease Treatment Choices (ETC) Model for calendar year (CY) 2022.

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 that CMS has long recognized home dialysis – peritoneal dialysis (PD) and home hemodialysis (HHD) – as important treatment options that offer patients significant quality of

life advantages, including clinically meaningful improvements in physical and mental health.^{1,2} In the final rule implementing the new ESRD PPS on January 1, 2011, the agency indicated that the new bundled payment would “encourage patient access to home dialysis,” and “make home dialysis economically feasible and available to the ESRD patient population.”^{3,4} The most recently available data show that in 2018, there were nearly 69,000 patients performing dialysis in the home, or 12.5% of all dialysis patients.⁵ We acknowledge that all patients must have good access to the treatment option that best meets their clinical needs, whether that is PD, HHD, or in-center dialysis, but specifically thank CMS for its support of home modalities and urge continued growth in this area – specifically with respect to people of color, who suffer from ESRD disproportionately and are significantly less likely to be treated with home dialysis than white patients.

We are pleased to offer the following specific comments related to this year’s proposed rule.

I. Calendar Year (CY) 2022 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

The Alliance strongly supports CMS’s creation of the ESRD PPS Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) program as an important means for encouraging innovative dialysis technologies. This add-on payment helps cover the implementation costs of new home dialysis innovations, making them more widely available to the growing number of patients who need them. We offer the following comments to ensure that the intent and impact of TPNIES program is fully realized.

A. The Alliance thanks CMS for its expansion of TPNIES to include capital-related assets that are home dialysis machines and urges the inclusion of all capital-related assets that impact or are utilized by home dialysis patients.

The Alliance thanks CMS for finalizing policy to expand this add-on payment to include home dialysis machines in last year’s ESRD PPS final rule. Still, the current ESRD bundled payment lacks incentives for facilities to adopt new supplies and equipment, which has limited innovation and the uptake of new dialysis products, including products for home dialysis. To

¹ Pravoverov LV, Zheng S, Parikh R, et al. Trends Associated With Large-scale Expansion of Peritoneal Dialysis Within an Integrated Care Delivery Model. *JAMA Intern Med.* 2019;179(11):1537–1542, doi:10.1001/jamainternmed.2019.3155.

² NX Stage. The Benefits of More Frequent Home Dialysis. NX Stage. 2021. <https://www.nxstage.com/patients/benefits-of-home-hemodialysis>.

³ 75 Fed. Reg. 49,030, 49,058 (Aug. 12, 2010).

⁴ 75 Fed. Reg. 49,060 (Aug. 12, 2010).

⁵ 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-incidence-prevalence-patient-characteristics-and-treatment-modalities>.

this end, we urge CMS to consider expanding TPNIES coverage to all capital-related assets that impact or are related to the care of home dialysis patients, to ensure that care for these patients continues without interruption while also incentivizing innovation. In addition, the goal of the expansion to home dialysis machines was to encourage opportunities for greater access to home dialysis. Through this payment pathway, manufacturers now have an opportunity and incentive to put forward products that improve patient care. The Alliance supports patients – particularly underserved patients - having increased access to innovations of home dialysis technologies that demonstrate improved outcomes, including the ability to begin and to stay on home dialysis.

B. CMS should instruct Medicare Administrative Contractors (MACs) to provide public, timely, and consistent payment determinations.

We recommend that CMS modify the regulatory language on MAC invoice pricing determinations to exclude language that gives MACs flexibility to determine pricing based on “charges and payment amounts required for equipment and supplies that may be comparable or otherwise relevant.” This line undermines CMS approvals for applicants of TPNIES as, by definition, approved products have achieved a substantial clinical improvement over existing products.

Current policy confers discretion to the MACs to establish TPNIES payment rates based upon invoices received. Without more defined payment parameters and public transparency, there could be significant variation in regional payments and the program as a whole could be undermined. To resolve these ambiguities and increase patient access, we recommend that CMS more clearly define the payment parameters and instruct the MACs to publish an online database that provides a discrete TPNIES payment amount, no later than March 31 of the first year of TPNIES eligibility.

C. CMS should establish a formal premarket process to improve feedback to TPNIES applications.

We recommend that CMS establish a formal process to provide premarket feedback on the data needed to support a TPNIES application and guidance throughout the TPNIES application process. We ask that this process provide reasonable and clear parameters for applicants regarding the types of evidence and studies that technical expert panel reviewers want to see. A process like that of the Food and Drug Administration (FDA) when considering approval of new products would provide an opportunity for CMS and applicants to discuss an evidentiary standard that balances robust evidence of substantial clinical improvement (SCI) with the need for patients to access these technologies as soon as possible. We also ask that the process be iterative to ensure that proposals are given actionable guidance throughout the course of the application process allowing for the inclusion of new evidence as it becomes available during

the entirety of the rule making process. In addition, applicants should have transparency into who their reviewers are and be able to present evidence and data to the review team in addition to CMS staff overseeing the program.

D. CMS should articulate a formal appeal process for appealing adverse determinations.

We recommend that CMS establish a formal appeal process for manufacturers whose applications for TPNIES were denied. We are concerned that, without an opportunity to review CMS's initial determination, situations may arise in which new technologies fail to obtain a favorable TPNIES determination due to technical errors or insufficient information in the initial application. A formal appeals process would ensure that applicants have an opportunity to seek additional, independent review as necessary. The standard process for seeking review of Medicare Part A/B claims may not apply here. However, we are mindful that CMS has in the past – and has authority to do going forward – set forth a framework for conducting administrative appeals within the Office of Medicare Hearings and Appeals (i.e., a hearing before the Departmental Appeals Board). We encourage CMS to apply the same reasoning here.

E. CMS should include more robust guidance on SCI criteria.

We thank CMS for considering the importance of quality-of-life metrics and patient-reported outcomes related to equipment and technology for dialysis care, especially home dialysis. However, CMS has not sufficiently explained how it will apply and evaluate this information, particularly within the ESRD context.

The Alliance's member organizations have raised the concern that the SCI metric as drafted is overly subjective and could easily be applied inconsistently. Further, the Alliance believes that the current SCI criteria may not correctly incentivize access to new and innovative kidney dialysis equipment and supplies, which is the intended purpose of TPNIES. The Alliance is also concerned that CMS lacks a transparent process for reviewing whether a substantial clinical improvement exists. Therefore, as it relates to the TPNIES evaluation process, we ask that CMS clarify and make public how the agency plans to consider real-world evidence and patient experience with respect to the SCI standard and implement a more transparent process for reviewing whether SCI exists.

We also ask that CMS waive SCI review for novel products as determined by the FDA. Specifically, we ask that this expedited review apply to products that receive FDA marketing authorization under the de novo and Breakthrough pathways, which are used for novel products and create a more stringent regulatory review and data submission process. This would also align with the NTAP policy of automatic payment for Breakthrough devices.

F. The Alliance recommends that CMS extend TPNIES eligibility to at least three years.

We recommend that CMS extend the TPNIES adjustment period from two years to at least three years. CMS has expressly stated that 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 requires providers to cover the incremental cost of using new technologies under the existing bundled rate at the conclusion of the two-year TPNIES period. However, two years is an inadequate amount of time after considering the scale of resources and time necessary to build a responsible support and distribution infrastructure nationwide. This is especially true for companies in their earlier stages. Furthermore, a three-year adjustment period will provide companies with more time to collect data on a technology's safety and efficacy, and allow for greater cooperation between CMS, manufacturers, and other third parties in standing up potential data infrastructure. Therefore, we urge CMS to extend eligibility to at least three years, if not permanently.

G. The Alliance requests that CMS implement a post-TPNIES payment adjustment to ensure appropriate reimbursement upon the expiration of TPNIES.

The Alliance respectfully raises concerns that CMS does not plan to incorporate additional dollars into the ESRD PPS base rate for new equipment and supplies upon TPNIES's expiration. The availability of a short-term add-on payment to smooth over costs is one important factor an innovator will consider when making decisions to invest in developing a new technology. However, we are concerned that without the assurance of sustained and adequate reimbursement outside of the TPNIES period, an opportunity to ensure that optimal clinical gains for patients and better value for the Medicare program could be missed. As a threshold matter, we strongly urge CMS to reconsider its decision not to update the ESRD base rate upon the expiration of TPNIES.

H. The Alliance advises that CMS make certain adjustments to the TPNIES payment.

Adjustments can be made to the TPNIES payment paradigm that will further incentivize development. Many facilities, especially small and medium size facilities, may not have the financial reserves to purchase new devices, and therefore may prefer to maintain subscriptions with manufacturers or lease equipment. We believe that these arrangements should be accounted for under TPNIES. To this end, we urge CMS to consider business arrangements other than outright purchase of home dialysis machines and equipment, if CMS can take steps such that that a TPNIES payment does not exceed the lease or subscription payment. This would allow facilities greater financial flexibility to facilitate beneficiary access to innovative dialysis equipment.

II. Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

A. AKI patients should be given the option to receive dialysis care in the home recognizing they may require different degrees of care from their physician and interdisciplinary team than ESRD patients. This should be considered with provisions made based on the site of renal dialysis services for those patients.

We appreciate CMS's solicitation of comments regarding differences in care between ESRD and AKI (acute kidney injury) patients, and potentially modifying the site of care to allow for payment of home dialysis treatments for AKI patients. AKI is an acute condition, that in many cases does not have to progress to ESRD. For these AKI patients, the treatment goal is to recover kidney function. When an AKI patient is discharged from the hospital to continue their recovery, the current policy can limit their options in two important ways:

- i. *Catheter placement:* If an AKI patient begins dialysis in the hospital using PD, it is critical for them to stay on PD, to ensure continuity of treatment and to avoid another invasive catheter placement procedure. Depending on what nearby facilities offer, this may not be possible or may require arduous travel at a time when rest is critical.
- ii. *Site of care:* While some AKI patients are best cared for in skilled nursing facilities (SNF) post-discharge, it is not an appropriate site for all patients. In many geographic areas, few available SNF staff have the requisite training to help AKI patients dialyze and an economy of scale is lacking in order for SNFs to invest in such training. To the extent that a SNF has invested in training and staff resources, they are often certified as a home dialysis facility – which precludes that SNF from being reimbursed to provide dialysis to non-ESRD patients. CMS should clarify that SNFs are able to treat AKI patients and collect reimbursement under the PPS as a hospital outpatient department would be able to, providing they have appropriately trained staff for delivering peritoneal dialysis, hemodialysis, or both.

An AKI patient post-discharge would also require more frequent visits from their physician, nurse, social worker, dietitian, and other members of their interdisciplinary team, to be supplemented with telehealth and remote patient monitoring (RPM). These patients would also require training on their preferred modality.

B. CMS should provide for home dialysis treatments for AKI patients discharged from the hospital, subject to the decision of a patient's Managing Clinician.

The Alliance for Home Dialysis supports Medicare payment for home dialysis for AKI patients when the managing clinician determines that an AKI patient can safely dialyze at home. Home modalities can be at least equivalent to in-center care, when delivered with proper guardrails and support as described above in Section A. In these circumstances, intensive training for

home dialysis should also be reimbursed by Medicare, via the addition of training codes (CPT 90989 and 90933) being added to the telehealth list. We would also request that a dialysis facility be eligible to bill for training as part of their facility reimbursement.

III. End-Stage Renal Disease Quality Incentive Program (QIP)

The Alliance is pleased to have long participated in the ESRD QIP rulemaking process and appreciate CMS's willingness to engage with us on these important issues. The ESRD QIP offers tremendous opportunities to drive improvements in the quality, safety, and efficacy of dialysis care. We reach out to raise a request related to the QIP's consideration of home dialysis.

A. The Alliance requests that CMS institute a survey to assess dialysis stakeholders' experience with the ESRD QIP to evaluate whether the QIP adequately considers and provides data on the experience of the home dialysis community.

Stakeholders in the home dialysis community, including member organizations in the Alliance, have previously communicated to CMS concerns regarding whether and how the experience of home dialysis patients is represented in the QIP. These concerns have overwhelmingly fallen into three buckets: (i) home dialysis exclusion from the QIP In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) survey; (ii) QIP scoring methodology of small and so-called "home-only" clinics; and (iii) QIP scoring methodology of peritoneal dialysis (PD) adequacy. More broadly:

- i. The Alliance believes that the ESRD QIP offers tremendous opportunities to drive improvements in the quality, safety, and efficacy of dialysis care. Unfortunately, the experiences of home patients are not currently considered in the ICH-CAHPS survey, an important component of the ESRD QIP. The Alliance believes such exclusion significantly limits the ability to assess and improve the quality of care provided to home patients, and to compare care across modalities and settings. Furthermore, metrics designed for in-center conventional dialysis do not apply to all the clinical and/or quality-of-life benefits of home dialysis and may impose additional burdens on facilities without enhancing the home dialysis patient's experience of care. The Home Dialysis Care Experience instrument is a 26-item patient-reported experience measure that assesses patient experience of care for both PD and HHD patients. We encourage CMS to work with the authors of the instrument to expeditiously develop the instrument into a QIP measure.⁶
- ii. Data show that home patients benefit on average from clinical advantages such as
 - a. longer residual renal function⁷

⁶ Rivara MB, Edwards T, Patrick D, Anderson L, Himmelfarb J, Mehrotra R. Development and Content Validity of a Patient-Reported Experience Measure for Home Dialysis. *Clin J Am Soc Nephrol.* 2021 Apr 7;16(4):588-598.

⁷ Mayo Clinic Staff. Peritoneal dialysis overview. Mayo Clinic. July 4 2021. <https://www.mayoclinic.org/tests-procedures/peritoneal-dialysis/about/pac-20384725>.

- b. less frequent hospitalizations⁸
 - c. higher likelihood to receive a transplant⁹
 - d. survival advantage in the early years¹⁰
 - e. lower mortality vs. in-center¹¹
 - f. reduced need for antihypertensive drugs¹²
 - g. reduced need for phosphate binders¹³
 - h. reduced post-dialysis recovery time¹⁴
 - i. flexible schedule for work, life, and travel¹⁵
 - j. liberalization of diet¹⁶
 - k. improved sleep¹⁷
 - l. increased physical and emotional wellbeing¹⁸
 - m. reduced depressive symptom burden¹⁹
- iii. These differential outcomes are not fully reflected in the current QIP methodology scoring. Specifically, we are concerned that the Kt/V measure, which is used to quantify HD and PD treatment adequacy, is not a good indicator of quality, and in fact, that heavy reliance on this metric can lead to poor patient outcomes, including over-dialysis.²⁰ While Kt/V levels are included as Kidney Disease Outcomes Quality Initiative (KDOQI) minimum guidelines, they were not intended to be seen as harsh cut-offs for quality. Instead, we would urge CMS to coordinate a panel of experts to determine a

⁸ Auguste BL, Agarwal A, Ibrahim AZ, et al. A Single-Center Retrospective Study on the Initiation of Peritoneal Dialysis in Patients With Cardiorenal Syndrome and Subsequent Hospitalizations. *Can J Kidney Health Dis.* 2020;7:2054358120979239. Published 2020 Dec 8. doi:10.1177/2054358120979239.

⁹ Tang S, Lai KN. Peritoneal dialysis: the ideal bridge from conservative therapy to kidney transplant. *Journal of Nephrology.* (2020) 33:1189–1194. <https://doi.org/10.1007/s40620-020-00787-0>.

¹⁰ Marshall MR, Walker RC, Polkinghorne KR, Lynn KL. Survival on Home Dialysis in New Zealand. *Plos One.* 2014 May 7. <https://doi.org/10.1371/journal.pone.0096847>.

¹¹ Marshall, Mark R, Home Versus Facility Dialysis and Mortality in Australia and New Zealand. Article in Press.

¹² Kotanko P, Garg AX, Depner T, et al. Effects of frequent hemodialysis on blood pressure: Results from the randomized frequent hemodialysis network trials. *Hemodial Int.* 2015;19(3):386-401. doi:10.1111/hdi.12255.

¹³ Daugirdas JT, Chertow GM, Larive B, et al. Effects of frequent hemodialysis on measures of CKD mineral and bone disorder. *J Am Soc Nephrol.* 2012;23(4):727-738. doi:10.1681/ASN.2011070688.

¹⁴ Jaber BL, Lee Y, Collins AJ, et al. Effect of daily hemodialysis on depressive symptoms and postdialysis recovery time: interim report from the FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study. *Am J Kidney Dis.* 2010;56(3):531-539. doi:10.1053/j.ajkd.2010.04.019.

¹⁵ Chertow, G. M., Alvarez, L., Plumb, T. J., Prichard, S. S., & Aragon, M. (2020). Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system. *Hemodialysis International*, 24(4), 480-486. doi:10.1111/hdi.12869.

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Jaber BL, Lee Y, Collins AJ, et al. Effect of daily hemodialysis on depressive symptoms and postdialysis recovery time: interim report from the FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study. *Am J Kidney Dis.* 2010;56(3):531-539. doi:10.1053/j.ajkd.2010.04.019.

¹⁹ Ibid.

²⁰ Wang AY, Zhao J, Bieber B, et al. International comparison of peritoneal dialysis prescriptions from the Peritoneal Dialysis Outcomes and Practice Patterns Study (PDOPPS). *Perit Dial Int.* 2020;40(3):310-319. doi:10.1177/0896860819895356

metric better reflective of home dialysis than Kt/V, which could include measures like the use of non-glucose iso-osmolar solutions and volume control.

- iv. The Alliance is concerned that the current makeup of the QIP score could be a barrier to home dialysis uptake at small dialysis facilities or stand-alone home-only programs. The Alliance appreciates CMS's commitment to fairness in the QIP, and its understanding that, sometimes, a small sample size can put a facility at risk for a QIP payment reduction because one or two low scores on one measure can dramatically alter the facility's or program's score overall.²¹ However, the Alliance has become aware that small sample size remains a problem when measuring small facility or home-only performance. The clinical section of the QIP, comprising 75% of the total score, includes only two measures for most home only programs: a Kt/V score and a score for hypercalcemia. Therefore, compared with larger programs, which are scored on many more clinical data points, home-only programs have 75% of their score dependent on just two measures. The Alliance is concerned that this uneven weighting will cause small clinics to stop providing a home dialysis modality because they do not want to risk a poor QIP score as a result.

IV. End-Stage Renal Disease Treatment Choices (ETC) Model

The Alliance commends the Biden Administration's commitment to the End-Stage Renal Disease Treatment Choices Model, a measure designed to increase access to home dialysis for thousands of Americans who live with ESRD. We believe that this model will transform kidney disease treatment and improve the quality of life and care for ESRD patients. In support of the Administration's implementation of the ETC Model, we provide the following comments on the changes included in this year's proposed rule.

A. The Alliance applauds the intent to provide robust incentives for providers to increase the rates of home dialysis in their communities.

The Alliance appreciates the opportunity to comment on the agency's proposal to revise achievement benchmark scoring methodology by increasing achievement benchmarks by 10 percentage points every two measurement years (MYs) for MY3 – MY10. The stated purpose of this change aligns with the Alliance's effort to increase utilization of home dialysis. Higher benchmarks could potentially provide additional incentive for ETC Model participants to increase their rates of home dialysis and at a quicker pace. While we support the intent of increased benchmarks, the Alliance would like to ensure that these benchmarks remain attainable for ETC Model participants.

²¹ CMS Center for Clinical Standards and Quality. ESRD QIP FAQs. 2015 May 4. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/ESRDQIPFrequentlyAskedQuestions.pdf>.

B. The Alliance supports CMS’s efforts to address socioeconomic factors in order to reduce disparities in modality choice and improve equity in home dialysis rates.

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. The data makes clear that, in the United States, people of color have less access to home dialysis therapy.²² These patients, who may be appropriate candidates for home dialysis, often do not receive adequate education about their treatment options during the stages of their kidney disease when they could plan for the type of dialysis modality that best suits them. As a result, too many “crash” into dialysis in the emergency room, where traditional hemodialysis is the most seamless option.²³ Further, if the home modality is sought out, individuals with limited resources or knowledge of this modality may require more assistance to successfully access and utilize home dialysis.²⁴ We therefore support the inclusion of a Health Equity Adjustment in order support the additional time, effort and resources that are necessary for providers to help all patients access home dialysis.

C. The Alliance appreciates CMS efforts to address socioeconomic factors by incentivizing access to nocturnal in-center dialysis but cautions that exclusionary language may limit the reach of this treatment to the greatest number of eligible patients.

The Alliance has long advocated for policy changes to remove socioeconomic barriers to home dialysis – such as limited financial resources, housing insecurity, lack of social support, or personal preference – and the ETC Model has been no exception.²⁵ We support the intent of the proposal to add nocturnal in-center treatments to the home dialysis rate, because it incentivizes a modality with improved health outcomes for a population who may not be able to choose home dialysis because of these same socioeconomic factors.

However, we are concerned by the language excluding large dialysis organization (LDO) ESRD facilities from the modified home dialysis rate and suggest expanding the inclusion of nocturnal dialysis to apply to all dialysis providers. The exclusion of LDOs prevents the clinical benefits of nocturnal dialysis from reaching the greatest number of beneficiaries. Including nocturnal in-

²² Mehrotra R, Soohoo M, Rivara MB, et al. Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States. *J Am Soc Nephrol*. 2016;27(7):2123-2134. doi:10.1681/ASN.2015050472.

²³ Molnar AO, Hiremath S, Brown PA, Akbari A. Risk factors for unplanned and crash dialysis starts: a protocol for a systematic review and meta-analysis. *Syst Rev*. 2016;5(1):117. Published 2016 Jul 19. doi:10.1186/s13643-016-0297-2.

²⁴ Chan CT, Wallace E, Golper TA, et al. Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference Outcomes Report. *Am J Kidney Dis*. 2019;73(3):363-371. doi:10.1053/j.ajkd.2018.09.015.

²⁵ Lee E. Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures. Alliance for Home Dialysis. September 16 2019. <http://homedialysisalliance.org/wp-content/uploads/2019/09/Alliance-for-Home-Dialysis-ETC-Model-Letter.pdf>.

center dialysis in the home dialysis rate for all facilities would be consistent with CMS's admirable goals of holistic health equity, which the Alliance applauds and shares.

D. The Alliance commends steps taken by CMS to improve access to kidney disease education for ETC Model participants but encourages additional changes that could accomplish even more.

The Kidney Disease Education (KDE) benefit is an important tool for patients and providers. The Alliance has previously advocated for policies that will reduce barriers and improve access to this important education, including elimination of patient cost-sharing and expanding eligibility for the KDE benefit. We therefore support the proposal to implement a programmatic waiver allowing qualified staff who are ETC Participants to furnish kidney disease patient education services via telehealth. The Alliance agrees that such a change would improve utilization of this important benefit as it would remove barriers to access and provide greater flexibility for the patient. This waiver will also help achieve one of the core tenets of the ETC Model – to improve beneficiary choice of dialysis modality – as research shows that patients who receive modality education before beginning dialysis have a greater grasp of their treatment options and are more likely to choose home therapy.²⁶

In previous comment letters, the Alliance has suggested that CMS waive the 20% beneficiary coinsurance requirement associated with KDE services.²⁷ Given the relationship between poverty and prevalence of CKD, 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 this rule proposes to allow ETC participants to reduce or waive the beneficiary coinsurance for KDE services, subject to certain requirements. However, we are concerned that the requirements needed to qualify for the coinsurance waiver are overly onerous and may present an additional barrier to access. We understand that CMS considered paying 100% of the KDE benefit but chose not to. In the spirit of increasing access to the greatest possible extent, the Alliance recommends that CMS revisit this consideration, and propose to fully cover KDE services. If CMS does not choose to cover 100% of the payment for KDE services, we request that CMS expand the coinsurance patient incentive to all beneficiaries, including those that have secondary insurance, to ensure that KDE services are utilized by the greatest possible number of beneficiaries.

²⁶ Golper TA, Saxena AB, Piraino B, et al. Systematic barriers to the effective delivery of home dialysis in the United States: a report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis. *Am J Kidney Dis.* 2011;58(6):879-885. doi:10.1053/j.ajkd.2011.06.028.

²⁷ Silverman S. CMS 1691-P Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendment to Correct Existing Regulations Related to the CBP for Certain DMEPOS. Alliance for Home Dialysis. September 10 2018. <http://homedialysisalliance.org/wp-content/uploads/2018/09/Alliance-ESRD-PPS-CY19-FINAL.pdf>.

Additionally, to further expand the uptake of KDE, which is utilized by less than 2% of eligible Medicare beneficiaries according to the United States Renal Data System (USRDS), CMS should allow dialysis facilities to bill for and be reimbursed for providing KDE, through CKD Stage 5.

E. The Alliance applauds CMS for considering the inclusion of a patient experience measure for home dialysis care in the ETC Model and recommends that CMS implement a home dialysis patient experience measure in other relevant CMS programs, such as the ESRD QIP.

Home dialysis patients have historically experienced unique and important quality of life benefits, including more autonomy and flexibility over when they dialyze and greater ability to maintain employment. Unfortunately, the experiences of home patients are not currently considered in the ESRD QIP. The Alliance believes such exclusion significantly limits the ability to assess and improve the quality of care provided to home patients.

The Alliance has long advocated for CMS to implement a patient experience metric for home dialysis patients. We are happy to see that CMS is considering the inclusion of a measure to capture the beneficiary experience of home dialysis care in the ETC Model, and we look forward to helping the agency to develop such as measure. As the agency is aware, there are private sector efforts to develop a survey tool to measure home dialysis patient experience. We encourage CMS to work closely with these efforts, and actively support the psychometric testing and validation necessary to ensure that it is a valid and reliable instrument that can be utilized broadly across providers in assessing the experience of home dialysis patients. Additionally, we ask that any validated measure not be confined to the ETC Model, but rather implemented more broadly across other relevant CMS programs, such as in the ESRD QIP.

V. Request for Information: Peritoneal Dialysis (PD) Catheter Placement

The Alliance for Home Dialysis thanks CMS for providing an important forum to consider steps that the agency can take to increase access to PD catheter placement, particularly through changes to Medicare payment policy through the ESRD Treatment Choice (ETC) Model. This imperative is more striking given the goals for home dialysis uptake contained within the Advancing American Kidney Health executive order and models therein, especially the ETC Model. Because of 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.²⁸

These obstacles took on more importance upon the onset of the COVID-19 pandemic, when we, and many other stakeholders, became concerned that PD access procedures were not

²⁸ 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-incidence-prevalence-patient-characteristics-and-treatment-modalities>.

immediately listed as essential and could be postponed. At the time, we urged CMS to clarify that these procedures were necessary to begin home dialysis, and we are grateful that CMS was able to do so.²⁹ However, barriers remain in ensuring that PD catheters are placed in a timely manner for all patients who seek one, which will be discussed here, along with a potential solution encompassing a new voluntary “track” within the ETC Model.

A. Key Barriers to PD Catheter Placement

As CMS notes, there are several significant barriers impacting PD catheter placement:

- i. Lack of dedicated hospital-based catheter insertion teams for unplanned peritoneal dialysis starts; instead, these patients are often given a central venous catheter and reflexively shuttled to in-center hemodialysis, even if home dialysis would be a better option.^{30,31}
- ii. Inadequate training of surgeons and interventional radiologists on PD catheter insertion methodology.³²
- iii. Obstacles related to scheduling of operating room time.³³

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. This difference in reimbursement is especially stark when compared to reimbursement for vascular access used for insertion of a central venous catheter. When examining the most common vascular access codes (CPT 36818-36821) and the most common PD catheter insertion code equivalents (CPT 49418, 49421, and 49324), the weighted average difference in vascular access code and PD code reimbursement rates is \$360.62, in favor of vascular procedures.³⁴ This difference in reimbursement helps explain a motivation to perform more vascular procedures as opposed to PD catheter insertions and raises the question of whether, should the reimbursement be equalized, more PD catheter insertions would be performed.

²⁹ Wright DR. Key Components for Continued COVID-19 Management for Dialysis Facilities. Center for Medicare and Medicaid Services. August 17 2020. <https://www.cms.gov/files/document/qso-20-36-esrd.pdf>.

³⁰ Pajek J. Overcoming the Underutilisation of Peritoneal Dialysis. *Biomed Res Int*. 2015;2015:431092. doi:10.1155/2015/431092.

³¹ 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.

³² 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>.

³³ 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.

³⁴ Dialysis Vascular Access Coalition. CY 2021 Physician Fee Schedule Proposed Rule. Dialysis Vascular Access Coalition. October 5 2020. https://7c6286a424ee4fee92b9ed0f0d031061.filesusr.com/ugd/4d8e3a_16c9def3fa2f4b378156df8c2ac98a76.pdf

B. Increasing PD Catheter Placement through the ETC Model

We believe that if CMS wants to increase PD uptake, 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 impact of this reimbursement change could be measured. Such incentive would entail creating a voluntary track or option where participants receive a payment increase per PD placement (of at least an additional \$360.62 per PD catheter procedure) to equalize the reimbursement between PD catheter insertion and vascular placement within the model. This would allow for comparison of rates of PD catheter placement within and outside the model, to evaluate whether the payment increase within the model increased the rate of PD catheter placement.

Under the ETC Model, the managing clinician, who is typically a nephrologist, is required to coordinate home dialysis access creation when patients begin therapy, including PD catheter insertion. In large part, nephrologists work with access specialists to do this, and do not perform the placements themselves. While the managing clinician can establish and maintain these relationships with surgeons and other specialists like radiologists, the ETC Model does not currently provide direct incentive for these specialists to participate with the managing clinician. Consequently, the ETC Model, as currently structured, does not specifically address the providers involved in the placement of PD catheters and their role in encouraging the uptake of home dialysis. We urge CMS to consider establishing a voluntary track or option of the ETC Model to better target this issue. Such a track could incentivize access specialists to partner with ETC managing clinicians for the purposes of placing PD catheters, thereby addressing a key barrier to home dialysis access for patients.

i. Incentivizing Clinician Participation

To implement, CMS would make it known that if surgeons or other access specialists partner with ETC managing clinicians, they will be eligible for a payment bump of at least \$360.62 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 the model's focus on increasing home dialysis.

During ETC Model rulemaking, CMS received comments and contemplated providing additional payments directly to providers beyond the managing clinician, recognizing that it had the flexibility and authority to potentially broaden the model participants. While the final model ultimately chose not to include transplant providers, this rulemaking did not address the importance of PD catheter placement in the overall model framework. Unlike the transplant surgeons, PD catheter placements do not have other direct CMS policies that can work outside

the model to address these concerns. Accordingly, we believe it is appropriate to create a separate PD catheter placement incentive under the ETC Model.

ii. Considerations on Site of Care and Net Spending

We would not expect this proposed ETC Model track to require additional net spending because we would expect to see PD catheter insertions *replace* vascular procedures that would otherwise be performed. Overall, around 53,000 vascular access code units appear in 2019 physician summary data, whereas PD code units appear slightly more than 22,000 times.

Perhaps more importantly, we would not expect to see transfers in site of service. It is our understanding that most PD codes billed in the inpatient setting are due to patients “crashing” into dialysis and beginning urgent start PD. These patients are very sick, presenting to the emergency department needing immediate dialysis, and are admitted inpatient due to their status, not the intricacy or simplicity of the PD access procedure itself. Conversely, the outpatient patient population tends to be prepared for dialysis onset, so we do not anticipate a shift from outpatient vascular access or PD catheter placement procedures to inpatient procedures. Instead, we anticipate this proposed demonstration track would focus on outpatient access placements, and the anticipated switch from vascular access to PD catheter within the outpatient setting. Overall, we believe that such a demonstration track would be appropriate as a part of the ETC Model.

iii. Additional Technical Considerations

Under this proposed track to address PD catheter placement, beneficiaries would still be attributed to a managing clinician based on the MCP. The access specialist would be able to bill as usual for each PD catheter placement, but include a modifier established by CMS to identify placements done in conjunction with the managing clinician under the ETC Model in order to receive the extra payment. Using this modifier, CMS would be able to determine whether the incentive payment increased the relative number of PD catheters placed within the ETC Model as compared to claims data showing the service mix for vascular access and PD codes outside the ETC Model.

iv. Timing for Implementation

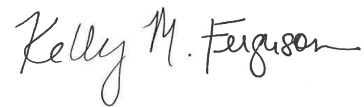
CMS could accomplish this change in the final ESRD rule, as the ETC Model has already undergone extensive notice and comment rulemaking and this RFI provided the additional opportunity for stakeholder feedback specific to PD catheters. Establishing this incentive as soon as feasible makes the most sense for both beneficiaries and providers to complement the current efforts established by CMS. Furthermore, we propose that participation in this portion of the model would not be mandatory, rather it would be a voluntary track where participants

could opt-in to further test broader and more comprehensive incentive payments. CMS has developed similar tracks within models in other cases, which allow variations in incentives tested but that share the same overall goal or has expanded the scope of existing models.³⁵ We would welcome the opportunity to further discuss the exact framework for such a model and how it would improve beneficiary care.³⁶

VI. Conclusion

The Alliance appreciates the opportunity to provide comments to the ESRD PPS and QIP proposed rule for calendar year 2022. Please do not hesitate to reach out to Alliance members or staff to discuss how we can work together. Should you need any further information, please contact Kelly Ferguson at kferguson@homedialysisalliance.org.

Sincerely,

A handwritten signature in black ink that reads "Kelly M. Ferguson". The signature is written in a cursive, flowing style.

Kelly Ferguson
Policy Director

³⁵ See *e.g.*, the various tracks for Accountable Care Organizations, including the Medicare Shared Savings Program and Next Generation Accountable Care Organization.

³⁶ We believe that the Center for Medicare and Medicaid Innovation has broad waiver authority, including under the new Anti-Kickback Statute safe-harbor specific to CMMI, to help ensure flexibilities for model participants.



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