August 21, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1805-P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure,

On behalf of the nearly 30 organizations working together to advance kidney care through Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model" (Proposed Rule). This letter focuses on those aspects of the Proposed Rule that KCP did not address in the August 9 letter, including the budget neutrality calculation with regard to the geographic wage index, the low volume payment adjuster, technical issues related to the outlier payment proposal, the expanded access to home dialysis modalities for individuals with acute kidney injury and the home dialysis training add-on, the facility- and patient-level adjusters, and the ESRD Treatment Choices (ETC) model proposals and request for information.

Kidney Care Partners is a non-profit, non-partisan coalition of nearly 30 organizations comprising patients, physicians, nurses, dialysis professionals, researchers, therapeutic innovators, transplant coordinators, and manufacturers dedicated to working together to improve the quality of care for individuals living with kidney disease.

I. KCP recommends that CMS not apply the budget neutrality adjustment to the modifications to the geographic wage index.

KCP agrees that the ESRD PPS should have a geographic wage index tailored to ESRD facilities; however, given that the wage index affects KCP members in dramatically different ways, the coalition cannot take a position on whether CMS should implement the proposed changes in 2025 or at a later time. KCP is united in its belief that CMS should not apply the budget neutrality factor that reduces the base rate when it modifies the wage index.

While we appreciate that CMS has applied a budget neutrality factor to the geographic wage index historically, the adjustments have been relatively small and based on updates to the OMB definitions of Metropolitan Statistical Areas that result from the decennial U.S. Census. However, the substantial and unprecedented changes CMS proposes are the result of developing and applying an entirely new methodology. Given the unique aspect of this proposal, KCP urges CMS not to apply the budget neutrality factor when it shifts to an ESRD-specific wage index.

This approach would be consistent with the statutory requirements that are unique to ESRD PPS. The Social Security Act (SSA) does not mandate that CMS apply a budget neutrality factor when it implements the geographic wage index. The only language related to adjusting the based rate applies to the 2011 implementation of the PPS.

> In implementing the [ESRD PPS] the Secretary shall ensure that the estimated total amount of payments under this subchapter **for 2011 for renal dialysis services shall equal 98 percent of the estimated total amount of payments** for renal dialysis services, including payments under paragraph (12)(B)(ii), that would have been made under this subchapter with respect to services furnished in 2011 if such system had not been implemented. In making the estimation under subclause (I), the Secretary shall use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization.[1]

CMS recognized as much when it implemented the drug designation policy and determined that adjustments to the ESRD PPS could add new dollars to the payment system (including the base rate) without applying a budget neutrality adjustment.[2] This authority differs from that the Congress passed for the hospital inpatient, hospital outpatient, and physician payment systems.[3] These other statutes expressly require CMS to establish the wage index to be budget neutral.[4] The ESRD statute does not. The ESRD PPS "may include such other

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[1]42 U.S.C. § 1395rr(b)(14)(A)(ii) (emphasis added).
[2]*See* 42 C.F.R. § 413.234.
[3] *See* 42 U.S.C. § 1395ww(d)(8)(D) ("The Secretary shall make a proportional adjustment in the standardized amounts determined under paragraph (3) to assure that the provisions of subparagraphs (B) and (C) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) **do not result in aggregate payments under this section that are greater or less than those that would otherwise be made**.")(emphasis added); *Id.* § 1395l(t)(9)(B)("If the Secretary makes adjustments under subparagraph (A) [*periodic review and adjustments components of prospective payment system*], then the adjustments for a year may **not cause the estimated amount of expenditures under this part for the year to increase or decrease** from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made.")(emphasis added); *Id.* § 1395w–4(c)(2)(B)(ii)(II) (Subject to [certain exemptions], the adjustments under subclause (I) for a year may not cause the amount of expenditures under this part for the year to differ by more than $20,000,000 from the amount of expenditures under this part that would have been made if such adjustments had not been made.")(emphasis added).
[4]42 U.S.C. § 1395ww(d)(3)(E)(i)("[T]he Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a

payment adjustments as the Secretary determines appropriate, such as a payment adjustment . . . by a geographic index, such as the index referred to in paragraph (12)(D),[5] as the Secretary determines to be appropriate."[6]

Given that CMS does not have to apply a budget neutrality factor and MedPAC found that the average Medicare margins for facilities is zero,[7] we ask that CMS not apply the budget neutrality factor when it implements the new geographic wage index. Moreover, eliminating the budget neutrality factor would constitute a positive step toward addressing the significant miss in the market basket projections KCP highlighted in our August 9 letter on the Proposed Rule.

KCP appreciates that the proposed ESRD specific wage index addresses the weaknesses in the legacy methodology including the fact that the ESRD labor structure differs substantially from that used in the inpatient hospital setting and the four year time lag when hospital data are used. KCP requests that CMS consider the interaction of the geographic wage index and the other payment adjusters, particularly the rural adjuster. Additionally, we ask that CMS study the cost of contractor labor and the potential differential in benefits to ensure that the relative differences in labor costs are accounted for in the policy.

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factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. [. . .] Any adjustments or updates made under this subparagraph for a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment."); *Id.* § 1395(t)(2)(D) ("[S]ubject to [certain exemptions], the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner."); *Id.* § 1395w–4(e)(1)(H)(v)("[T]he Secretary shall, not later than January 1, 2012, make appropriate adjustments to the practice expense geographic adjustment described in subparagraph (A)(i) to ensure accurate geographic adjustments across fee schedule areas, including—(I) basing the office rents component and its weight on office expenses that vary among fee schedule areas; and (II) considering a representative range of professional and non-professional personnel employed in a medical office based on the use of the American Community Survey data or other reliable data for wage adjustments. Such adjustments [. . .] shall be made in a budget neutral manner.")

[5]Paragraph (12)(D) also does not include a budget neutrality requirement: "(D) The Secretary shall adjust the payment rates under such system by a geographic index as the Secretary determines to be appropriate. If the Secretary applies a geographic index under this paragraph that differs from the index applied under paragraph (7) the Secretary shall phase-in the application of the index under this paragraph over a multiyear period."

[6]42 U.S.C. § 1395rr(b)(14)(D)(iv)(II).

[7]https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch5_MedPAC_Report_To_Congress_SEC.pdf

II. KCP supports the adoption of the MedPAC recommended changes to the Low Volume Payment Adjustment methodology, but is concerned that the methodology CMS proposes to determine the payment rates is not consistent with these recommendations and urges CMS to align the methodology with that used by MedPAC before implementing the policy.

As noted in previous letters, KCP strongly supports the adoption of a three-tiered methodology for the low-volume facility adjuster required by the Congress. We are pleased that CMS appears to have abandoned the proposed census-track based model outlined in the CY 2022 ESRD PPS proposed rule in favor of a methodology closer to the MedPAC recommendations. While the proposal outlined in this Proposed Rule more closely resembles the MedPAC recommendation, it does not follow the methodology MedPAC or The Moran Company (now HMA) had outlined for its implementation. Therefore, while we continue to urge CMS to adopt a methodology relying on three-tiers for assessing the adjustment, the model proposed requires significant modification before it is implemented.

As a threshold matter, KCP reiterates that it does not support the use of census tracts to identify geographic areas with low demand to evaluate the need to incentive facilities to remain in these areas to protect beneficiary access to dialysis treatments. As presented by the CMS technical expert panel (TEP) contractor, this model is complicated and lacks transparency. It also seems likely to perpetuate the concern that basing adjusters on ZIP codes fails to appropriately target providers with actual low-volume. The tiered model considered by MedPAC and supported by KCP has the advantage of being based on actual patient census numbers over a period of time and includes a mechanism to make sure that bad actors do not "game" the system by limiting facility capacity. It is also transparent in that facilities must attest to their populations. These attestations can be easily confirmed using claims data.

KCP has several concerns with the methodology CMS proposes to implement a LVPA with a tiered approach. First, the proposals leaves in place the rural adjuster, which MedPAC and HMA have found is not targeted to facilities with higher costs and overlaps substantially with the LVPA.[8] KCP agrees with MedPAC that the rural adjuster should be eliminated. The removal of the dollars currently allocated to the rural adjuster would then be available to support a more robust LVPA. This step would eliminate the need for the substantial budget neutrality calculation CMS proposes as well. The approach would also ensure that the facility-level adjusters are targeted to those facilities with higher costs to protect access for those individuals who rely on these low-volume facilities for their care.

We recognize that CMS has stated that it disagrees with the MedPAC assessment that the rural adjuster overlaps with the LVPA and includes facilities that do not have

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[8] MedPAC. "Improving Medicare Payments for Low-Volume and Isolated Outpatient Dialysis Facilities." Available at: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-document-library/dialysis-oct-2019-public.pdf (Oct. 3, 2019).

higher costs.[9] In light of the analyses by HMA and MedPAC reaching the opposite conclusion, we encourage CMS to re-evaluate its findings that are inconsistent with those of these two independent organizations. For example, in analyzing the CY 2025 ESRD PPS Proposed Rule, HMA continues to find that both tiers of the new two-tier LVPA significantly overlap with the rural adjustment.

Table 1. Low Volume / Rural Overlap

	# of Facilities	% rural 2025	% rural 2024
Low Volume Tier 1 (0-2999)	202	48.5%	50.0%
Low Volume Tier 2 (3000-3999)	128	44.5%	46.1%

MedPAC has found that about 50 percent of rural facilities were high-volume, meaning they furnished more than 6,000 treatment. Such high-volume facilities, according to MedPAC, have on average lower adjusted treatment costs than low-volume facilities.[10] A related challenge with the methodology underlying the CMS LVPA revision proposal is that CMS does not appear to have accounted for the different rates of rural facilities in the two tiers, which may partially explain the variance CMS measured in setting these adjustment amounts.

Second, KCP has concerned about the definition of the tiers. Like MedPAC ,we believe that the low volume adjuster should be defined using the following categories for the three tiers. KCP continues to recommend the following tiers for the revised LVPA.

- <4,000 treatments
- 4,001-5,000
- 5,001-6,000

These tiers are consistent with the HMA analysis that identified cut points based on the facility-level costs. MedPAC also found that facilities with relatively low volume (defined as between 4,000 and 6,000 treatments) should be included in the LVPA.[11] The flawed methodology CMS applies has distorted the fact that the three tiers suggested by MedPAC better align with the costs these facilities face than the current LVPA policy or the rural adjuster. KCP agrees with MedPAC that targeting the tiers to less than 4,000 treatments, between 4,001 to 5,000 treatments, and between 5,001 to 6,000 treatments would better align the payment adjustment with those facilities that have higher costs.[12]

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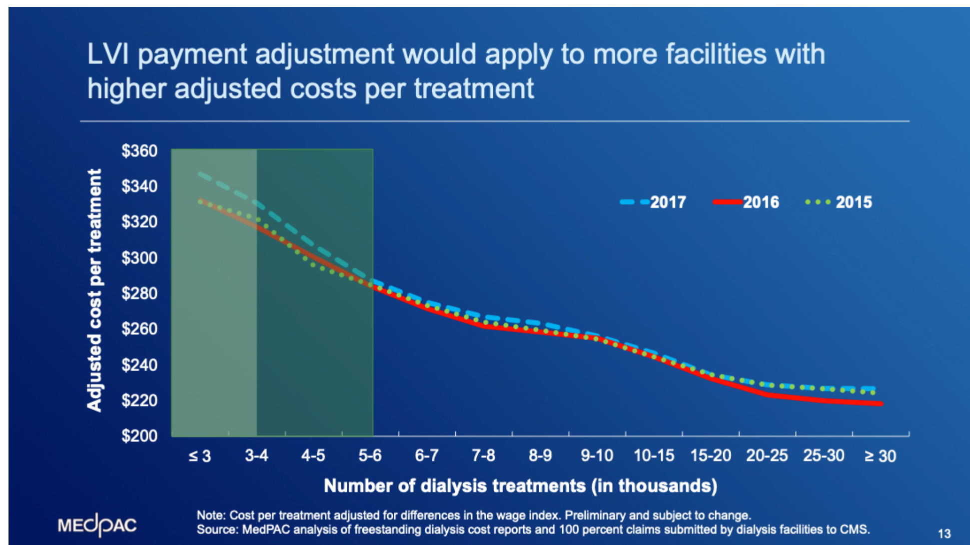
[10] *Id.*
[11] *Id.*
[12] *Id.*



Third, KCP is concerned that he CMS LVPA adjustment calculation for the proposed three tier approach has not considered whether the facility would be eligible for the adjustment or not. In both the CMS two tier and three tier proposals, the adjuster for the first two tiers are identical. This result occurs despite the addition of 27 percent more facilities to Tier 1 and 75 percent more facilities to Tier 2. The adjuster values should be calculated based upon the facilities which qualify for the adjustment rather than on all facilities meeting the volume criteria for a single year. Moreover, HMA notes that none of the facilities CMS projects for low volume status in 2025 have more than 3,000 treatments in the 2025 impact file. HMA has concluded that it is likely that CMS has underestimated the number of facilities that will be eligible to claim the higher tier of LVPA. This analytical choice calls into question all the adjuster amounts CMS has calculated for both scenarios. MedPAC's analysis also found that while Tier 1 payments would be roughly the same as the current adjustment amount for all eligible facilities, those in Tiers 2 and 3 would experience payment increases of about 18 percent.[13] We believe CMS needs to re-evaluate its analysis given MedPAC's findings.

Finally, KCP supports the use of the median treatment amount over the prior three years to be the basis for qualifying for the LVPA. HMA has found that both tiers of the LVPA benefit about equally from the expansion of the LVPA definition to the median treatment amount during the previous three years. For example, about two thirds of the 2025 projected LVPA facilities were not low volume facilities in 2023. About 81 percent of the lowest tier and 76 percent of the higher LVPA tier were not low volume facilities in 2024. We agree that this approach would help to address the cliff about which MedPAC Commissioners and the kidney care community have raised concerns.

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[13] *Id.*

Thus, while KCP supports the tiered-methodology MedPAC recommends, we are concerned that CMS' proposed methodology falls short of that proposed by MedPAC. It also fails to address the overlap between the rural and LVPA adjusters. Before a change is made to the LVPA, we urge CMS to adopt the MedPAC methodology for implementing the LVPA revisions so that the concerns raised as addressed.

III. In addition to the concerns outlined in our August 9 comment letter, KCP believes that the more technical proposals related to the outlier methodology require additional consideration before being implemented.

KCP appreciates that the ESRD PPS outlier payment is finally meeting the one percent withhold amount, which has not consistently occurred since the inception of the ESRD PPS. As a result we are concerned that the modifications outlined in the proposed rule could disrupt this delicate balance now that it has finally been achieved. While we agree that composite rate drugs and devices should be eligible for outlier payments,[14] the issues with the change in proxies raised by HMA's analysis of the proposal should be addressed before the policy is finalized. And, as noted in the August 9 KCP letter, CMS should adopt a policy that creates a permanent adjustment to the base rate when new drugs and devices are added to the base rate regardless of their status within existing functional categories rather than try to use the outlier payment alone to reimburse for such drugs. If the base rate were adequately funded, the outlier pool would be less likely to be subject to disruption and serious over- or under-payment.

In terms of the proxies used to predict the outlier payments, we are puzzled by the rationale CMS offers for replacing the market basket proxies for drugs and biologicals for the outlier payment and then embracing the market basket proxies for labs and supplies. The proposal to cease using the market basket proxy for pharmaceuticals and instead creating a new ESRD specific drug index results in a -0.7 percent projected decrease in drugs for purposes of the outlier calculation. This change will result in a lower MAP and FDL than if the prior calculation had been used and may also result in the outlier pool exceeding the 1 percent threshold if CMS is incorrect and prices increase in 2025.

For labs and supplies, CMS proposes to replace the current CPI projection for labs and supplies with the equivalent market basket proxies. The net result of the outlier changes appears to be a lowering of the MAP and FDL amounts relative to what they otherwise would have been. This results in a significantly lower FDL for 2025 and an increased number of claims which CMS projects will qualify for adult outlier payments.

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[14]KCP remains troubled by the policy that "drugs and biological products that are substitutes for composite rate drugs and biological products are considered to be included in the composite rate portion of the ESRD PPS," consistent with our previous letters particularly those related to the post-TDAPA. However, we have not reiterated those concerns in this letter but would like to work with CMS to address these concerns.

The net effect of these changes on adult patients will likely be to increase and possibly overshoot the 1 percent outlier payment rather than undershoot the outlier payment target. Because the net result of these changes will likely increase rather than decrease overall outlier payments, we urge CMS to tread cautiously and not return to the situation where the outlier pool withhold exceeded the amount the outlier payment provided especially if that means CMS will increase the withhold amount in coming years.

IV. KCP supports providing individuals with AKI access to home dialysis modalities, but opposes the additional budget neutrality adjustment for the training add-on because the adjustment has already been included in the ESRD base rate and there is no evidence that utilization will differ significantly between the two populations.

KCP strongly supports the proposal to extend coverage and reimbursement for home dialysis modalities to individuals with acute kidney injury (AKI). As demonstrated throughout the pandemic, initial concerns about the appropriateness of these modalities for individuals with AKI have been replaced by scientific evidence of the effectiveness of these modalities in this population. We also support the proposed modifications to the Conditions for Coverage that will account for the change in the underlying policy.

However, KCP does not support the budget neutral adjustment for the home dialysis training add-on. The ESRD base rate that CMS proposes using for AKI reimbursements already includes the budget neutrality adjustment related to the home dialysis training add-on. This fact has been true since the extension of the coverage for AKI treatments in dialysis facilities. As a result, CMS has been underpaying facilities for AKI patients since the inception of the benefit. A separate AKI budget neutrality adjustment for the add-on is unnecessarily duplicative.

The budget neutrality calculation is not required. A budget neutrality adjustment would only be necessary if the use of home dialysis in the AKI population were to occur at a substantially different rate than it does in the ESRD population. There is no evidence to suggest that the utilization would differ substantially. The potential utilization of home dialysis training also appears is based on assumptions about the number of patients who will select home dialysis and the number of training sessions they will attend that simply may not be true.

If CMS were to adopt the proposed $8.50 per treatment cut, it would create a significant barrier to individuals with AKI being able to select home dialysis. With MedPAC recognizing a zero Medicare margin, imposing an $8.50 per treatment cut is simply not sustainable for facilities who treat individuals with AKI. This approach would be contrary to the efforts of CMS through the ETC Model and other programs to incentivize the selection of home dialysis. To be consistent with the Administration's policy goals and to recognize that it has already applied a budget neutrality adjustment for the home training add-on in the

ESRD context, we urge CMS not to adopt this second budget neutrality adjustment for the home dialysis training add-on in the AKI benefit.

V. CMS should adjust the other payment adjustments based on the other proposed modifications.

KCP is concerned that CMS has proposed several changes in the Proposed Rule that impact the other payment adjusters. Yet CMS has not proposed to modify these adjusters based on those changes. For example, the wage index modifications would redistribute money among all facilities, which means that the facility-level (and potentially patient-level) adjusters would also be affected. We urge CMS to address these interaction to protect the integrity of the payment system.

VI. KCP urges CMS to make sure dialysis patients who reside in Skilled Nursing Facilities (SNFs) do not lose access to phosphate binders/lowering drugs once they are included in the ESRD PPS payment.

Approximately 85,000 dialysis patients are admitted to SNFs annually.[15] These individuals receive phosphate binders from the SNF care team. As we understand it, SNFs have implemented sophisticated partnerships and processes to make sure that these individuals receive their medications consistent with coverage under the Part D program. Based on preliminary conversations with SNFs, it does not appear that they realized that phosphate binders may be shifting to the ESRD PPS payment system under Part B beginning January 1, 2025. While ESRD facilities have engaged with some of these providers, the SNFs understandably would like additional guidance from CMS given the complexity of medication management in the SNF setting. To promote a smooth transition for these patients, KCP encourages CMS provide additional guidance to SNFs and to support coordination of that guidance with the information being provided to dialysis facilities as quickly as possible.

VII. ETC changes and RFI

A. KCP supports the proposed modification to the definition of "ESRD beneficiary" for the ETC Model.

KCP supports the proposed modifications to the ETC Model definition of ESRD beneficiary. We agree that the definition should clarify that the beneficiary's latest transplant date must be identified by at least one of the following: (1) two or more MCP claims in the 180 days following the date on which the kidney transplant was received; (2) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date; or (3) indication of a transplant failure after the beneficiary's date of

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[15]Michael Aragon. "Growing kidney patient population creates opportunity for more control and better care." McKnights Long-Term Care News (Nov. 30, 2023).

transplant based on data from the Scientific Registry of Transplant Recipients (SRTR). We agree that if a beneficiary meets more than one of these criteria, then they should be considered an ESRD Beneficiary for the purposes of ETC model attribution starting with the earliest month in which the transplant failure was recorded.[16] We also agree that it is not necessary to remove the last clause of the current definition: "MCP dialysis claim less than 12 months after the beneficiary's latest transplant date with kidney transplant failure diagnosis code documented on any Medicare claim."

B. KCP appreciates the opportunity to provide comments on the Request for Information (RFI)

KCP appreciates the opportunity to work with CMS on improving the ETC Model. Our responses to the RFI are outlined below.

- ***How should any future Innovation Center model that incorporates home dialysis incorporate what the community has learned from the ETC Model?***

KCP remains committed to making sure that individuals who require dialysis treatments have the opportunity to select home dialysis, if they determine that it is the appropriate modality for their treatment. As MedPAC[17] and others have noted, home dialysis is not always the right option for all patients. Consistent with our previous comments, it is important that any model (and the Medicare ESRD program for that matter) ensures that these individuals have the freedom to select the modality that best fits their needs. This freedom to select means that Medicare's payment policies should not include policies that incentivize providers and/or physicians to direct patients to home dialysis when it is not clinically or otherwise appropriate.

In addition, the results of the ETC Model demonstrate that financial bonus payments helped increase individual selection of home dialysis. Such bonus payments not only incentivize providers, but they also provide additional funding to support additional educational and other resources that can be made available to patients.

Moreover, it is important to reduce barriers to supporting patients with socio-economic challenges that make accessing home dialysis nearly impossible. As we have noted in previous comment letters, KCP recommends that CMS work with HHS and the states to revise federal and state local fraud and abuse laws to support dialysis facilities and physicians in their efforts to help individuals with kidney failure address socio-economic barriers to home dialysis.

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[16] *Id.* at 180-81.
[17] MedPAC. Report to the Congress: Medicare Payment Policy, "Ch. 6 Outpatient Dialysis Facilities." 197 (March 2022).

- ***What specific barriers to home dialysis could be addressed through the ESRD Prospective Payment System (PPS)?***

First, we reiterate our recommendations to improve care coordination and home dialysis selection through modifications to the federal fraud and abuse laws. Current Stark and anti-kickback laws create barriers to care coordination for nephrologists and dialysis facilities, which can create unintended barriers to individuals selecting home dialysis modalities.

For example, dialysis facilities employ dieticians, social workers, and other professionals as part of their care for patients and to help develop each patient's individualized plan of care. These professionals should be allowed to engage with each patient's physician and care teams outside of the facility as well. Yet, current law prohibits the coordination, because physicians are also referring patients to the facilities that employee these professionals. Another example relates to encouraging more home dialysis options for patients. Facilities could provide training, equipment, and/or space to physicians to help them educate their patients prior to starting dialysis about their modality options. But, again, current law blocks this type of coordination.

In previous letters, KCP has recommended the following policies to remove barriers created by the current Stark and anti-kickback fraud and abuse laws:

- Allowing ESRD facility personnel to provide education of CKD patients;

- Providing safe harbors for providers who furnish telehealth equipment needed for home dialysis;

- Allowing health care providers to share population health tools and predictive modeling technology to support practitioners with management of CKD patients and transplant progression;

- Allowing licensed health care professionals to provide education on all modalities to a hospitalized patient with kidney failure at the request of the patient's care team, including discussion of in-center and home dialysis modalities, management of kidney failure without dialysis, and kidney transplantation. The decision regarding modality choice should be the result of a shared decision making process between the patient and the nephrologist.

Second, we urge CMS to take up the home dialysis measure set developed by the Kidney Care Quality Alliance (KCQA). These measures were developed with the input from individuals receiving dialysis, nephrologists, nurses, and other stakeholders. The first measure assesses the percent of all dialysis patient-months in the measurement year in which the patient was dialyzing via a home dialysis modality, while the second measure assesses the percent of all new home dialysis patients in the measurement year for whom

greater than or equal to 90 consecutive days of home dialysis was achieved. This measure set is superior to current metrics because it holds facilities accountable not only for starting patients on home dialysis modalities, but also for ensuring that these individuals remain on home dialysis. It addresses patients' concerns about the potential incentive created by current metrics to start patients on home dialysis even if it is clinically or otherwise not appropriate for the individual patient. CDRG found the set to be reliable and valid. When a small group at the NQF reviewed them, a few members suggested that there was not sufficient data to support the home dialysis could be a preferred modality because of better outcomes for some patients. As a result, the set was not recommended for endorsement. Given CMS' priority to incentivize greater adoption of home dialysis among individuals who require dialysis, we urge CMS to work with KCP to reconsider this measure set and adopt these metrics for inclusion its quality programs, including for the ETC Model.

- ***What approaches could CMS consider to increase beneficiary access to home dialysis modalities in Medicare Advantage?***

Among other things, CMS could take three steps to help reduce barriers to individuals enrolled in MA plans accessing home dialysis modalities. First, having access to a comprehensive in-network group of health care providers is one of the most significant challenges facing individuals who rely upon Medicare for coverage of their dialysis treatments and related services. It is important to restore the Network Adequacy standards and ensure that dialysis facilities, nephrologists, and other specialists are included in MA plans' networks to support individuals receiving home dialysis. It is equally important that there are sufficient numbers of providers within a reasonable distance to ensure that patients have timely access to these providers. Individuals who select home dialysis must still have access to in-center dialysis treatments from time-to-time, as well as to specialists to support the best possible treatment outcomes.

Unfortunately, we continue to hear from patients and others in the kidney care community that some plans have such narrow networks that patients have difficulty accessing vascular access surgeons, nephrologists, or even a dialysis facility near their homes. Other patients have been listed as inactive on transplant waitlists because MA plans remove their center from the network. Being listed as inactive can lead to delays in transplant. If patients fear not being able access the health care services they need when they need them, they are less likely to select home dialysis modalities as well.

Second, payment rates to MA plans need to reflect the complexity of the patient population and support the provision of innovative treatment options. Some plans do not recognize the ESRD PPS pass-through payments associated with the TDAPA and TPNIES policies. As a result, MA enrollees do not have access to the innovative products that qualify for these payment add-ons. We continue to encourage CMS to require plans to recognize and reimburse facilities for TDAPA and TPNIES payments or, as it does with other providers, allow dialysis facility to seek reimbursement for these add-ons from CMS when

there has not been sufficient time for MA-provider contracts to be adjusted to account for them.

Third, CMS should require MA plans to provide the same level of transparency that the fee-for-service (FFS) program does when it comes to patient modality choice, outcomes, and similar quality data. Having access to such data will empower patients to make more informed decisions about their dialysis treatment options and care.

- ***How should nephrologist payment from traditional, fee-for-service Medicare and from MAOs account for clinician-level barriers to prescribing and retaining patients on home modalities?***

In previous requests for information about home dialysis and clinical-level barriers, KCP has made recommendations that we offer again in this letter.

First, KCP supports increasing the payment for Kidney Disease Education (KDE) codes. We understand that because these are G-codes, CMS has the ability to increase the payment amount without going through the RUC. The KDE benefit provides critically important information to individuals who need dialysis about optimal dialysis starts and modality selection. However, fewer than one percent of patients with kidney failure access the benefit prior to initiating dialysis. The utilization rates are even lower for people of color.[18] Therefore, we believe that establishing reimbursement rates that are more closely aligned with the cost of providing these services would promote the utilization of these services and result in more patients selecting home dialysis modalities.

Second, we ask CMS to increase the CPT code value for nephrologists supporting home dialysis training which has never been adjusted for inflation since its adoption in 1984. When CMS created this code, it set a one-time payment amount at a $500 for completed training. Unfortunately, this training fee has remained at $500 even today despite inflation and enormous increases in cost of living. An adjustment of this fee to $1,500 to $2000 would be a step in the right direction for incentivizing the nephrologists to offer home modality to their patients.

[18]Shukla, A. M., Bozorgmehri, S., Ruchi, R., Mohandas, R., Hale-Gallardo, J. L., Ozrazgat-Baslanti, T., Orozco, T., Segal, M. S., & Jia, H. (2021). Utilization of CMS pre-ESRD Kidney Disease Education services and its associations with the home dialysis therapies. Peritoneal dialysis international : journal of the International Society for Peritoneal Dialysis, 41(5), 453–462. https://doi.org/10.1177/0896860820975586.

VIII. Conclusion

Thank you again for the opportunity to provide these comments on the Proposed Rule. Our counsel in Washington, Kathy Lester, will be reaching out to schedule a meeting, but please do not hesitate to reach out to her if you have any questions in the meantime. She can be reached at klester@lesterhealthlaw.com.

Sincerely,

Mahesh Krishnan MD MPH MBA FASN
Chairman
Kidney Care Partners

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
Atlantic Dialysis
Baxter
Centers for Dialysis Care
Cormedix
CSL Vifor
DaVita
Diality
Dialysis Care Center
Dialysis Patient Citizens
Fresenius Medical Care
GlaxoSmihKline
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
The Rogosin Institute
U.S. Renal Care
Unicycive