



August 22, 2022

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) 2023. 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 choices 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}. When CMS implemented a bundled payment in 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} Recent data show that in 2018,

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)

there were nearly 69,000 patients performing dialysis in the home, or 12.5% of all dialysis patients⁵. 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 patients⁶. We are pleased to offer the following specific comments related to this year’s proposed rule.

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

The ESRD QIP offers tremendous opportunities to drive improvements in the quality, safety, and efficacy of dialysis care; CMS’s Request for Information (RFI) on Quality Indicators for Home Dialysis Patients⁷ is a particularly welcome opportunity for the home dialysis community to provide meaningful input towards a quality measurement system for these patients that recognizes their unique experience. For purposes of responding to the RFI, we reiterate below many of our requests from recent years and as always, are happy to provide further input from our clinical experts as it is helpful.

A. ICH-CAHPS and patient engagement

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 priority for home dialysis indicators should be outcome measures, patient-reported outcome measures (PROMs), and patient-reported experience measures (PREMs). Work in the PREMs area has been significant, and we urge CMS to examine the Home Dialysis Care Experience instrument developed by Rivara, et al. The Home Dialysis Care Experience instrument is a 26-item patient-reported experience measure that assesses the patient experience of care for both PD and HHD patients. CMS should work with the authors of HDCE⁸ to expeditiously evaluate and test the validity of the instrument as a potential first PREM for home dialysis. Further, the agency should conduct an engagement survey of home dialysis patients.

B. Treatment adequacy

Data shows that home patients using each modality benefit from clinical advantages; a few examples are provided below. Please note that each item listed may apply to only PD or HHD.

- (1) longer residual renal function⁹

⁵ <https://adr.usrds.org/2021/end-stage-renal-disease/2-home-dialysis>

⁶ <https://www.healio.com/news/nephrology/20211118/racial-disparities-persist-in-home-dialysis-use-across-the-us>

⁷ <https://www.govinfo.gov/content/pkg/FR-2022-06-28/pdf/2022-13449.pdf>, page 38553

⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8092066/>

⁹ Mayo Clinic Staff. Peritoneal dialysis overview. Mayo Clinic. July 4 2021.

<https://www.mayoclinic.org/testsprocedures/peritoneal-dialysis/about/pac-20384725>.

- (2) less frequent hospitalizations¹⁰
- (3) higher likelihood to receive a transplant¹¹
- (4) survival advantage in the early years¹²
- (5) lower mortality vs. in-center¹³
- (6) reduced need for antihypertensive drugs¹⁴
- (7) reduced need for phosphate binders¹⁵
- (8) reduced post-dialysis recovery time¹⁶
- (9) flexible schedule for work, life, and travel¹⁷
- (10) liberalization of diet¹⁸
- (11) improved sleep¹⁹
- (12) increased physical and emotional wellbeing²⁰
- (13) reduced depressive symptom burden²¹

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. 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. We offer the following suggestions with respect to the Kt/V measure:

- (1) The current adequacy measures should be broken up by modality, to better understand the care delivered.

¹⁰ 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.

¹¹ 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>.

¹² 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>.

¹³ Marshall, Mark R, Home Versus Facility Dialysis and Mortality in Australia and New Zealand. Article in Press

¹⁴ 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.

¹⁵ 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.

¹⁶ 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.

¹⁷ 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.

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ 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.

²¹ Ibid.

(2) CMS should consider, in consultation with clinical experts, lowering the threshold of patients for whom a physician must obtain adequate Kt/V, to allow for some individualization of therapy, particularly in the case of HHD patients.

(3) We urge CMS to coordinate a panel of experts to determine whether other metrics, such as non-glucose iso-osmolar solutions or volume control, should be included in order to provide a fuller view of the care delivered than Kt/V alone.

C. Other measures for consideration

Other quality indicators to consider are listed below. As CMS considers quality indicators for home dialysis patients, we would urge that any measures adopted be validated by the National Quality Forum.

(1) A standardized transplant or waitlist rate

(2) Vaccination rate for select vaccinations

(3) A measure to determine adherence to dialysis prescription, such as the percentage of patients who are dialyzing according to their doctor's prescription.

(4) percentage of patients meeting agreed-upon guidelines for adequate blood pressure control as measured by flow sheet data

(5) A measure to capture the rate of retention; as federal policies like the ETC Model provide robust incentives to assist patients in starting a home modality, it is important to understand how many patients can continue with their home therapy in the long term.

D. QIP Score Effect on Home-Only Programs and Smaller Dialysis Facilities

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, 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 overall²². This risk is exacerbated by the fact that a home program has fewer measures to report, and those measures are not met as easily at home. 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.

II. Request for Information on Potential Future Inclusion of Two Social Drivers of Health Measures and Request for Information on Advancing Health Equity Under the ESRD PPS

²² CMS Center for Clinical Standards and Quality. ESRD QIP FAQs. 2015 May 4. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/ESRDQIP/Downloads/ESRDQIPFrequentlyAskedQuestions.pdf>.

Although the burden of kidney disease is felt in all communities across the country, the degree of burden differs significantly depending on socioeconomic, racial, cultural, political, and geographic factors. Research shows that communities of color are disproportionately affected by chronic kidney disease (CKD) and possess a much higher risk of developing kidney failure due in part to this population's increased propensity to experience dialysis risk factors, such as hypertension and diabetes²³. In 2018, approximately 0.59% of all Black Americans, 0.33% of all Hispanic Americans, and 0.32% of all American Indians/Alaska Natives experienced end-stage renal disease (ESRD)²⁴. Compared to white people, the prevalence of ESRD was about 3.4 times greater in Black Americans, 1.9 times greater in American Indians/Alaska Natives, and 1.3 times greater in Asian Americans²⁵.

We at the Alliance have applauded the Biden-Harris Administration's commitment to sustained engagement with outside stakeholders in its efforts to address systemic inequities in health care. Given the disproportionate burden of chronic kidney disease (CKD), acute kidney injury (AKI), and ESRD, the attention given to these inequities in the CY2023 Proposed Rule presents welcome opportunities to further share what we have come to learn about these patients and help you to drive policy change. To that end, we thank CMS for its request for public comment on adding a new Screening for Social Drivers of Health measure to the ESRD QIP measure set in the next rulemaking cycle. We can affirm that many ESRD patients struggle with transportation access, housing instability, and other social drivers of health that inhibit their ability to receive appropriate treatment and care. We are further encouraged by the agency's Request for Information on Advancing Health Equity Under the ESRD PPS and see several important opportunities for CMS to consider within the scope of that RFI.

For a more holistic view of the issues at hand, we have attached as Appendix A to this letter the Alliance's Response to the Office of Management and Budget's (OMB) Spring 2021 RFI on Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government.

III. 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.

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. Barriers such as lack of caregivers and lack of upstream care – barriers disproportionately faced by low-income communities and communities of color – partially account for relatively low home dialysis uptake in the United States. In fact, the data makes clear that, in the United States, people of color have less access to home dialysis therapy²⁶. These patients, who may be appropriate candidates for home dialysis, often do not receive adequate

²³ <https://www.niddk.nih.gov/health-information/kidney-disease/race-ethnicity>

²⁴ <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

²⁵ <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

²⁶ 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.

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, which is not the ideal circumstance to plan for living life on dialysis and often keeps those with limited resources from obtaining the assistance they would need to successfully use a home modality.²⁷ We applaud last year’s inclusion of a Health Equity Incentive to support the additional time, effort, and resources that are necessary for providers to help all patients access home dialysis – and appreciate CMS’s efforts to address socioeconomic factors by incentivizing access to nocturnal in-center dialysis and applauds the agency’s action in the CY2022 final rule to extend that incentive equally to all facilities and Managing Clinicians.

A. Changes to the PPA Benchmarking Methodology

Last year’s rule increased achievement benchmarks by 10% over rates observed in Comparison Geographic Areas every two Model Years (MYs), beginning in MY3 (2022) and finalized proposals to stratify achievement benchmarks based on the proportion of attributed beneficiaries who are dually eligible for Medicare and Medicaid or receive the Low-Income Subsidy (LIS) during the MY. While the intent of these changes was to recognize that beneficiaries of lower socioeconomic status have lower rates of home dialysis, we appreciate the agency’s subsequent recognition that the stratification increased the likelihood that the lowest benchmark could be set at a home dialysis rate or transplant rate of zero, counter to the intention of the provision²⁸. We support the proposed requirement to specify that, an ETC participant’s aggregation group must have a home dialysis rate or a transplant rate greater than zero to receive an achievement score for that rate.

B. Kidney Disease Education (KDE)

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 the 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 therapy²⁹. In previous comment letters, the Alliance has suggested that CMS waive the 20% beneficiary coinsurance requirement associated with KDE services. Given the relationship between poverty and the prevalence

²⁷ 4 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

²⁸ <https://www.govinfo.gov/content/pkg/FR-2022-06-28/pdf/2022-13449.pdf> Page 38563

²⁹ 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.

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.

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. CKD and ESRD patients who need KDE should have access to the best clinical experts possible to deliver that education, regardless of whether that expert is employed at a dialysis facility or elsewhere. To avoid “patient steering” and “marketing” in such instances, we encourage CMS to implement balanced guardrails. For example, educational materials should not be branded with the name of a dialysis provider. The substance of the education should only be clinical information. When facilities are involved in conducting KDE sessions, those sessions should be conducted in a provider-neutral manner. CMS should consider a role in approving educational material or modules before they are deployed.

C. Publication of Participant Performance

CMS’s efforts to share information about the performance of ETC participants will be critical to understanding whether the model is working as intended and whether cost and quality of care goals are met. The agency’s proposal to publish patient de-identified results from all MYs of the ETC Model on an aggregate and individual basis is an important measure of transparency to help stakeholders understand the impact of this Specialty Care Model.

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

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. Under existing CMS guidance, the home dialysis benefit is not permitted for patients with AKI. Hospitals in several COVID-19 hotspots, however, have experienced massive influxes of COVID-19-infected patients, many of whom experience AKI as a complication of their illness. Currently, under the Public Health Emergency (PHE), waivers have been issued to hospitals that allow for acute hospital care to be delivered at home. Many providers are offering this option to patients with various acute care needs. Dialysis for AKI is eligible for such a waiver only if the patient is admitted to the hospital as an inpatient. However, when an AKI patient is stable enough to be discharged from the hospital, they are no longer able to receive home dialysis under such a waiver program and instead are required to go to an in-center dialysis facility three or more times per week to receive their dialysis treatments. While home dialysis could be an appropriate modality for some of these patients, especially considering pandemic-surge-driven hospital room and staff shortages, several additional policy barriers keep these patients from accessing it:

- (1) *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 for in-center patients, this may not be possible or may require arduous travel at a time when rest is critical.
- (2) *Site of care:* A skilled nursing facility (SNF) may be the most appropriate discharge destination for some patients, but it is not appropriate for most. In many geographic areas, few available SNF staff have the requisite training to help AKI patients dialyze, and an economy of scale is lacking 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.
- (3) *Access to interdisciplinary care at home:* While stable enough to be discharged as an inpatient, many AKI patients may still need more frequent monitoring and/or assistance from their physician, nurse, social worker, dietitian, and other members of their interdisciplinary team. Both dialysis and these ancillary services can be accomplished in the home. In addition, new technology has allowed for real-time remote patient monitoring for clinicians to see vital signs and treatment data for their patients to even more closely mimic inpatient dialysis care.³⁰ Additionally, CMS can ensure safe care at home for AKI patients by also paying for staff-assisted home dialysis through an adjustment to the PPS. Providing staff assistance will allow patients to socially distance themselves if they desire. In addition to delivering dialysis treatments, staff assistance in the home can also help with catheter care education to prevent infections. In fact, the CDC has developed patient education materials that can be leveraged by staff treating patients in the home to educate patients on proper hemodialysis catheter care.³¹
- (4) *Access to training at home:* Last, as the time frame for recovering kidney function is often unknown, there is an opportunity for AKI patients to also be trained for home or self-care dialysis at home. For those patients who do not recover, this reduces dependence on health care staff and provides a smoother transition to HHD or PD for these patients. We would also request that a dialysis facility be eligible to bill for training as part of their facility reimbursement.

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 appropriate resources, as detailed above. The current policy against payment for AKI at home also exacerbates the current

³⁰ <https://rogosin.org/home-dialysis-means-a-better-quality-of-life/>

³¹ https://www.cdc.gov/dialysis/clinician/index.html#anchor_1556295206

disparity in the use of home dialysis among people of color, as Black Americans are more likely than White Americans to develop AKI.³²

While CMS has not proposed an allowance for AKI patients to receive care at home in this rule, CMS could establish a waiver now that extends to outpatient AKI dialysis under the current PHE. Longer-term CMS should permanently allow for AKI dialysis at home to be reimbursed, include an adjuster to the PPS for AKI patients to receive staff-assisted dialysis at home, and reimburse for home training for these patients. We urge the agency to provide clarity and a clear pathway for these services, and When the agency solicited input on this topic last year through an RFI, the kidney community broadly supported reimbursing home dialysis for AKI patients. We encourage the agency to include a formal proposal to this effect in the CY2024 Proposed ESRD PPS Rule.

V. Facilities need Clarity on a Telehealth Training Add-On Payment

During the COVID-19 pandemic, some facilities began offering certain elements of home dialysis training via telehealth, which would normally be performed in person in the clinic setting. The Alliance believes that while certain aspects of training, like the teaching of cannulation techniques and inspection of dialysis machinery, 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 the challenges that facilities and clinical offices face due to staff shortages, particularly for nurses, who often perform the in-person training. 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 and dialyze on a different schedule than 3 times per week, telehealth can contribute to the flexibilities they need to continue living life as normally as possible. Therefore, CMS should give regulatory consideration to offering the potential for telemedicine training to supplement in-person training.

While we understand that there are no explicit requirements in regulation that home dialysis training must be in person, most of the time, training is billed as an adjustment to the ESRD PPS. This adjuster does not currently contemplate telehealth training, constraining facilities' ability to deliver these services. We request that the agency change this policy so that facilities can recoup the cost of providing these services.

VI. PD Catheter Payment Policy

We appreciated CMS's request (RFI) in last year's rule for input on how it might test and use Medicare payment policy, under the ETC Model, to promote the placement of PD catheters. As you know, the Alliance has long urged the agency to use the tools at their disposal to break down very real barriers to the insertion of PD catheters³³ and submitted a demonstration proposal (attached to this letter as

³²Grams ME, Matsushita K, Sang Y, Estrella MM, Foster MC, Tin A, *et al.* "Explaining the racial difference in AKI incidence." 25 *J Am Soc Nephrol* 1834–41. (2014).

³³ 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>.

Appendix B) in response to this request. Domestic and international stakeholders³⁴ are united in agreement about what government policies can address these barriers and are eager to be partners in this important effort. As CMS pledged in the Final Rule to continue to review all input on this question, we urge you to use this rulemaking cycle to implement the thoughtful changes offered by the kidney community in response to last year's RFI.

VII. Calendar Year (CY) 2022 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

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. Indeed, we are encouraged to see this year's TPNIES applications include devices specifically intended for use in home dialysis and appreciate the agency's work in evaluating these applications thoughtfully with the best interest of patients in mind.

Below, we share with you select comments in direct response to the content of this year's rule.

(1) Offset for capital-related assets

While the Alliance does not support the use of a per treatment offset for these assets, we recognize and appreciate the relatively measured approach used by the agency through the application of a market basket increase.

(2) 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.

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

We have long expressed our concerns about CMS's previous intentions not to adjust the ESRD PPS payment rate to account for the expiration of drugs and devices' short-term add-on payments, at which time those products enter the ESRD PPS bundle. The availability of a short-term add-on payment like TPNIES is one important factor an innovator will consider when making decisions to invest in developing

³⁴ <https://www.sciencedirect.com/science/article/pii/S259005952100100X>

new technology. However, we are concerned that without the assurance of sustained and adequate reimbursement outside of the TPNIES period, an opportunity to ensure optimal clinical gains for patients and better value for the Medicare program could be missed. We appreciate the agency's recognition of this challenge in its Request for Information (RFI) on an Add-On Payment Adjustment After the TDAPA Period Ends³⁵ and we strongly urge CMS to make sustained, adequate funds available for TPNIES-approved products beyond the TPNIES period.

We appreciate CMS's continued request for input on the TPNIES program and wish to reiterate some recent Alliance comments on the program, below.

- (4) The Alliance urges the inclusion of all capital-related assets that impact or are utilized by home dialysis patients.

We appreciate CMS's decision in the CY2022 PPS rule to allow capital-related assets that are home dialysis machines to qualify for TPNIES payment. Still, the current ESRD bundled payment lacks incentives for facilities to adopt new supplies and equipment. This lack of incentive has limited innovation and the uptake of new dialysis products, including products for home dialysis. To 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 stay on home dialysis.

- (5) 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 the 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 an existing product. 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 which would undermine the program's intent. 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.

- (6) 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

³⁵ <https://www.govinfo.gov/content/pkg/FR-2022-06-28/pdf/2022-13449.pdf> Page 38523

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 receive 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 rulemaking 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.

(7) 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 are initially unsuccessful. We are concerned that, without an opportunity to review CMS's initial determination, situations may arise in which innovative 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 an additional, independent review as necessary. We note that 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.

(8) 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. Without that explanation, we are concerned 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 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 applies 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.

(9) The Alliance advises that CMS make certain adjustments to the TPNIES payment.

Many facilities, especially small and medium 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 TPNIES should account for these arrangements. To this end, we urge CMS to consider business arrangements other than the outright purchase of home dialysis machines and

equipment, if CMS can take steps such 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.

VIII. ESRD Conditions for Coverage (CoC)

We have noted that CMS has included on its Unified Agenda a priority named “Culturally Competent and Person-Centered Requirements to Increase Access to Care and Improve Quality for All (CMS-3418).” As you are aware, the ESRD Conditions for Coverage (CfCs) have not been holistically updated since 2005. The COVID-19 pandemic has highlighted the power of innovative approaches and technologies and underscored the urgent need for a coordinated national response to make available high-quality dialysis care delivery at home. To sustain this era of innovation in dialysis care and prepare for future ESRD population growth, the kidney community requires policy support in the form of modernized regulations that still fulfill the fundamental purpose of protecting ESRD patients and ensuring the highest safety standards wherever patients choose to dialyze. CMS must create distinct and separate guidance that is applicable to home programs and facilitate improvements in staffing and care models that can best support individual patients at home. We urge the agency to act comprehensively to improve equitable access to home dialysis through holistic changes to the CFC regulations and in the development of interpretive guidance specific to home programs.

Conclusion

The Alliance appreciates the opportunity to provide comments on the ESRD PPS and QIP proposed rule for the calendar year 2023. 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,

Kelly Ferguson

Kelly Ferguson
Policy Director