



August 17, 2022

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

**Re: CMS-1768-P: 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,

On behalf of the more than 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 [ESRD] Prospective Payment System [PPS], Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury [AKI], End-Stage Renal Disease Quality Incentive Program [QIP], and End-Stage Renal Disease Treatment Choices [ETC] Model Proposed Rule” (Proposed Rule). This letter is the second of two that focuses on the ESRD CY 2022 ESRD PPS proposals regarding the following:

- The outlier policy generally, as well as the proposed methodology for calculating the fixed-dollar loss amounts for adult patients;
- The TPNIES offset;
- The proposed changes to the functional category definitions; and
- The Requests for Information (RFIs) related to health equity issues for adults and pediatric individuals with kidney disease.

In our letter dated August 4<sup>th</sup>, we provided our comments on: (1) the options for a new policy to adjust the base rate for functional category drugs after the end of the transitional drug add-on payment amount (TDAPA) period; (2) the ESRD market basket policies, including the annual update, rebasing, and revising the market basket using CY 2020 data; (3) the revised definition of “oral-only drugs” and confirmation that CMS will apply TDAPA to phosphate binders and adjust the base rate after the TDAPA period ends if they are added to the bundled for 2025; and (4) AKI policies. Our comments on the ESRD QIP and ETC Model will be provided in separate letters.

Kidney Care Partners is a non-profit, non-partisan coalition of more than 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.

As noted in our first letter, the ESRD PPS serves as the foundation for not only traditional Medicare payments, but it is also the foundation for the Medicare Advantage program and other innovative payment models. It is also somewhat unique in the Medicare program in terms of the fact that the vast majority of the beneficiaries who rely upon it are people of color. We appreciate the opportunity to work with CMS to protect access and address barriers to care that lead to health inequities.

### **I. KCP Supports the Proposed Outlier Payment Methodological Changes.**

KCP thanks CMS for taking steps to address the concerns the kidney care community and MedPAC have raised about the adult outlier pool not paying out the full 1.0 percent withhold amount. While we continue to believe that it may be appropriate to set the target withhold at less than 1.0 percent in certain years, KCP supports the proposal to “prospectively calculate the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years.”<sup>1</sup> We also support excluding the drugs and devices that receive the add-on adjustments from the trend-line analysis to avoid the potential for a large error in the calculation. We agree that this methodology based on a three-year data trend should more accurately reflect the needs of individuals for whom the outlier pool is constricted while reducing the potential negative impact on individuals who do not qualify for outlier payments. We anticipate that once CMS finalizes this policy the agency will monitor the impact of the change. We encourage CMS to continue sharing any under- or over-payment from the outlier pool and consider ways to adjust the withhold as needed.

### **II. KCP Supports TPNIES, but Remains Concerned that the Offset Creates a Disincentive for Adopting Innovative Products.**

KCP continues supports a transitional payment adjustment for truly innovative devices that will be added to the ESRD bundle. As we have noted in previous letters, it is important to provide a sustainable pathway for the adoption of innovative products. The historically slow pace of innovation in the treatment of kidney diseases is a clear example of an inequity in the delivery of health care that CMS can provide incentives to address.

Conceptually, TPNIES should encourage innovators to develop new products for the treatment of kidney failure; however, KCP remains concerned that the offset amount being applied to TPNIES blunts the potential positive impact of the add-on policy. As The Moran Company’s analysis from 2020 showed, the offset combined with the 65 percent fraction of the MAC-determined preadjusted treatment amount would undervalue any innovative product that would meet the TPNIES qualifying criteria. Even with perfect adherence and

---

<sup>1</sup>87 Fed. Reg. 38464, 38492 (June 28, 2022).

patient health, the maximum TPNIES amount would be 26 percent of the cost of the device paid over two years. Given that the proposed TPNIES amount is only a portion of the cost providers incur when using the device, it does not make sense to further reduce the TPNIES amount with the offset. Limiting the incentive in such a manner is unlikely to drive the innovation CMS seeks to promote, further limiting it as the offset proposal would only further reduce the likelihood of adoption.

As the first products begin to receive TPNIES, KCP also asks CMS to reassess its policy and allow TPNIES to apply for at least three years to allow for two full years of data collection and adjust the base rate to account for the additional of the innovative product once the TPNIES period ends. As with new drugs and biologicals, it is important for CMS to make sure that the base rate account for the cost of providing innovative devices.

### **III. KCP Questions the Need for the Functional Categories and Encourages CMS to Eliminate Them as a Basis for Reimbursement Policy.**

KCP always appreciates CMS's efforts to clarify provisions of the ESRD PPS policies; however, we are concerned that the proposed modifications to the functional category descriptions/definitions perpetuate an outdated structural aspect of the PPS. From our recent review of the initial proposed and final rules establishing the ESRD PPS, we recognize that the functional categories were constructed by the contractor as a way to define the scope and reimbursement rate for the initial payment structure. The contractor relied on the UB92s from 2004-2008 to categorize drugs provided in the dialysis unit, which is only one site of service for beneficiaries. As a result of this analysis, the contractor created the major categories for anemia management and bone mineral metabolism, plus eight other categories that were less significant in terms of funding. The contractor used these functional categories to define the scope of the bundle at that time and assess the money to incorporate when separately billed drugs/biologicals were added to the bundle.

More than 10 years have passed since the functional categories were crafted from practice patterns and billing guidance that are nearly 20 years old. KCP is concerned that these categories no longer reflect current best practice guidelines and seal the payment structure in the past. In previous letters, KCP has raised concerns about the bundle rate when linked to functional categories providing sufficient resources for facilities to provide innovative products. We appreciate CMS's recognition of this concern and the RFI options that seek to address it. Another example of how the functional categories fall short relates to the potential for a functional category to include two drugs that would be used together; linking the rate to a functional category built on data that did not recognize such a practice pattern. Doing so now could create unintended barriers to providing the optimal care for patients.

As noted in our August 4<sup>th</sup> comment letter, we wrote that it is essential that CMS assess the bundle payment rate when new products enter the bundle regardless of their functional category status to ensure adequate funding and promote access to innovative

treatment options. As other new, innovative products are launched, the bundle needs to be flexible to account for these products and not unintentionally stifle access to them. We recommend that CMS work with the kidney care community to eliminate the functional category designation from the ESRD PPS and modernize the bundle's payment structure to promote optimal access to innovation.

In terms of the proposed modifications to the descriptions/definitions, we are concerned about the phrase "secondary to dialysis" being added to the antipruritic and bone mineral metabolism categories. The physician members of KCP have pointed out that these products are not secondary to dialysis, which is a procedure and not a patient condition. Rather, they are secondary to kidney disease. We suggest that CMS adopt the more clinically appropriate language. We also recommend that to the extent CMS maintains the functional categories, it define them by the FDA indication(s), which is a more objective way to ensure consistency in the categories.

#### **IV. Request for Information on Health Equity Issues within the ESRD PPS**

KCP appreciates the opportunity to provide comments and suggestions on policies that could advance health equity under the ESRD PPS. CMS correctly highlights in the preamble to the Proposed Rule that "FFS beneficiaries receiving renal dialysis services are disproportionately young, male, disabled, Black/African- American, low income as measured by dually eligible Medicare and Medicaid status, and reside in an urban setting."<sup>2</sup> Our members report that many of these individuals experienced challenges accessing medically necessary health care and preventive services prior to their kidney failing. These challenges, we believe, are inextricably linked in many instances to socio-economic status (SES) and social determinants of health (SDOH). We support the Biden-Harris Administration's efforts to identify areas where federal policy could help to address these barriers.

As a threshold matter, CMS should recognize that many of the disparities in health care that individuals who ultimately enroll in the Medicare program experience occur before their kidneys fail. These disparities likely contribute to their kidney failure, the need for dialysis, the initial modality selection, and lack of access to an early transplant option. These disparities also likely lead to additional comorbidities that must be managed along with their kidney failure. These individuals also experience disparities in the access to pre-dialysis care.

For example, Black, Asian, Native Hawaiian or Pacific Islander, and multiracial populations were more likely to be diagnosed later in the disease process. Compared to 58% of White patients, 74% of Blacks were diagnosed with ESRD at an eGFR of less than 10 mL/min/1.73 m<sup>2</sup>. ([USRDS Figure 1.20](#) by race and by ethnicity). The systemic barriers to accessing basic healthcare likely play a substantial role in these individuals developing

---

<sup>2</sup>*Id.* at 38524.

kidney disease and progressing to kidney failure; for example, Medicare–Medicaid dual eligibility status has been found to correlate with a lower likelihood of pre-ESRD nephrology care.<sup>3</sup>

Once an individual develops kidney disease, Black and Brown individuals have a higher prevalence of ESRD. According to the USRDS 2020 Annual Data Report,<sup>4</sup> the adjusted prevalence of ESRD was 3.4 times higher in Blacks than Whites in 2018. ([USRDS Figure 1.8](#) by race) Ten years earlier, that ratio was 3.8, highlighting the slow progress in addressing the disparity in ESRD prevalence. ESRD prevalence in Hispanic populations was found to be more than 1.5 times higher than in non-Hispanics in 2018. ([USRDS Figure 1.8](#) by ethnicity).

As CMS recognizes, the disparities continue once an individual is diagnosed with kidney failure. Dialysis patients are often poorer and sicker than other Medicare beneficiaries and rely on federal and state subsidies and welfare programs, such as Medicaid. In 2018, ESRD beneficiaries made up about 1% of total Medicare enrollment and 2.5% of dual-eligible enrollment.<sup>5</sup> The dual-eligible population may also have different social risks, with associated implications for health outcomes and service use. Dually eligible beneficiaries with ESRD are more often people of color and have higher costs compared to non-duals, despite similar utilization patterns to their non-dual-eligible counterparts.<sup>6</sup>

While we provide suggestions in response to the specific questions highlighted in the preamble of the Proposed Rule, we ask CMS to work with KCP to address the disparities related to these non-dialysis additional comorbidities that will require solutions that are outside of the Medicare ESRD program as well.

### ***Response to Specific RFI Questions***

- ***What kind of refinements to the ESRD PPS payment policy could mitigate health disparities and promote health equity?***

KCP has provided extensive comments to the Office of Management and Budget and the Department of Health and Human Services during the last two years highlighting several recommendations to promote health equity for individuals with kidney disease. In terms of the ESRD PPS payment system specifically, we have recommended that CMS:

---

<sup>3</sup>Nee R et al. Impact of poverty and race on pre-end-stage renal disease care among dialysis patients in the United States. *Clin Kidney J.* 2017;10(1):55-61.

<sup>4</sup> United States Renal Data System. [2020 USRDS Annual Data Report](#): Epidemiology of kidney disease in the United States. Chap. 1. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

<sup>5</sup>Avalere. [Comparison on Dually and Non-Dually Eligible Patients with ESRD](#). July 9, 2020.

<sup>6</sup>*Id.*

- Provide greater access to patient education and support services
  - Expand the types of providers and health care professionals reimbursed for providing the KDE benefit.
  - Expand access to mental health support, nutritional, and social services for individuals with kidney failure and identify ways to provide financial support and assistance and provide new funding to support the provision of these services.
  - Allow 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 and support shared decision-making process between the patient and the nephrologist.
  - Support transitional care units, which are already subject to and comply with the ESRD Conditions for Coverage (CfCs), and consider ways to expand access to pharmacy management services.
  - Permit dialysis facilities to provide reasonable assistance to support individuals selecting home dialysis.
  - Identify and increase awareness for social service programs that would address financial barriers to individuals selecting home dialysis.
  - Engage the Office for Civil Rights to improve educational materials and address health literacy concerns.
- Promote a set of basic safety standards augmented by additional standards tailored to each dialysis setting
  - Refine the ESRD CfC so that those policies that should apply to all dialysis organizations, such as infection control and patients' rights, act as an umbrella set of policies; ensure that all types of facilities, including home dialysis, transitional care units, dialysis facilities providing dialysis in nursing homes, and mobile dialysis units, are also subject to specific CfC requirements that are tailored to the unique nature of providing dialysis treatments in these different settings.
- Incentivize certain types of care and innovation
  - Pilot a bonus incentive payment for surgeons, hospitals, and surgery centers to bring reimbursement for PD catheter placement in line with AV Fistula reimbursement.
  - Adjust the ESRD PPS base rate by adding new money to support remote monitoring.
  - Incentivize nursing homes to accept individuals who have selecting PD home dialysis.
  - Establish a pilot program to test staff-assisted home dialysis that relies on new money and is not budget neutral to the current PPS.

- Improve the current infrastructure to support an increase in the percentage of patients who select home dialysis.
- Address the instability of the vascular access payments during the last several years have placed patient access to PD catheter and HHD vascular placement at risk by improving patient access to nephrologists, surgeons, hospitals, and surgery centers.
- Allow the use of telehealth for home monitoring, provided that patients have at least one in-person visit each month.
- Enforce the statutory requirement that MA plans provide at least the same level of coverage that beneficiaries in traditional Medicare receive, including reimbursement policies like TDAPA and TPNIES that incentivizes the adoption of innovation.
- Return to applying network adequacy standards in the MA program for nephrologist and dialysis facilities.
- Support care coordination
  - Establish aligned requirements for all providers in the ecosystem to talk with patients about transplant and other modality options at every stage in the process, particularly prior to starting dialysis. Individuals with little to no nephrology care prior to “crashing” into dialysis will often be suffering from chronic uremia and volume overload, which again can make it difficult to receive and process “early” transplant education.
  - Rely upon consistent, clear, non-branded materials accessible to patients with differing levels of health literacy, for patient advocacy groups use with patients.
  - Allow health care providers to share population health tools and predictive modeling technology to support practitioners with management of CKD patients and transplant progression.

The data CMS cites in the preamble support these areas as ones in which clear inequities exist. We would welcome the opportunity to provide additional detail regarding each of these recommendations to support their adoption in the Medicare program.

- ***Are there specific comorbidities that should be examined when calculating the case-mix adjustment that would help better represent the ESRD population and help address health disparities? Please describe in detail and provide specific data or recommendations for analytical frameworks and data sources that CMS should use in evaluating such comorbidities.***

No, there are no additional comorbidities that KCP or its members believe are needed within the ESRD PPS. Based on available data today, KCP does not recommend additional case-mix adjusters. The work of the TEP contractor demonstrated that there were no clinically or statistically significant patient characteristics that suggest additional

case-mix adjusters. The vast majority of TEP members voiced their opposition to new case-mix adjusters at this time as well.

In addition, CMS data show that the current case-mix adjusters are not targeted appropriately and need to be eliminated or revised. KCP recommends that CMS refine the patient-level adjusters so they do correlate with higher costs. These are the onset of dialysis adjuster, the BSA adjuster, a single adult age adjuster, and pediatric age adjusters as recommended by the ASPN.

The current adjusters have resulted needed resources being diverted away from patient care. In 2015, MedPAC compared reporting of the comorbidities on 2013 dialysis facility claims with the prevalence of the comorbidity reporting on the physician (carrier) and inpatient and outpatient hospital claims. MedPAC found that individuals with these comorbidities were identified on dialysis facility claims only a fraction of the time the comorbidities for the patients were reported on the physician, inpatient, and outpatient hospital claims. Using 2019 data, The Moran Company found that between a small percent of the adjusters are claimed.

<b>MedPAC Findings<sup>7</sup> (2013 data)</b>	<b>The Moran Company Findings (2019 data)</b>
19 percent of the time for pericarditis	9 percent of the time for pericarditis
25 percent of the time for gastrointestinal tract bleeding with hemorrhage	10 percent of the time for gastrointestinal tract bleeding with hemorrhage
47 percent of the time for hereditary hemolytic/sickle cell anemias	43 percent of the time for hereditary hemolytic/sickle cell anemias
36 percent of the time for myelodysplastic syndrome	16 percent of the time for myelodysplastic syndrome

All of the comorbidity adjusters were claimed less frequently than they were in 2013. These adjusters were based on the use of separately billed drugs, particularly ESAs.<sup>8</sup> The changes in the market and new products makes the relevance of these adjusters less relevant than they were a decade ago.

The money not claimed is not returned to the system and cannot be redirected to patients who would otherwise benefit from the dollars being spent specifically on patient care. As the preamble notes, dialysis patients are disproportionately young, male, disabled, Black/African-American, low income as measured by dually eligible Medicare and Medicaid status, and reside in an urban setting. The dollars being lost could be directed to

<sup>7</sup>MedPAC. "Letter to Acting Administrator Andrew Slavitt, Centers for Medicare & Medicaid Services." (Aug. 6, 2015).

<sup>8</sup>CMS, "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Proposed Rules." 80 *Fed. Reg.* 37808, 37817 (July 1, 2015); *see also* CMS, "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Final Rule and Proposed Rules." 75 *Fed. Reg.* 49030, 49099 (April 12, 2010).



improve health equity, improve patient education about home modalities, help patients navigate the transplant process, and improve the placement of fistulas. All of these metrics are associated with decreased dialysis survival and which Blacks are less likely to receive.<sup>9</sup>

- ***Are there specific subpopulations whose needs are not adequately accounted for by the current ESRD PPS payment policy and should be evaluated for potential health disparities?***

As CMS notes in the preamble, the factors of race, ethnicity, SES (dual eligibility status and receipt of premium subsidies for Part D), and living in a socioeconomically disadvantaged neighborhood based on the Area Deprivation Index (ADI) represent a significantly greater segment of the Medicare ESRD population than the non-ESRD Medicare population.<sup>10</sup> These factors mean that the ESRD population as a whole experiences greater challenges that can make it more difficult to receive the health care services they need. This includes access to adequate nutrition (many live in food deserts), availability of transportation (making it difficult to get to appointments), lack of adequate housing (which can make the selection of home dialysis impossible), lack of additional coverage (which can lead to transplant centers refusing to include them on a kidney transplant waitlist), and many others.

These factors argue for the Medicare program to increase funding in the ESRD program by, among other things, appropriately reimbursing for innovative treatment options to demonstrate a commitment to these individuals and signal to researchers and innovators that new products will be supported for a population that otherwise could not afford to adopt them. They also indicate that CMS could address disparities by eliminating many of the barriers created by fraud and abuse laws that prevent dialysis care teams (required by the Conditions for Coverage) from coordinating with other providers or even providing education services. The recent proposal in the ETC model to prohibit facility-employed social workers, dieticians, and others from working with physicians to provide services under the Kidney Disease Education (KDE) benefit is an example of a policy heading in the wrong direction. KCP has shared a set of recommended modifications to improve the overall delivery of care to the ESRD population to HHS and OMB in previous letters. We would welcome a meaningful dialogue on these suggestions with the Biden-Harris Administration to support the ESRD population and eliminate the barriers that perpetuate health disparities.

---

<sup>9</sup>Lauren M. Kucirka, Sc.M., Morgan E. Grams, M.D., M.H.S., Justin Lessler, Ph.D.(3), *et al.* "Age and Racial Disparities in Dialysis Survival." JAMA. 2011 August 10; 306(6): 620–626. doi:10.1001/jama.2011.1127.

<sup>10</sup>87 Fed. Reg. at 38524.

- ***What are the challenges, and suggested ways to address, defining and collecting accurate and standardized, self-identified demographic information (including information on race and ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, and language preference) for the purposes of reporting, stratifying data by population, and other data collection efforts that would refine ESRD PPS payment policy?***

KCP supports reporting and stratifying data by population. We continue to recommend that CMS collect data using the Z-codes, such as the following:

- **Z55** – Problems related to education and literacy
- **Z56** – Problems related to employment and unemployment
- **Z57** – Occupational exposure to risk factors
- **Z59** – Problems related to housing and economic circumstances
- **Z60** – Problems related to social environment
- **Z62** – Problems related to upbringing
- **Z63** – Other problems related to primary support group, including family circumstances
- **Z64** – Problems related to certain psychosocial circumstances
- **Z65** – Problems related to other psychosocial circumstances

We welcome the opportunity to identify the precise Z-codes that could be collected and analyzed to support a better understanding of how the SDOH impact the ESRD population.

- ***What impact do SDOHs have on resource use and treatment costs for patients who are medically underserved?***

In the case of individuals with kidney failure, we do know some things already about the significant impact that SDOHs have on their treatment choices, outcomes, and quality of life. Medicare–Medicaid dual eligibility status has been found to correlate with a lower likelihood of pre-ESRD nephrology care.<sup>11</sup> KCP continues to support legislative efforts to increase kidney disease screening programs, expand access to the KDE program, and eliminate fraud and abuse barriers that make it difficult for individuals (especially low-income individuals) to obtain pre-dialysis services. In 2018, ESRD beneficiaries made up about 1 percent of total Medicare enrollment and 2.5 percent of dual-eligible enrollment.<sup>12</sup> The dual-eligible population may also have different social risks, with associated implications for health outcomes and service use. Dually eligible beneficiaries with ESRD

---

<sup>11</sup>*Supra*, note 3.

<sup>12</sup>*Supra*, note 5.

are more often people of color and have higher costs compared to non-duals, despite similar utilization patterns to their non-dual-eligible counterparts.<sup>13</sup>

Race and ethnicity also impact outcomes. As noted above, Black and Brown individuals with kidney disease are often diagnosed later in the progression of the disease which impacts their prognosis. If patients do not know they have CKD at these stages, it is less likely that they can access early interventions which affect modality choice and outcomes. It can also increase the cost of providing services given the complexities these individual experience, as well as issues, such as a lack of reliable transportation or support network, that can impact their ability to comply with their treatment plan. The vast majority of individuals with kidney disease remain unaware they have the disease. Only 7.2 percent were aware of their kidney disease between 2003 and 2006, and between 2015 and 2018, the percentage who were aware increased only to 12.1 percent. Those with more advanced stages of kidney disease were also more likely to be aware than those with earlier stages, although recognition was still low even in stage 3 (16.9 percent, compared with 61.9 percent for stage 4 and 86.3 percent for stage 5 in 2018).<sup>14</sup>

CKD Stage 3b (eGFR 30-44) is a crucial stage when intervention can help slow the progression of the disease. Interventions during stage 4 are also very important with regard to the preparation for kidney replacement therapy modality selection, preparing for a transplant, or selecting conservative care. If patients do not know they have CKD at these stages, these interventions do not occur.

SDOH have a dramatic impact on the ability of individuals who require dialysis to select home dialysis options. The lack of a care partner, inadequate space for the home dialysis equipment and supplies, problems with housing, lack of access to nutritional food and meals, and mental health issues can make home dialysis a less attractive option. Another practical barrier is the lack of transportation, especially during the period of home dialysis training that requires frequent trips to the home dialysis training location. Some Medicaid programs provide financial support, assistance, or coverage for varying levels of transportation. Others do not.

SDOH also affect care transitions that can negatively impact outcomes and quality of life. Because of the lack of pre-dialysis care, the first year of dialysis is often the most difficult for patients and presents a significant risk of mortality.<sup>15</sup>

SDOH also affect other patient treatment outcomes. Individuals who lack access to fresh foods or have few options for nutritional meals experience worse outcomes than those who can access healthier food options. Individuals who are obese require longer dialysis sessions, which can affect their cardiovascular system, as well as their quality of

---

<sup>13</sup> *Id.*

<sup>14</sup> *Supra*, note 4.

<sup>15</sup> *Id.*

life. Current treatments for managing anemia can be more difficult when individuals have cardiovascular diseases, which impacts their outcomes and quality of life.

SDOH have a negative impact on accessing transplant. There are significant gaps in health equity when it comes to access to kidney transplantation. Transplant centers often face challenges when it comes to treating more medically complex patient, the majority of whom are Black or Brown. Despite recent changes, the MS-DRG payment to transplant centers often does not cover the cost of transplant, particularly those more medically or surgically complex patients. There is also little reimbursement for patients needing complex social services after transplantation. Moreover, patient advocates report that some patients fear the loss of disability payments or other low-income subsidies if they were to pursue a transplant.

The vast majority of people with kidney failure do not have access to a transplant because for the tens of thousands of patients on kidney transplant waitlists, there are only a few thousand organs available for transplant. In 2018, for example, USRDS reports that there were 78,675 on the waiting list for kidney transplants<sup>16</sup>, but as the preamble of the “Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities” notes only 3,755 kidneys were recovered from deceased donors.<sup>17</sup> The statistics are sobering.

- USRDS reports that “[a]mong patients listed for a deceased donor kidney transplant between 2009-2013, the percentage receiving a transplant, including from a living donor, was 19.5 percent after 1 year, 37 percent after 3 years, and 47.5 percent after 5 years.”<sup>18</sup>
- Black patients also experience median wait-times once on a waitlist twice that of White patients.<sup>19</sup>
- USRDS data shows that only 13.5 percent of prevalent dialysis patients were on a wait-list for a kidney transplant at the end of 2018.<sup>20</sup> Black patients are also less likely to be placed on a waitlist than White patients, as the USRDS data cited above indicates.<sup>21</sup>

Individuals with lower socio-economic status have more difficulty navigating the transplant waitlisting process. Patients should also be able to have greater transparency into the process as well; one option would be to adopt a patient-facing tool by transplant centers to allow patients to access their waitlist and transplant status. The consistency in how the information is described and shared will help patients, especially those with limited education, understand the process better. Navigating the transplant waitlisting

---

<sup>16</sup>*Supra*, note 4, Ch. 6.

<sup>17</sup>*Federal Register* at 68596.

<sup>18</sup>*Supra*, note 4.

<sup>19</sup>*Supra*, note 4 (Figure 6.9 by race)

<sup>20</sup>*Supra*, note 4.

<sup>21</sup>*Id.*

process could also be improving communications among transplant centers, dialysis facilities, and nephrologists. Providing patients with transparent information may also require helping them navigate this information to ensure that they understand what it means.

CMS could also help patients at this stage in the transplant system by removing barriers that make care coordination more difficult and by breaking the silos within HHS as well. The Biden-Harris Administration could also work with transplant centers eliminate overly restrictive transplant waitlist criteria that create barriers for individuals in need of a kidney transplant that eliminate factors such as multiple comorbidities, family support, access to dedicated transportation resources, insurance coverage requirements and similar factors that reinforce the SDOH barriers that Black and Brown individuals with kidney failure already face and that keep them off of transplant waitlists. Improve quality metrics related to transplant to increase transparency. Seek support for the KCQA transplant measures; note concerns with the transplant center measures that create risk aversion among these providers.

- ***Which SDOHs should data collection include?***

KCP continues to recommend that CMS collect SDOH data using Z-codes to account for and report on the most common non-clinical barriers to home dialysis, including housing or financial insecurity, minimal caregiver support, other mental and certain physical illnesses, or advanced age to provide information about these barriers and develop policies to overcome them. Having this information will help address the false inferences about an individual patient's ability to successfully perform post-operative care. As noted above, we support using Z-codes, such as the following:

- **Z55** – Problems related to education and literacy
- **Z56** – Problems related to employment and unemployment
- **Z57** – Occupational exposure to risk factors
- **Z59** – Problems related to housing and economic circumstances
- **Z60** – Problems related to social environment
- **Z62** – Problems related to upbringing
- **Z63** – Other problems related to primary support group, including family circumstances
- **Z64** – Problems related to certain psychosocial circumstances
- **Z65** – Problems related to other psychosocial circumstances

- ***How should data regarding SDOH be collected? How should such data be used in the ESRD PPS to help mitigate health disparities and promote health equity?***

KCP supports collecting Z-codes through one of the existing mechanisms already at CMS's disposal. We also encourage that these codes be reported on a regular basis. Our

experience with the 2728 shows that collecting patient-level data only once is not sufficient to understanding the impact of patient characteristics on care. We also want to emphasize that it is important that no additional burden will be placed on patients by requiring them to submit SDOH information via a survey. To the extent it can, we recommend that CMS use existing data sources, even if that requires CMS to cross-walk data collected by other providers. Moreover, we ask that CMS provide additional clarity as to how the data will be used and how it will inform payment policies. It is important that the additional burden associated with collecting SDOH information lead to improvements for patients accessing high quality care.

We agree that the Z-code data should be made public and support stratifying patient information using them. However, data alone will not solve the problem. We know that merely highlighting the problems and expecting nephrologists and facilities to solve them will not work. Additional resources and flexibilities need to be provided to address the existing disparities. We encourage CMS to work with KCP to support Congressional efforts to expand services earlier in the progression of the disease and to develop other programs that permit providers to address SDOH once an individual experiences kidney failure.

- ***How can CMS use existing data sources to better identify unmet needs among specific subpopulations that could result in health disparities?***

There is a wealth of data available from CMS sources, as well as from entities like the USRDS, that have already identified unmet needs among the ESRD population. KCP has shared in this letter and others several recommendations based on these data that would help address the unmet needs of Medicare beneficiaries, especially those who are low-income. Some of these proposed solutions include:

- Expanding the Medicare Wellness Benefit to support kidney disease screening, especially among at-risk populations;
- Expanding the KDE benefit to include later stage CKD, pre-dialysis patients to better prepare them for dialysis;
- Incentivizing surgeons to provide home dialysis accesses and reduce reliance on catheters;
- Eliminating fraud and abuse rules prohibiting coordinating care among facilities and nephrologists;
- Permitting providers to provide stipends or other support for individuals wishing to dialyze at home;
- Supporting respite in-center dialysis for home dialysis patients when they or their care partners require a break from at home dialyzing;
- Incentivizing research for new treatment options for kidney disease at all stages, including ESRD;
- Ensuring adequate and sustainable reimbursement for adopting new treatment options into the ESRD PPS;

- Eliminating policies that result in funding designated for the ESRD program from being withheld and not available for patient care; and
- Addressing inequities in the transplant waitlist system.

These are only some of the ideas KCP has shared during the last few years. We would welcome the opportunity to work with CMS to find ways to implement these recommendations.

- ***How can CMS revise case-mix categories in the ESRD PPS to better represent underserved populations?***

As noted above and as CMS has recognized in previous rulemaking, the existing case-mix adjusters were established to support patients who require additional ESAs. Clinical practice and the cost of ESAs has changed significantly since the case-mix adjusters were created. As the CMS TEP documents show, there is little to no variation in cost today based on the current comorbidity adjusters. Using them results in dollars being withheld and not available for patient care. These should be eliminated because they do not represent the needs of the underserved population or other individuals who receive dialysis.

We continue to recommend that the age and weight adjusters be modified. We recommend using the BSA adjuster to address the needs of obese patients. These patients outcomes are often driven by SDOH. We also recommend that there be a single adult age adjuster, given that age is not a predictive factor of cost and is unrelated to unmet needs. For pediatric patients, we recommend the adjusters recommended by the American Society of Pediatric Nephrology. We continue to support the use of an onset of dialysis adjusters, which helps to address the needs of patients who were not able to access pre-dialysis services. Given the existing data, we do not believe there is a need for additional adjusters. Adding adjusters when the data do not support them will only take dollars away from patient care for the average patient. In the context of the Medicare ESRD program that average patient is young, Black, male, disabled, low income, and residing in an urban setting. The members of the recent TEP supported these recommendations as well.

- ***Are there actions CMS could potentially consider under the ESRD PPS to help prevent or mitigate potential bias in renal dialysis technologies, treatments, or clinical tools that rely on clinical algorithms? What are the relevant considerations for evaluating the effectiveness of such actions?***

KCP is aware of the concerns related to the calculation of the eGFR and supports efforts to ensure that diagnostic tools and algorithms do not create bias. However, we believe that while addressing these concerns is important, there is a more fundamental set of steps that would be more likely to ensure that individuals living with kidney disease have access to the services they need.

First, we urge CMS to expand the Medicare Wellness visit to include kidney disease screening. Given the low-income status and youth of many individuals living with kidney disease, we recommend that CMS, the Centers for Disease Control and Prevention, and HHS work with the States to implement similar screening programs in the Medicaid program. Similar efforts should be made with commercial insurers.

Second, we encourage CMS to expand reimbursement options for physicians to ensure there are adequate resources for treating individuals with CKD. There should be no artificial barriers constructed among providers when it comes to care coordination for this population.

Third, we ask that CMS continue working with KCP and our members to make sure that the ESRD PPS evolves to address the unmet needs. Currently, the system is built on assumptions and data that for the most part are more than two decades old. Modernizing the system, increasing flexibilities, and promoting innovation are all steps that CMS could take to address long-time gaps in treatment options and unmet need among dialysis patients. We have included several recommendations in our August 4<sup>th</sup> letter, our letters to OMB and HHS on health equity and the kidney care ecosystem, and in this response as well.

Finally, we reiterate our recommendations that CMS and the Health Resources and Services Administration (HRSA) engage actively with transplant centers to remove the barriers that Black and Brown individuals with kidney failure face in terms of accessing transplant waitlists and ultimately transplant organs.

## **V. Health Disparities Faced by Pediatric Patients Receiving Renal Dialysis Services within the ESRD PPS**

KCP supports the recommendations of our member organization, the American Society of Pediatric Nephrologists (ASPN). As with the adult population, pediatric patients experience health inequities, particularly when it comes to developing kidney disease and the ability to access kidney transplants.<sup>22</sup> SDOH also disproportionately affect these younger patients, as well as their adult care partners. Lack of adequate housing, nutrition, and transportation are problems these children face in addition to the kidney disease they are fighting. Like their adult counterparts, children with kidney disease who are Black or Brown often are rejected from transplant waitlists because socio-demographic factors that they cannot meet. It is also particularly troubling that organs from Black individuals are often considered to come from high-risk donors based on existing transplant algorithms, further reducing access.

---

<sup>22</sup> Laster M, Soohoo M, Hall C, et al. Racial-ethnic disparities in mortality and kidney transplant outcomes among pediatric dialysis patients. *Pediatr Nephrol.* 2017;32(4):685-695. doi:10.1007/s00467-016-3530-2; Leonard MB, Donaldson LA, Ho M, Geary DF. A prospective cohort study of incident maintenance dialysis in children: An NAPRTC study. *Kidney Int.* 2003;63(2):744-755. doi:10.1046/j.1523-1755.2003.00788.x; Moxey-Mims M. Kidney Disease in African American Children: Biological and Nonbiological Disparities. *Am. J. Kidney Disease*, 2018;72(5):S17-S21. doi.org/10.1053/j.ajkd.2018.06.025.



To address these issues, we support the ASPN recommendations, including:

- Providing housing assistance for families with children with kidney failure;
- Supporting adult care partners to allow children to dialyze at home;
- Addressing food insecurity and promoting access to nutritious foods by expanding access to nutrition assistance programs and making sure that these programs cover the nutrition supplements that children with kidney disease need;
- Establishing Medicare reimbursement for care coordination services; and
- Enhancing telehealth payments for pediatric nephrology visits to help address the shortage of pediatric nephrologists.

We also support ASPN's recommendations related to the age, weight, and pediatric-specific comorbidities as payment adjusters. CMS also should account for the unique specialization and costs associated with pediatric care teams when assessing the adequacy of the pediatric base rate. It is important that these adjustments are not made in a budget neutral manner and new money is incorporated into the system to account for the needed modifications.

## **VI. Conclusion**

KCP appreciates the opportunity to provide comments on the Proposed Rule. We look forward to working with CMS to address the recommendations highlight in this and the August 4<sup>th</sup> letter. Please do not hesitate to reach out to our counsel in Washington Kathy Lester if you have any questions. She can be reached at 202-534-1773 or [klester@lesterhealthlaw.com](mailto:klester@lesterhealthlaw.com). Again, thank you for the opportunity to provide comments.

Sincerely,



John Butler  
Chairman

cc: Elizabeth Richter, Deputy Director  
Jason Bennett, Director, Technology, Coding, and Pricing Group  
Ing Jye Cheng, Director, Chronic Care Policy Group

**Appendix: KCP Members**

Akebia Therapeutics  
American Kidney Fund  
American Nephrology Nurses' Association  
American Society of Nephrology  
American Society of Pediatric Nephrology  
Ardelyx  
AstraZeneca  
Atlantic Dialysis  
Baxter  
Cara Therapeutics  
Centers for Dialysis Care  
Cormedix  
DaVita  
Dialysis Patient Citizens  
DialyzeDirect  
Dialysis Vascular Access Coalition  
Fresenius Medical Care  
Greenfield Health Systems  
Kidney Care Council  
NATCO  
Nephrology Nursing Certification Commission  
Otsuka  
ProKidney  
Renal Healthcare Association  
Renal Physicians Association  
Renal Support Network  
Rockwell Medical  
Rogosin Institute  
Satellite Healthcare  
U.S. Renal Care  
Vertex  
Vifor Pharma