



January 28, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

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

Dear Secretary Becerra and Administrator Brooks-LaSure,

On behalf of Kidney Care Partners (KCP), I want to convey our appreciation for the Administration's efforts to develop and implement system-wide policy changes to improve organ donation, organ transplantation, and improve access and care for patients who require dialysis. KCP appreciates our ongoing partnership with the Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) and efforts during the last two decades to address barriers and gaps in care for patients living with kidney failure and who disproportionately rely upon Medicare and Medicaid for coverage. We are pleased that the RFI takes the important step of recognizing the need to develop and align policies across all providers who provide services to individuals with kidney disease. The current fragmented approach and scarce number of organs available has resulted a significant lack of access to the best therapeutic option for kidney disease is a kidney transplant. At the same time, we recognize that additional payment and legal barriers need to be eliminated to ensure that those individuals who require dialysis have choice in modality and access to innovative therapies to improve outcomes in care.

KCP is an alliance of more than 30 members of the kidney care community, including patient advocates, health care professionals, providers, and manufacturers organized to advance policies that support the provision of high-quality care for individuals with chronic kidney disease (CKD), including those living with End-Stage Renal Disease (ESRD). Our mission is to involve patient advocates, care professionals, providers and manufacturers to ensure:

- Individuals living with kidney diseases receive optimal care;
- Individuals living with kidney diseases are able to live quality lives;

- Dialysis care is readily accessible to all those in need; and
- Research and development lead to enhanced therapies and innovative products.

To respond to the questions in the Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities (Ecosystem RIF), KCP convened a work group of patient advocates, clinicians, dialysis professionals, and transplant experts in three half-day seminars to develop consensus-driven recommendations. Following these discussion-based seminars, the work group convened two additional times to review draft recommendations for submission to the entire KCP membership for its approval.

Our work group focused on those questions that we believe KCP possesses a particular expertise that could assist the Department in its ongoing policy initiatives. In some instance, we have proposed detailed policy modifications – either at the regulatory or legislative levels. In other instances, we have highlighted particularly problems and areas of concern, but suggest that more data or evaluation is necessary before a detailed policy can be proposed. We recognize that for the Department, as for KCP, the RFI is only one step of an ongoing and likely recursive process, and KCP remains committed to partnering with HHS and CMS throughout the entirety of this important initiative.

We applaud HHS and CMS for working to address inequities in organ donation, transplantation, and dialysis. It is worth reviewing the most recent data from the U.S. Renal Data System (USRDS) to emphasize how important it is to address the systemic inequities.

Patients with kidney disease are disproportionately from communities of color and experience inequities in the delivery of health care. Disparity in the incidence of ESRD between Blacks and Whites is striking, and progress in closing this gap has been slow. According to the USRDS 2020 Annual Data Report,¹ 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.

Likewise, 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) Additionally, Black, Asian, Native Hawaiian or Pacific Islander, and multiracial populations were more likely to be diagnosed later in the disease process. For example, compared to 58 percent of White patients, 74 percent of Blacks were diagnosed with ESRD at an eGFR of less than 10 mL/min/1.73 m². ([USRDS Figure 1.20](#) by race and by ethnicity)

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

Black and Hispanic patients also frequently experience barriers to receiving a transplant or being able to select home modalities.² Black patients are less likely to initiate peritoneal dialysis (5.9 percent) or receive a preemptive kidney transplant (20.9 percent) than White patients (8.1 percent and 33.2 percent, respectively). Among patients who were initially wait-listed in 2013, median wait-time was 5 years for Black patients but only 3.4 for years for White patients, a difference of more than 1.5 years. ([USRDS Figure 6.9](#) by race) Between 2017 and 2018, the number of Black patients on the waiting list for a kidney transplant decreased 4.7 percent, compared to only a 1.2 percent decrease in White patients. The number of White patients on the waiting list with active status increased 0.5 percent between 2017 and 2018, compared to a 1.0 percent decrease in Black patients. In 2018, the prevalence of preemptive wait-listing was 5.0 percent among White patients and 3.9 percent among Blacks, and one-year cumulative incidence of wait-listing or transplantation was 13.7 percent in White patients and 10.3 percent in Black patients. The pattern of racial disparities also differs markedly by source of transplant; rates of deceased donor transplantation among Black and White patients have been equivalent during the past 3-4 years, whereas a large disparity in the living donor transplant rate remains and accounts for the difference in overall transplantation rates between Black and White individuals in 2018. Hispanic or Latino patients were also less likely to receive a preemptive transplant (1.75 percent) than non-Hispanic patients (2.56 percent).³

Dialysis patients are often poorer and sicker than other Medicare beneficiaries and rely on federal and state subsidizes and welfare programs, such as Medicaid. In 2018, ESRD beneficiaries made up about 1 percent of total Medicare enrollment and 2.5 percent of dual-eligible enrollment.⁴ 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.⁵ The systemic barriers to accessing basic healthcare likely play a substantial role in these individuals developing 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.⁶

²*Id.* Ch. 6.

³*Id.*

⁴Avalere. [Comparison on Dually and Non-Dually Eligible Patients with ESRD](#). July 9, 2020.

⁵ *Id.*

⁶ 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.

Executive Summary

The RFI requests comments in the areas of transplant; Organ Procurement Organizations (OPO); chronic kidney disease (CKD) awareness and care; innovation in kidney care; dialysis in the home setting, nursing homes, mobile settings; and nephrologist joint ventures. In this letter, KCP organizes its responses and recommendations in the order the questions are presented in the RFI and groups questions thematically to reduce repetition in the text. This executive summary provides a brief overview of KCP's responses.

Transplant and OPO-Related Overview

The best therapeutic option for individuals living with kidney failure is a kidney transplant. Yet, the vast majority of people with kidney failure do not have access to a transplant. The primary reason is that 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 transplants⁷, but as the preamble of the RFI notes only 3,755 kidneys were recovered from deceased donors.⁸ USRDS also 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.”⁹ Black patients also experience median wait-times once on a waitlist twice that of White patients.¹⁰

As noted above, even if there were enough organs available to transplant every person on the waitlist, the current processes involved in waitlisting a patient leads to only a fraction of patients being actually listed. 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 2018.¹¹ Black patients are also less likely to be placed on a waitlist than White patients, as the USRDS data cited above indicates.¹²

The kidney transplant system fails to support the vast majority of people for whom it is their best option. As described in detail below, KCP recommends that HHS work across the agencies responsible for transplant and consider the following initiatives or policy changes:

⁷*Supra*, note 1, Ch. 6.

⁸*Federal Register* at 68596.

⁹*Supra*, note 1.

¹⁰*Supra*, note 1 (Figure 6.9 by race)

¹¹*Supra*, note 1.

¹²*Id.*

- Improve communications and transparency among patients, transplant centers, OPOs, dialysis facilities, and nephrologists.
- Require updates and standardization of the transplant data systems, including making forms consistent across different groups and establishing application programming interface (APIs).
- Promote care coordination within the transplant system.
- Expand educational opportunities for patients, including providing earlier access to the Medicare Kidney Disease Education (KDE) program, expanding the providers who can provide and be reimbursed for the KDE services, and providing non-branded materials to patient groups.
- Incentivize the adoption of clear and transparent transplant waitlist criteria that can be easily accessed by patients and providers.
- Rely on metrics that incentivize transplanting sicker or more complex patients and addressing inequities and eliminating those that create disincentives these patients.
- Align measures across all kidney care providers.
- Increase transparency of the data already collected regarding organs that are not accepted by transplant centers and provide an internet-based portal through which patients could access information about organs offered to them specifically and not accepted.
- Revise the hospital Conditions of Participation to require hospital to report timely notification of eligible deaths to OPOs and CMS.
- Collect Z-codes and other social determinants of health data.
- Address patient access issues, including transportation to/from transplant center appointments prior to and after transplant, as well as post-transplant coverage and access to disability insurance or other assistance post-transplant.
- Reform reimbursement to transplant centers, dialysis facilities, and nephrologists for transplanting and providing care management to kidney patients seeking transplant.
- Enhance education to increase living donor kidney transplant and remove barriers for living donors to donate kidneys.

Kidney Health and Dialysis-Related Overview

In terms of the CKD population, similar concerns exist but for different reasons. According to the USRDS, nearly 15 percent of the U.S. adult population had CKD, based on data from 2015-2018. Less than 50 percent of individuals with CKD are Medicare beneficiaries before they are diagnosed with ESRD, which means they rely upon commercial insurance or Medicaid programs for their coverage.¹³ Patients aged 18-44 years old were least likely to receive pre-ESRD nephrology care. Incident patients without pre-ESRD nephrology care had a greater than 80 percent probability of initiating

¹³*Id.* CKD Ch. 1.

hemodialysis with a catheter.¹⁴ Often this occurs in the hospital setting. The vast majority of individuals with kidney disease remain unaware. Only 7.2 percent were aware of their kidney disease in 2003-2006, and by 2015-2018, 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).¹⁵

As described in detail below, KCP recommends that HHS work across its agencies and with other stakeholders to help individuals slow the progression of CKD and empower them to select the modality that works best for them by considering the following initiatives or policy changes:

- Increase awareness of CKD and expand CKD screening, especially by including CKD screening in the annual Medicare wellness visit.
- Clarify that physician transitional care management codes can be billed with the Monthly Capitated Payment codes to promote home monitoring.
- Make the telehealth flexibilities available during the pandemic permanent.
- Give patients' providers and dialysis facilities access to patients' health data to improve management of kidney disease.
- Expand the KDE benefit by offering it to individuals beginning at Stage 3b CKD and increase the providers and health care professional who can be reimbursed for providing these services.
- Encourage commercial payers and Medicaid programs to improve their efforts to identify enrollees/beneficiaries with kidney disease and slow its progression.
- Provide individuals with access to primary care physicians (PCPs) by authorizing more residency slots for PCPs, encourage Accreditation Council for Graduate Medical Education (ACGME) to include nephrology as a core elective during residency and to expand home dialysis and transplant training programs during residency.
- Support more wide-reaching, simple and clear media awareness campaigns.
- Expand access to mental health support, nutritional, and social services for individuals with kidney failure and identify ways to provide financial support and assistance.
- 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.

¹⁴*Id.* ESRD Ch. 1.

¹⁵*Id.*

- 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.
- 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.
- Make sure that home dialysis patients have access to back-up in-center services and respite services as needed.
- 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.
- Support mobile dialysis units in underserved rural areas, require them to be owned by or have a written agreement with in-center facilities to ensure patient access to in-center back-up dialysis in the event of an emergency, and subject mobile dialysis units to the CfCs including general provisions and other tailored CfC requirements to address the unique nature of mobile dialysis units.
- Establish a pilot program to test staff-assisted home dialysis.

Organ Procurement Organizations Overview

As noted above, the kidney transplant system fails to support the vast majority of patients for whom it is their best treatment option. We appreciate that HHS and CMS seek additional suggestions about how the OPO CfCs could be adjusted to improve access to transplant. As described in detail below, KCP recommends that HHS and CMS take the following initiatives or policy changes with regard to OPOs to improve access to transplant:

- Consider risk-adjusting the organ transplant rate based on donor-specific information.
- Improve ways to measure OPO performance accurately, improve public reporting and transparency around the metrics and outcomes, and hold OPOs accountable when they do not meet performance standards.
- Support the ETC LC's efforts to set national best practices for OPOs to transport organs, which should include implementing a modern, real-time tracking system for use during organ transportation.

- Increase monitoring of discarded organs and eliminate the ranking of kidneys against each other by using a metric that relates to the value the organ will provide to the recipient.
- Improve the reimbursement rate for donor management services.

Nephrologist Joint Venture-Related Overview

As described in detail below, KCP believes that CMS can use the data about joint venture arrangements it already collects through PECOS and create greater transparency about these arrangements by making these data more accessible to patients in a user-friendly manner.

Section I. Overarching RFI Questions

A. Improve Systems of Care for Patients in Need of a Transplant

KCP supports efforts to improve systems of care for all patients in need of a transplant. As described in detail throughout this letter, we believe the core aspects of the current system on which HHS and CMS should focus are providing create communication and transparency among patients, transplant centers, OPOs, dialysis facilities, and nephrologists. We also believe expanding existing CKD screening programs, kidney disease education programs, and pre-dialysis care are essential not only to slowing the progression of CKD, but are also critically important to allowing individuals with kidney failure to improve their opportunity to receive a kidney transplant. The health care system also needs to improve the education and training of primary care physicians and encourage more residents to become nephrologists. Medicaid programs and commercial insurers should also be encouraged to identify and better manage enrollees/beneficiaries with CKD.

In terms of the transplant system directly, more needs to be done to ensure waitlists can be accessed all patients with kidney failure. Transplant center and OPO metrics should hold these entities accountable while avoiding the unintended consequence of them disincentivizing transplants that rely on less than perfect organs or transplanting patients who make be sicker, older, or have socio-economic challenges. The reimbursement structure should also support transplanting more challenging organs and individuals.

B. Increase Organs Available for Transplant

KCP also believes that there are many immediate steps that can be taken to increase the availability of organs for transplant, as described in detail below. In brief, these include improving awareness and donor education campaigns, as well as increasing the accessibility of data already collected on discard rates and transplant center decisions not to accept organs. The reimbursement structure should also support transplanting more challenging organs and individuals.

C. Encourage Patients to Select the Modality that Is Best for Them

The response below addresses the following question set out in the opening section of the RFI related to encouraging patient choice in modality section:

3. Encourage the use of dialysis in alternate settings or modalities over in-center hemodialysis where clinically appropriate and advantageous.

Since its founding, KCP has promoted empowering patients to select the treatment modality that is best for them as individuals. One of the organization's first and most important policy achievements was the establishment of the Kidney Disease Education (KDE) benefit to improve patient education prior to starting dialysis. While the KDE benefit needs to be improved, it has served an important role in empowering more patients to make their own choice of treatment modality. However, more needs to be done, as HHS recognizes. Empowering each patient and increasing his/her ability to select the treatment modalities that is best for that individual requires a commitment from the federal government to:

- Improve physician education;
- Expand access to CKD screening;
- Incentivize medical professionals to specialize in nephrology;
- Provide CKD treatment and education earlier in the progression of the disease and before an individual's kidneys fail;
- Increase the number of organs available for transplant;
- Reward transplant centers for transplanting higher-risk patients; and
- Address patients' socio-economic problems that drive patients' decision-making.

We are concerned that the wording of the RFI question inaccurately suggests that in-center dialysis is always an inappropriate option for patients. The question should not be how to encourage the use of alternative settings or modalities over in-center hemodialysis, but how to remove the barriers to individuals selecting the modality that is the best option for them.

CMS should encourage patient education and choice and avoid policies that favor one modality over another. To do otherwise risks an overly paternalistic approach to a group of patients who have been marginalized and ignored for too long. It is important that Medicare adequately reimburse providers for the services provided. Doing so eliminates any financial disincentive that could interfere with patient choice. As KCP has commented previously, however, the major barriers to increasing home dialysis are unrelated to the Medicare ESRD payment system. CMS needs to tackle these barriers to give patients a true choice.

This goal requires improving access to transplant. The treatment option with the best outcome for patients is a kidney transplant. Yet, there are only a fraction of the organs available for transplant that are needed, and many of those are never offered to patients on the waitlist for a variety of reasons. CMS and HHS should focus its efforts on addressing the problems with the current transplant waitlisting system and the organ acquisition programs to make sure that all patients diagnosed with kidney disease who need a transplant can receive one.

It also requires eliminating barriers to home dialysis, the vast majority of which are outside of the Medicare program. For some patients, home dialysis – whether PD or HHD – may be cost effective and provide the best outcomes. However, researchers have begun to question the universality of studies that suggest home modalities are less expensive and preferable for every patient. Most data reflect cost and outcomes for relatively younger and wealthier patients. Whether these findings hold true for older, more complex patients with significant socio-economic status (SES) concerns is unclear. Nevertheless, KCP supports the goal to expand access to home modalities and believes that when properly educated and trained, many more patients can do at home self-care. KCP believes CMS efforts to address barriers to home modalities, such as housing instability, access to care partners, and earlier education and screening are important to achieving this goal.

We also recommend that CMS support nephrologists by increasing the home dialysis training fee to reflect the cost of living increases that have occurred since it was established. The federal government needs to work to eliminate the SES and social determinants of health (SDOH) barriers that prevent patients from being empowered to make their own choices.

CMS should also create incentive payments for nephrologists and facilities linked to home dialysis adoption. First, it could increase the physician payment for home training from \$500 (which has been the rate for more than 30 years) to \$1750, which is the \$500 amount updated for current dollars. The initial \$500 could be paid at the outset, while the increase of \$1250 could be paid out after a patient has completed six months of successful home dialysis treatments. Second, it could establish bonus incentive payment for surgeons, hospitals, and surgery centers to bring reimbursement for PD catheter placement in line with AV Fistula reimbursement.

It also requires supporting in-center dialysis and modernizing the ESRD PPS for patients who cannot access a transplant or for whom home dialysis is not the best modality. In-center patients also deserve attention and support in terms of reforming the payment system to support sustained access to innovative treatment options. These options include not only new drugs and devices, but also access to technological advances including home monitoring. As the bundle expands to included new items, CMS needs to recognize that the base rate, which was built on 2007 services and rates (but not costs), needs to be adjusted to support these items. While they will improve patient services and

outcomes, they will not offset the major driver of facility costs, which is labor. The federal government should also identify ways to address the SES and SHOD barriers in-center patients face.

CMS can also continue to explore waivers to fraud and abuse laws, that create unnecessary silos in the provision of care and stop care coordination services from taking place.

The RFI provides HHS with a strong starting point to address these issues, but it is important that attention remain on all types of treatment modalities and that the focus remain on empowering patients and letting them select the modality that is right for them.

D. Supporting Innovation

The response below addresses the following question set out in the opening section of the RFI related to encouraging innovation:

4. Ensure that the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) policies appropriately incentivize the creation and use of future new treatments and technologies.

KCP would like to work with CMS to move the bundle away from the products and services patients received in early 2000s to one that recognizes not only the care improvements of today, but anticipates and supports the innovations of the future.

Individuals living with kidney disease, especially kidney failure, have not experienced the same level of medical innovation that others living with conditions like cardiac disease or cancer have been able to access during the last 30 years. The relative stagnant reimbursement system coupled with the lack of a long-term pathway for sustaining innovative treatment option has led to this unacceptable situation.

In the context of the Medicare ESRD program, the work HHS and CMS have done to remove barriers to adopting innovative products and services for kidney care is an important starting point to incentivize innovation and innovative treatment options. The Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) and Transitional Drug Add-on Payment Adjustment (TDAPA) have been a positive step toward removing the barriers created by the ESRD PPS. Yet, as currently designed, these policies do not address the need for long-term stability because they do not include policies to adjust the base rate, even in an incremental way, when new certain new products are added to the bundle.

TDAPA provides a two-year transition payment for certain new products that are renal dialysis services, but current policy only provides for an adjustment to the bundled

rate incrementally when these drugs or biologicals are added to the PPS bundle and are outside of the functional categories. The current policy will not adjust the base rate when new innovative drugs and biologicals that would be within existing ESRD functional categories are added into the bundle. Yet, the majority of the functional categories are some of the very areas where innovation is really needed.

While we understand that there may be challenges to establishing a TPNIES for capital-related asset devices more generally, these challenges should not be allowed to create a barrier to incentivizing the adoption of truly innovative capital-related assets generally. In addition, we recommend that CMS also apply TPNIES for three years to allow it to assess the effect of adding the devices to the PPS bundle and evaluate the base rate to determine if an incremental adjustment would be necessary to support ongoing access to the device. We support structuring TPNIES to help bring innovative products to all kidney care patients.

Adjusting the base rate for truly innovative products is essential to expanding innovation to those living with kidney disease. The statute establishing the payment system anticipated such adjustments,¹⁶ so there is sufficient authority to provide for these incentives.

KCP recognizes that the ESRD PPS itself should be reexamined in light of innovations in care delivery. KCP encourages CMS to modernize the ESRD PPS to support innovative care options, promote patient choice, and eliminate barriers to care coordination. The successes of the Comprehensive ESRD Care (CEC) model that created the ESRD Seamless Care Organizations (ESCOs) should be used to inform these changes. CMS reported that the ESCOs saved money by reducing hospitalizations and extra dialysis treatments. At the same time, there were quality improvements in terms of reduced catheters and increased phosphate binder utilization. The CEC Model was the first Medicare Accountable Care Organization model that targeted a specific population. The successes of this model should not simply be set aside. We appreciate that CMMI has incorporated some of these concepts into the kidney care voluntary models, it should also identify policies that could be added to traditional Medicare to allow patients to benefit from such policies as well. More specifically, KCP would like to work with CMS to identify ways to adjust the payment system to support the care coordination services and other aspects of the program that the current PPS program does not allow or support the cost of providing.

Reforms in the ESRD PPS need to be adopted in the Medicare Advantage program, as well. We also ask that CMS coordinate the policy with the MA program, so that the same funding for TDAPA and TPNIES products is also available under the MA program.

¹⁶42 U.S.C. § 1395rr(b)(14).

While the size of the CKD population should attract innovators, the lack of awareness and adequate insurance coverage creates barriers that need to be addressed. Patient organizations remain concerned about policies that allow commercial insurers to push patients into Medicare and reduce their incentive to appropriately identify and manage patients with CKD. This activity adds stress to the Medicare system and does not align incentives across all payers. It is important to create the right incentives for commercial payers and Medicaid plans to provide CKD services as well.

Section II: Transplant Centers

As noted above, the only curative option for individuals living with kidney failure is a kidney transplant. Yet, the vast majority of patients with kidney failure do not have access to a transplant. Even if there were enough organs available to transplant every patient on the waitlist, the current processes involved in waitlisting a patient leads to only a fraction of patients being actually listed. The kidney transplant system needs to be modernized to support all patients with kidney disease.

A. Improving Communication

The responses below address the following questions set out in the Transplant Center section of the RFI related to communications, information sharing, and education:

1. For patients and their families: Are transplant programs meeting your specific needs and are you satisfied with the care that you have received? Specifically, what type of information are you receiving from your transplant program or transplant surgeon?

6. Are there additional requirements that CMS could implement that would improve the manner, effectiveness and timeliness of communication between OPOs, donor hospitals, and transplant programs?

11. How can transplant programs facilitate greater communication and transparency with patients on their waiting list regarding organ selection while limiting undue delays or undue anxiety to their patients?

12. Did the transplant program provide you with information specific to your unique needs, medical situation, and potential transplant outcomes?

13. Did the transplant program provide you with any information about waiting times specific to your type of organ transplant? If so, what was the waiting time estimate that the transplant program gave you?

14. Did the transplant program or transplant surgeon provide you with any information on organ offers that were made for you and were declined by the transplant program or surgeon? If so, was the reason for a decline explained to you?

17. For patients who are or were on dialysis, what information did you receive on organ transplantation from your dialysis center? Do you believe the dialysis center supported organ transplantation? Why or why not?

1. Adopting Technology Solutions

One of the most challenging aspects of the current transplant system is the lack of communication and transparency. Part of the challenge centers on technology issues, such as lack of interoperability among electronic health records (EHRs). To address these issues, the Secretary could work with the Office of the National Coordinator of Health Information Technology (ONCHIT) to establish clear interoperability standards and to create APIs that allow nephrologists and dialysis facilities to have clear information on patients' status when they have been referred for transplant. This information should include, *inter alia*, electronic confirmation of receipt of the referral, where in the evaluation process the patient may be, and, once the evaluation is completed, electronic confirmation whether the patient has been accepted for waitlisting or are ruled out (specifying the reason(s) for the decision). On the other side of the equation, these system improvements would allow nephrologists and facilities to provide automated electronic updates, such as the death of a patient on the transplant waiting list, to transplant centers as well. There needs to be transparent communications among all the providers working with these patients.

In addition to providers being able to communicate with each other, patients should also be able to have greater transparency into the process as well. HHS should support the creation and/or adoption of a patient-facing tool by transplant centers to allow patients to access their waitlist and transplant status. These portals could also be used to provide patients with notices or alerts when the patient needs to follow-up on some aspect of the evaluation process, such as when a test is required or paperwork needs to be completed. It could provide updated information on waitlist times, organs offered and rejected along with the reasons why, and other information to help patients understand where they are in the process. It would also be helpful if these tools could be accessible on mobile devices so that patients can view them when at their dialysis facility or when with their nephrologist. Information should also be provided in a consistent way so that patients who are listed at different transplant centers can compare the information in a meaningful way.

While web-based systems would be an important part of such a tool, transplant centers should also provide options for patients who are not as comfortable with electronic platforms or may not have reliable broadband internet access. ONCHIT, CMS, and HRSA could work with the Office of Civil Rights (OCRs) to adopt best practices that others in

health care community have used to provide access to those patients living on the other side of the digital divide.

Another technology solution that KCP encourages CMS to continue is the current telehealth waivers that allow patients to use telehealth visits for their transplantation evaluation appointments. These waivers allow patients to access these visits during their dialysis session or at home and have helped increase the efficiency of the transplant evaluation itself. In addition, we recommend that CMS allow the use of telehealth for living donor evaluation services. While it may be more complicated, we strongly encourage CMS to provide federal reciprocity to allow patients living in one state to engage in telehealth visits with their transplant center when the center may be in another state. CMS has provided such reciprocity in other areas of health care during the pandemic, and we encourage CMS to work with the states to extend this reciprocity in the context of these permanent telehealth recommendations.

HHS, CMS, HRSA, and other agencies within the Department could also increase information transparency by sharing the information it has in aggregated files, such as the Common Working File (CWF) or SRTR data, that others in the transplant ecosystem cannot access. Some of these data items could be incorporated into the EHRs or other information systems. This step would create transparency, potentially eliminate inconsistencies or inaccuracies in the data, and provide for improved care coordination.

Similarly, HHS should require Medicare Advantage plans to provide data to nephrologists and dialysis providers about access to transplant referrals and transplant waitlisting. As more Medicare-eligible patients select Medicare Advantage coverage plans, it is crucial that transplant-related data available for patients with Medicare as their primary coverage be extended to Medicare Advantage beneficiaries.

While we have highlighted some information that should be part of these systems, KCP also encourages HHS to work through a learning collaborative to develop the list of data elements that should be in all such systems, recognizing that some transplant centers, dialysis facilities, and nephrologists may want to include other elements in addition to a minimum set.

2. Implementing Other Ways to Improve Communication

In addition to making sure that all providers and patients, as well as their care partners, have access to the transplant information, it is important that all parties in the transplant ecosystem have access to the right information. As noted in the previous section, HHS could work through a learning collaborative to establish a minimum set of information elements that should always be provided.

Providing patients with transparent information may also require helping them navigate this information to ensure that they understand what it means. Different patients will have different needs. Addressing these needs will help patients and their care partners remain engaged throughout the process. CMS should work with dialysis facilities and nephrologists to provide new payment system incentives, including considering providing new money add-ons for management and coordination services provided to patients referred for transplant and/or on the transplant waitlist that go beyond the set of services already anticipated under the PPS. Such assistance could be provided by members of the existing plan of care interdisciplinary teams already established by the ESRD Conditions for Coverage (CfCs). Given the chronic underfunding of the ESRD base rate, such incentives would require adding new dollars to the program.

In addition to providing reimbursement for additional care management and coordination services, 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 only way there can be true care coordination is to recognize that all providers in the transplant ecosystem, as well as the agencies that regulate them, need to work together. Information should be able to flow freely and laws and regulations that prohibit coordination need to be eliminated. In terms of transplant, we recommend that current federal fraud and abuse regulations be revised to support transplant coordination by:

- Removing fraud and abuse barriers by providing safe harbors from Stark/anti-kickback laws for providers who furnish telehealth equipment.
- Removing obstacles for clinicians, providers, and facilities to share knowledge and information to enhance patient understanding of medical conditions.
- Establishing payment options that will appropriately incentivize care coordination, especially for providers/suppliers who have historically been reluctant engage in such activities.

We encourage HHS to provide an opportunity for all stakeholders in the transplant ecosystem to engage in a discussion about what barriers they are experiencing, especially in relation to regulatory restrictions, and make recommendations about how to rebalance the policies to promote care coordination while still allowing the government to protect against inappropriate referrals or kickback schemes.

3. Improving Education

Education for patients is an also an essential component of improving communication in the transplant ecosystem. Currently, ESRD facilities are the providers required by regulation to educate patients about transplant, but this current focus on dialysis facilities alone does not recognize the patients' need for multi-provider and multi-faceted education. It is also dependent upon the 2728 being completed and filed, which is

not optimal timing for such education.¹⁷ While CMS's own data shows that among incidence dialysis patients in 2017-2019, 85.7 percent were informed of transplant options, per the CMS-2728, we know that this system is not working for all patients.

As a first step, KCP believes it is important to 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. When asked, patients indicate that they need to hear about transplant from a variety of their providers and have raised concerns about the federal government's emphasis of the training being focused at the dialysis facility. As many in the community recognize, individuals who learn they have kidney disease, especially in the later stages, experience significant depression and may not always process immediately the information they are receiving. This is the very time that most patients are entering a dialysis facility and being provided with their first educational sessions. It can often be too late for patients to make a modality decision. Patients 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. To expand educational outreach, we recommend creating consistent, clear, non-branded materials accessible to patients with differing levels of health literacy, for patient advocacy groups use with patients.

Another step to address the problem is to expand the existing KDE benefit. Currently, the KDE benefit provides limited reimbursement and support for six sessions to patients with Stage 4 CKD. Current law restricts the health care professionals who can provide these services to physicians, physician's assistants, nurse practitioners, or clinical nurse specialists; hospitals, critical access hospitals (CAH), comprehensive outpatient rehabilitation facilities (CORF), home health agencies (HHA), or hospices that are located in a rural area; or hospitals or CAHs paid as if they were located in a rural area.¹⁸ The program should be expanded to allow more patients to access KDE services and permit more providers to provide the services. It also should be expanded to include virtual education using telehealth platforms. "The Chronic Kidney Disease Improvement in Research and Treatment Act of 2021" introduced in the House and the Senate¹⁹ would allow dialysis facilities to provide kidney disease education services and expand access to these services to Medicare beneficiaries with Stage V CKD not yet on dialysis. We encourage the Administration to prioritize passage of this provision. CMS should also look at addressing the underfunding of this benefit, which has been highlighted as one of the reasons so few eligible providers have provided KDE services.

¹⁷*Supra*, note 1 (Table C.6 "Percent distribution of patients on dialysis treatment receiving or not receiving transplant options").

¹⁸42 CFR § 410.48.

¹⁹In the Senate, Senators Ben Cardin (D-MD) and Roy Blunt (R-MO) have introduced the legislation as S. 1971, while in the House Representatives Terri Sewell (D-AL) and Vern Buchanan (R-FL) have introduced it as H.R. 4065.

Additionally, the education provided should be effective and meaningful. A recent study conducted by researchers at Duke University²⁰ has shown that more work needs to be done to identify patient and family education programs with an evidence base that demonstrates improvement in increasing the actual number of kidney transplants performed. In addition, patients listen to other patients. We should not underestimate or ignore the negative impact that problems in the current system have on patient decision-making either. KCP believes it would help patients if experts including patients could establish clear best practices for what type of information will be most helpful to patients, how it can most effectively be delivered, and promote ways to make sure that as many providers and trusted sources are providing information in a consistent manner. Partners, family members, and, when appropriate, friends should be able to access these educational resources as well. Patients need support during transplant, so focusing education only on patients fails to recognize these other important relationships. We also believe that any regulatory mandate regarding the use of specific patient education methods or materials be supported by an evidence base demonstrating efficacy in achieving outcomes meaningful to patients, such as increased access to the waiting list or increased access to actual transplants.

Education for donors is another component of this ecosystem that needs to be improved. As the USRDS data indicates, the number one priority for the Administration and the kidney care community should be increasing the number of people willing to donate their kidneys. KCP encourages HHS to support UNOS, transplant societies, and others in the transplant community to promote becoming a living donor.

B. Implementing Changes to the Conditions of Participation (COPs)

The responses below address the following questions set out in the Transplant Center section of the RFI related to Transplant Centers COPs:

3. How can the current transplant program CoPs be improved in order to incentivize and ensure performance quality in organ transplantation?

18. Are there revisions that can be made to the transplant program CoPs or the OPO CfCs to reduce disparities in organ transplantation?

21. How can the CoPs/CfCs ensure that transplant programs, ESRD dialysis facilities, and OPOs distribute appropriate information and educate individuals in underserved communities on organ transplantation and organ donation?

²⁰Boulware LE et al. "Transplant social worker and donor financial assistance to increase living donor kidney transplants among African Americans: The TALKS Study, a randomized comparative effectiveness trial." *21 Am J Transplant* 2175-2187 (2021).

1. Improving Communications and Education

KCP recommends that the policy recommendations outlined in subsection A could be accomplished through amending the COPs; we do not repeat them again in this subsection.

2. Incentivizing the Adoption of Clear and Transparent Transplant Waitlist Criteria

While the number one hurdle to patients access transplant is the lack of viable organs for transplant, KCP recognizes that it remains important to address the reason why many patients are not accepted on transplant center waitlists. KCP has consistently called on HHS to find ways to work with transplant centers eliminate overly restrictive transplant waitlist criteria that create barriers for individuals in need of a kidney transplant. It is important that high-performing transplant centers, such as those that transplant HIV-positive organs or those that can address issues of sensitivity, are encouraged to continue to provide these more complex transplants. Their high performance should not be an excuse to all other transplant centers to select only the most perfect patients and organs for transplant. It is also important that the waitlist criteria for each transplant center is available, ideally on a public website, for patients and providers to be able to see and easily understand the transplant waitlist criteria.

The vast majority of individuals with kidney failure present with multiple comorbidities and are not easy or perfect candidates, but they still deserve the chance to receive a transplant.

The disparities in wait-listing are pervasive and well-documented:

- Black patients are less likely to receive a preemptive kidney transplant (20.9 percent) than White patients (33.2 percent).
- Among patients who were initially wait-listed in 2013, median wait-time was 5 years for Black patients but only 3.4 for years for White patients, a difference of more than 1.5 years.
- The number of White patients on the waiting list with active status increased 0.5 percent between 2017 and 2018, compared to a 1.0 percent decrease in Black patients.
- In 2018, the prevalence of preemptive wait-listing was 5.0 percent among White patients and 3.9 percent among Blacks, and one-year cumulative incidence of wait-listing or transplantation was 13.7 percent in White patients and 10.3 percent in Black patients.
- The pattern of racial disparities also differs markedly by source of transplant; rates of deceased donor transplantation among Black and White patients have been equivalent over the past 3-4 years, whereas a large disparity in living donor

transplant rate remains and accounts for the difference in overall transplantation rates between Black and White individuals in 2018.²¹

Transplant centers assess a myriad of demographic factors—*e.g.*, family support, ability to adhere to medication regimens, capacity for follow-up, insurance-related issues, among others. These factors should be used to support high-risk patients in accessing a transplant. It is important that the use of these types of sociodemographic factors only reinforces that those who face sociodemographic barriers when it comes to health care generally will now also experience them when it comes to trying to access a kidney or other organ transplant.

KCP recommends that CMS work closely with transplant programs to find a way to align and streamline the waitlist criteria and to provide more educational opportunities for racial and ethnic minority donors and recipients. There is no centralized set of criteria, and patients have to register with multiple transplant centers to improve their chances of finding a match. CMS may want to develop a pilot program to help patients navigate the complexities of the waitlist process as well. As noted below, CMS should also carefully examine how transplant centers are evaluated in terms of outcomes and eliminate any metrics that penalize transplant centers for waitlisting and/or transplanting more difficult patients.

CMS should engage with HRSA and consider the experience of the C.W. Bill Young Cell Transplantation Program, which is the national bone marrow and cord blood registry for the United States. Lessons learned from this highly successful program could be applied to improve aligned waitlisting criteria, as well as improving the listing of living donors and distribution of organs.

KCP also asks HHS to work with transplant centers to find ways to address the barriers that patients who do not have the resources to have easy access to transportation or post-transplant insurance coverage face. We hear regularly from our patient members concerns about overly restrictive criteria that disadvantage poorer or higher risk patients.

KCP would like to participate in efforts that HHS could lead to engage stakeholders from the kidney care community to address the problems associated with current waitlisting criteria. We believe that changes in this area, coupled with improvements in communication noted in the previous section would address a substantial portion of the problems that leads to inequities in the waitlisting system and the low percentage of patients who transplant centers accept on the waitlist.

²¹*Supra*, note 1, ESRD Ch. 6.

C. Improving Metrics

The responses below address the following questions set out in the Transplant Center section of the RFI related to transplant centers metrics:

8. The industry as a whole has acknowledged that changes cannot be made solely to one part of the transplantation system. Similar to the outcome requirements that OPOs must meet, should CMS again consider additional metrics of performance in relation to the organ transplantation rate, considering that the number of organs discarded remains high? What should these metrics be? Are there additional quality measures that CMS should consider to measure a transplant program's performance? For a meaningful evaluation of transplant program outcomes from the recipient point of view, please comment on meaningful outcome measures that should be included in the transplant outcomes evaluations.

10. How can CMS meaningfully measure transplant outcomes without disincentivizing transplantation of marginal organs or disincentivizing performing transplants on higher risk patients?

KCP supports efforts to improve accountability among all providers in the transplant ecosystem. Accountability needs to focus on metrics that matter to patients and that are reliable and valid. Otherwise, metrics provide incomplete or inaccurate information to patients and other providers which undermines informed decision-making and makes true accountability elusive. Similarly, metrics applied to different stakeholders should align, to avoid process improvement measure operating at cross-purposes. Conflicting metrics increase the barriers to coordination between stakeholders, ultimately at the expense of patients. Finally, measures need to be reviewed to ensure that they do not disincentivize taking on more difficult patients or perpetuate the current inequities.

In the case of transplant centers, KCP remains concerned that some of the quality metrics currently used to establish accountability create risk aversion among these providers. Rather than having transplant centers compete against each other for purposes of certification, KCP recommends that CMS follow the model of the ESRD Quality Incentive Program (QIP) or the KCC voluntary payment models, which set threshold achievement benchmarks for Medicare value-based payments or recertification, respectively. Those transplant centers that meet them would be deemed to have high quality, but those that do not could receive remedial support, or in some circumstances, be considered for decertification. Such a system must also address the situation in which a state or other geographic area may only have a single transplant center. There must be a way to support accountability while making sure that patients do not lose access to a transplant center.

There are currently two transplant center measures that raise serious concerns and that KCP recommends be eliminated. These measures should be replaced with patient-

driven measures that provide accurate and transparent information to patients and providers, as well as incentivize expanded access to transplant.

Specifically, KCP asks that the waitlist mortality ratio measure, recently approved by the UNOS Board of Directors as a component of a composite quality metric applied to transplant centers, be eliminated. We also believe the publicly reported “transplant rate” measure should be eliminated. The waitlist mortality ratio specifically penalizes transplant centers with a higher rate of mortality on the waiting list, and we believe this will result in centers avoiding evaluating and waitlisting higher risk patients, resulting in reduced access to the waitlist overall. We are particularly concerned this incentivized risk-averse listing behavior will come at the expense of access to transplantation for marginalized populations, including racial and ethnic minorities and dual-eligible patients. To that extent, the Waitlist Mortality Ratio metric is in tension with the Percent of Prevalent Patients Waitlisted (PPPW) metric applied to dialysis facilities, as well as the “transplant rate” component of the Modality Performance Score in the ESRD Treatment Choices (ETC) model, and the specific revision to the ETC model targeted at dual-eligible patients. While the committee that developed this measure sought to address the concern with the risk adjustment, the experience of our members suggests that this approach, which was tried and failed to work in the past, will not work now. Recipients’ factors such as age and cardiovascular issues are not adequately risk adjusted. In addition, the measure does not address whether it is a patient’s first, second, or third transplant, which is a factor that should be taken into account.

As regards the “transplant rate” publicly reported metric as applied to transplant centers (defined as the number of patients transplanted/total number of waitlist years by center), we believe this publicly reported metric which some patients use to determine their likelihood of being transplanted sooner, is misleading. Transplant centers can improve their “transplant rate” simply by reducing the size of their waiting list, without increasing the total number of transplants performed.

It is also important that when HHS establishes metrics for transplant centers that it recognizes the differences between kidneys and other solid organs and set up measures that are unique to kidney transplants. There is no reason why the same quality metrics must apply to all solid organ transplant programs. For example, waiting time plays a crucial role in kidney allocation, whereas liver, heart, and lung allocation is correctly driven by disease severity. Waitlist mortality metrics may or may not be appropriate in the allocating hearts, livers, and lungs, but is likely to have the undesirable consequence of reducing access to the waiting list in the case of kidney transplantation, particularly for older and medically higher-risk patients who can still benefit from kidney transplantation compared to maintenance dialysis. To the extent that aligning the measures requires changes in statutory authority, we encourage CMS and HHS to identify the needed changes and work with stakeholders and the Congress to enact them.

D. Considering Social Determinants of Health (SDOH) and Eliminating Disparities

The responses below address the following questions set out in the Transplant Center section of the RFI related to considering SDOH and eliminating disparities:

19. Further, are there ways that transplant programs or OPOs could or should consider social determinants of health in their policies, such as those relating to requesting consent for donation, patient and living donor selection, or patient and living donor rights? Social determinants of health are those conditions in the places where people live, learn, work, and play that affect a wide range of health and quality-of-life risks and outcomes. Obtaining consent for donation is vital to increasing the number of organs available for transplantation. However, studies have demonstrated that African Americans are half as likely as Whites to agree to donate a loved one's organs. In addition, studies have shown a "lower donation rate among racial/ethnic minorities, specifically including Blacks, Hispanics, and Asians". There are many factors that contribute to these differences, including medical mistrust and differing opinions on organ donation and transplantation. OPOs have a key role in educating the public on organ donation and reaching out to those in underserved populations to address concerns or misconceptions regarding organ donation. They must also obtain consent from families in underserved communities with cultural sensitivity, awareness, and empathy. In order to ensure that more organs are available for transplant to those in underserved populations that need them the most, we are therefore asking what role CMS can play to ensure that OPOs can better build trust and awareness in historically underserved populations and communities (including racial and ethnic minorities).

22. What changes can be made to the current requirements to ensure that transplant programs ensure equal access to transplants for individuals with disabilities?

23. What changes can be made to the current requirements to address implicit or explicit discrimination, such as decisions made based on faulty assumptions about quality of life and the ability to perform post-operative care?

As noted previously in this letter, there are significant gaps in health equity when it comes to access to kidney transplantation. As a first step to address this problem, KCP recommends 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.

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

We urge CMS to adopt the recommendations outlined in the metrics subsection to avoid accountability measures resulting in the unintended consequence of discouraging transplant centers to waitlist and transplant people from communities of color.

E. Supporting Preemptive Transplant

The response below addresses the following question set out in the Transplant Center section of the RFI related to supporting preemptive transplants:

8. To improve long-term outcomes and quality of life, how can we support and promote transplantation prior to the need for dialysis (preemptive transplantation)?

While there has been a lot of discussion about the potential biases inherent in the calculation of the eGFR, it is also true that there are other factors, such as the higher frequency of rapid progression of advanced CKD in marginalized populations. It may be appropriate to identify patients at higher risk of rapid progression to ESRD and allow for a different eGFR cutoff to list this subset of patients pre-emptively. KCP reiterates our recommendation to collect data on SDOH, such as Z-codes, to allow the community to better understand some of these factors and develop policy and clinical options to address them.

We also ask the federal government to address barriers facing non-citizens and non-residents. While policies allow these individuals without permanent resident status to donate organs, they face significant barriers in accessing transplantation, despite the fact that successful kidney transplantation is cost-saving compared to maintenance dialysis. Some patients, both adult and pediatric, must utilize emergency rooms relying on EMTALA to gain access for life saving dialysis. A transplant is a better option. State Medicaid programs are challenged by these policies, and we urge HHS to identify ways to address this disparity.

F. Addressing Ownership of Technology and Software

In addition to the recommendations already noted, we would like to suggest that HHS reconsider the issue of who owns the technology and software used by contractors in the transplant programs. It is important to promote accountability and efficiencies that

HRSA not become forced to use a previous contractor because the intellectual property upon which the transplant collection and allocation system rely is owned by an entity other than the federal government.

Section III: Kidney Health and ESRD Facilities

A. Addressing CKD

1. Slowing the Progression of CKD

The response below addresses the following question set out in the opening section of the RFI related to encouraging improving health care and decreasing the progression of CKD:

1. How can CMS increase the use of nutritional, lifestyle, and medical management interventions to improve health care and decrease the progression of CKD?

CKD affects an estimated 37 million Americans; yet only 10 percent of those affected are aware they have the disease. Without treatment, the prognosis of CKD advancing to kidney failure and death is grave. According to the U.S. Renal Data System (USRDS) 2020 Annual Report, the probability of dying within one year of diagnosis is roughly 1 in 4 in patients with stage 5 CKD and a little less than 1 in 5 in patients with stage 4 CKD. These numbers have not significantly changed during the last 10 years.

Communities of color disproportionately experience the burdens associated with the lack of early diagnosis. CKD disproportionately affects Black and Hispanic individuals. According to the USRDS 2019 Annual Report, the adjusted prevalence of ESRD (kidney failure) was 3.4 times higher in Blacks than Whites in 2018. The prevalence of CKD in individuals 66 years or older in the NHANES data from 2015 to 2018 identified 43.3 percent of Black Americans as having CKD, while the percentage for Whites with the disease was 37.9 percent. The systemic barriers to accessing basic health care likely play a substantial role in people of color developing kidney disease and progressing to kidney failure. The leading causes of CKD and ESRD are hypertension, diabetes, and obesity. Black and Hispanic individuals are diagnosed with these diseases more than other Americans.²² We know from several years of research that people of color have greater difficulties accessing preventive care and chronic disease management services. It is very likely that the challenges these individuals faced when trying to access basic health care services resulted in chronic diseases, such as diabetes, obesity, and heart disease, not being fully managed, which led to the development of kidney disease.

²² Richard V. Reeves & Faith Smith. "Up Front: Black and Hispanic Americans at Higher Risk of Hypertension, Diabetes, and Obesity: Time to Fix Our Broken Food System." *Brookings*. <https://www.brookings.edu/blog/up-front/2020/08/07/black-and-hispanic-americans-at-higher-risk-of-hypertension-diabetes-obesity-time-to-fix-our-broken-food-system/> (Aug. 7, 2020). accessed June 28, 2021.

KCP recommends that CMS work with the kidney care community to take the following steps to improve health care and decrease the progression of CKD.

a. Increasing Awareness and Screening

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).²³ 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.

One of the first step in addressing this health care inequality is diagnosing CKD in individuals as early as possible so that they can begin the process of managing their disease. Since 2012, the clinical community generally and the kidney care community in particular has learned more about how to effectively screen individuals for CKD. There have also been significant strides in treating early stages of CKD. Yet, without screening, these effective interventions are unlikely to be tried or prescribed because CKD has no distinguishing symptoms. A clinical test is needed to diagnose the disease. Our clinical experts also recommend that screening for CKD include the presence of albuminuria.

KCP remains committed to working with the federal government to find ways to address the challenges that individuals living with kidney disease face. Getting an accurate and timely diagnosis is one of those challenges. To that end, KCP strongly supports H.R. 4065/S. 1971, “The Chronic Kidney Disease Improvement in Research and Treatment Act of 2021” introduced in the House by Representatives Terry Sewell (D-AL) and Vern Buchanan (R-FL) and in the Senate by Senators Ben Cardin (D-MD) and Roy Blunt (R-MO). Section 101 of this legislation seeks to add CKD screening to the annual wellness benefit to allow Medicare beneficiaries at risk for kidney disease and kidney failure to learn if they in fact have the disease and seek treatment to slow the progression toward kidney failure or better prepare for transplant or dialysis.

We encourage CMS to engage with the USPSTF to provide a clear recommendation for CKD screening and to support Congressional efforts to expand beneficiaries’ annual wellness visits to include CKD screening.

²³*Supra*, note 9.

b. Clarifying Current Reimbursement Incentives

A second step that CMS could take is clarifying that the existing transitional care management codes (CPT codes 99495 and 99496) in the physician fee schedule that reimburse for at-home monitoring can be billed at the same time a nephrologist is billing the Monthly Capitated Payment (MCP). Once beneficiaries receive a diagnosis of kidney disease, it is important for him/her to have access to kidney care through a nephrologist to manage the disease and slow its progression. CMS already provides codes to monitor patients at home, but there is significant confusion about their interaction with the MCP. By simply issuing guidance that indicates nephrologists can bill both the MCP and these monitoring codes in the same month, similar to the guidance provided for transitional care codes, KCP believes access to important monitoring services would increase.

c. Leveraging Digital Health Solutions

CMS can also improve kidney health and encourage behaviors that slow the progression of kidney disease by leveraging digital health solutions. Making telehealth visits a permanent part of the Medicare program is one such step. However, CMS should also create coverage and reimbursement policies that promote remote monitoring between in-person visits. The investment in the equipment, as well as the time that nephrologists and their teams spend engaging with patients as a result of remote monitoring, should be incentivized.

Similarly, CMS should eliminate the silos within the health information system and ensure that all providers in the kidney care community can have a 360-degree view of patients' health data. The intent of the Health Insurance Portability and Accountability Act (HIPAA) privacy, security, and coding provisions was to provide the legal structure in which health care data could flow among providers seamlessly to improve care coordination. While we have the rules in place, the federal government needs to do more to allow for the flow of such information. Efforts like Blue Button seek to address problems of interoperability. Working with the Office of the National Coordinator for Health Information Technology (ONCHIT), CMS could move from the piloting phase and incorporate into Conditions for Participation and Conditions for Coverage requirements for such data sharing and transparency among providers. Having a complete understanding of a patient's health data is essential to managing kidney disease effectively and slow its progression.

d. Expanding the Kidney Disease Education (KDE) Benefit

According to the USRDS, patients aged 18-44 years were least likely to receive pre-ESRD nephrology care. Incident patients without pre-ESRD nephrology care had a greater

than 80 percent probability of initiating hemodialysis with a catheter.²⁴ To help address this gap, CMS could support Congressional efforts to expand the KDE benefit. Currently, the KDE benefit provides limited reimbursement and support for six sessions to Stage 4 CKD patients. It also restricts the health care professionals who can provide these services to physicians, physician’s assistants, nurse practitioners, or clinical nurse specialists; hospitals, critical access hospitals (CAH), comprehensive outpatient rehabilitation facilities (CORF), home health agencies (HHA), or hospices that are located in a rural area; or hospitals or CAHs paid as if they were located in a rural area are permitted to provide and be reimbursed for the services.²⁵

The KDE benefit was meant to help patients understand their disease and ways to slow its progression, as well as to provide access to information about modality choices and transplant before a patient crashes into dialysis. However, the KDE benefit has not been widely used. The program should be expanded to allow more patients to access KDE services and permit more providers to provide the services. “The Chronic Kidney Disease Improvement in Research and Treatment Act of 2021” introduced in the House and the Senate²⁶ would allow dialysis facilities to provide kidney disease education services and expand access to these services to Medicare beneficiaries with Stage 5 CKD not yet on dialysis. It would also be beneficial to extend the benefit to patients beginning at Stage 3b. In addition, the low reimbursement rate has been cited as another reason these services are not provided more frequently. CMS should re-examine the reimbursement rate for KDE sessions and set it at a level that incentivizes its use.

e. Supporting the Development of Best Practices for Treating CKD

KCP also supports the efforts of our health care professional members, including the American Nephrology Nurses Association (ANNA), the American Society of Pediatric Nephrology (ASPN), the American Society of Nephrology (ASN), and the Renal Physicians Association (RPA) in their work to develop best practices for treating and educating patients with kidney disease. CMS can support these efforts in the ways discussed above, but also by providing opportunities to increase awareness among primary care physicians and those outside of the nephrology specialty to adopt such best practices when it comes to identifying at-risk patients, providing screening opportunities, sharing educational materials, and referring patients with CKD to nephrologists.

²⁴*Supra*, note 1, ESRD Ch. 1.

²⁵42 CFR § 410.48.

²⁶In the Senate, Senators Ben Cardin (D-MD) and Roy Blunt (R-MO) have introduced the legislation as S. 1971, while in the House Representatives Terri Sewell (D-AL) and Vern Buchanan (R-FL) have introduced it as H.R. 4065.

f. Creating Incentives for Other Payers to Manage CKD

According to the USRDS data, more than half of patients with the late stages of CKD are under the age of 65. Thus, while Medicare can adopt policies to address health and disease progression in its own beneficiary population, much more needs to be done outside of the Medicare population.

In 2013, MACPAC reported that 41 percent of beneficiaries with ESRD are dual-eligible beneficiaries.²⁷ To that end, we encourage CMS to take a more hands-on approach through the Center for Medicaid and CHIP Services. KCP respects the critical role States have in providing health care to the low-income adults, children, pregnant women, elderly adults and people with disabilities, but the unique nature of federal coverage eligibility for individuals diagnosed with ESRD demands a closer federal partnership. Specifically, we recommend that CMS incorporate the suggestions identified above and throughout this letter in the Medicaid program as well.

There are also many individuals with commercial insurance who have CKD. As with those enrolled in Medicaid, these patients often do not have access to screening programs, education services, or nephrologists. More needs to be done through existing federal partnerships, such as the Affordable Care Act, to incentivize commercial insurers to identify patients with CKD and actively manage their care. Unfortunately, the fact that individuals under 65 years of age are eligible to enroll in Medicare shortly after their kidneys fail has created the perverse incentive for plans to minimize the management of kidney disease in their populations. While many plans do provide services, CMS needs to work with those who do not to slow the progression of kidney disease so that these patients do not end up with kidney failure and the responsibility of the federal government's program when it is too late.

2. Addressing Barriers to Accessing Routine and Preventive Health Care

The response below addresses the following question set out in the opening section of the RFI related to addressing barriers to accessing routine and preventive health care:

2. What are the barriers to access for routine and preventive health care? To what extent does low health literacy and cultural and attitudinal beliefs impact access to care?

Studies have shown that low socioeconomic status (SES) is associated with both the development and progression of CKD, and some suggest that SES may result in individuals

²⁷MedPAC & MACPAC. *Data book: Beneficiaries dually eligible for Medicare and Medicaid — December 2013*, 15 (<https://www.macpac.gov/wp-content/uploads/2020/07/Data-Book-Beneficiaries-Dually-Eligible-for-Medicare-and-Medicaid-December-2013.pdf>).

being diagnosed in later, more severe stages of the diseases.²⁸ Social and economic factors also affect health literacy. Low health literacy is more prevalent among men, racial/ethnic minorities, and low SES groups.²⁹ These are the very people who are disproportionately living with kidney disease. MedPAC has reported that “compared with all other Medicare [Fee-for-Service] FFS beneficiaries, FFS dialysis beneficiaries are disproportionately younger, male, and Black.... In 2019, 75 percent of FFS dialysis beneficiaries were less than 75 years old, 56 percent were male, and 35 percent were Black.”³⁰ Black Americans also have expressed serious distrust of the health care system.³¹ Together, the low health literacy and cultural/attitudinal distrust in the health care system create significant barriers for individuals most at risk for kidney disease and kidney failure.

It is critically important that as we address these issues, we also make sure that there are adequate numbers of physicians who are appropriately trained to understand and recognize CKD. More physicians are needed to diagnose individuals earlier in the disease progression, help patients manage the disease, and refer individuals to nephrologists. The shortage of primary care physicians and nephrologists must be addressed if there is to be a sufficient work force to support the estimated 37 million American living with kidney disease. The system is already strained when only 10 percent of that population is aware of their diagnosis.

Expanding access to health care has been an important step forward, but many of those at risk for kidney disease do not have a relationship with a primary care provider (PCP). Patients often turn to emergency rooms or urgent care centers which results in fragmented care and focuses not on wellness and prevention, but addressing acute problems. For those who have a relationship, the shortage of PCPs participating in the Medicare program can result in 6-9 month or even longer waits to get an appointment. For some patients, these waiting times drive them to the urgent care setting instead. For others, the hours of many PCPs do not fit within their work and family obligations, which again disrupts the continuity of care that having a PCP would have provided.

CMS can help address this issue by authorizing more residency slots for PCPs. In addition, we encourage CMS to work with medical schools to include CKD more prominently in the curriculum. It would also be helpful to incentivize medical students to pursue nephrology as a specialty. CMS should encourage ACGME to include nephrology as core elective during residency. In addition, fellowship programs should have robust home

²⁸Aminu K. Bello, *et al.* “Socioeconomic Status and Chronic Kidney Disease at Presentation to a Renal Service in the United Kingdom.” 3 *Clin. J. Am. Soc. Nephrol.* 1316-23 (2008).

²⁹Rikard, R.V., Thompson, M.S., McKinney, J. *et al.* “Examining health literacy disparities in the United States: a third look at the National Assessment of Adult Literacy (NAAL).” 16 *BMC Public Health* 975 (2016).

³⁰MedPAC. *Report to the Congress* 168 (March 2021).

³¹Commonwealth Fund. “Understanding and Ameliorating Medical Mistrust Among Black Americans.” (Jan. 2021) <https://www.commonwealthfund.org/publications/newsletter-article/2021/jan/medical-mistrust-among-black-americans>.

program and transplant evaluation components which are sorely lacking at present. HHS should examine existing programs addressing health care workforce shortages to ensure that PCPs, nephrologists, and nephrology nurses are included, and ideally prioritized, in these programs. While the existing programs do provide some support, it is clear that they have not been sufficient to expand physicians and health care professionals in these areas. As noted above, CMS should work with Medicaid programs to address access to PCPs and nephrologists.

HHS through the Centers for Disease Control and Prevention (CDC) could convene members of the kidney community, patients and patient advocates, physicians, nurses, other health care professionals, social workers, and dieticians among others to identify areas where improvement is needed in terms of outreach, educational materials, and other options for reaching out to communities of color and individuals with low health literacy and SES.

3. Improving Education for Patients

The responses below address the following questions set out in the opening section of the RFI related to improving education for patients to slow the progression of CKD:

3. How can we better educate patients about behaviors (such as diet and exercise) that may affect CKD progression? What is working? What is not working? How can pre-dialysis education and prevention programs be improved?
4. How can we increase awareness of known racial, ethnic, gender, sexual orientation, and economic disparities in care for CKD?
6. How can we improve health literacy among the general population, and individuals at higher risk about the prevention of CKD?

As noted in earlier subsections and highlighted in the case of patients with kidney failure below, educational efforts first and foremost need to be tailored address low health literacy and the general mistrust in the health care system. Improving access by allowing patients in earlier stages of CKD who can access the KDE benefit and the providers who can provide it would help. We also recommend as noted above improving access by expanding the number of PCPs and aligning their incentives with the policy goals of slowing the progression of CKD.

In addition to these steps, we recommend that CMS and HHS work with the kidney care community to develop better educational materials, tools, and outreach programs. More can be done to leverage trusted voices in local communities, especially when materials and programs that can be tailored to meet the community's needs.

We appreciate the recent public awareness campaigns that have been launched, but believe more can be done. All forms of media from more traditional TV advertising campaigns to social media should be leveraged. Successful public health initiatives of the past should be reviewed. Similar creativity and simple messaging needs to be brought to kidney disease awareness campaign to reach as many people as possible and start a national dialogue about CKD.

Kidney disease continues to be known as a silent killer because so few patients experience recognizable symptoms in the early stages of the disease. Patient advocates report that once diagnosed many patients fear that kidney disease is a death sentence and that there is nothing they can do. These fears can lead to depression. In such situations, the education they receive may not be something upon which they can act. One way to address this problem is to provide CKD patients with access to, and coverage of, mental health support.

It is also important that these patients have access to social workers and dietitians. Reimbursement needs to be linked to these services to support their use. While in-person options should always be provided, telehealth services should also be available for patients.

Given the disproportionate percentage of Black and Brown individuals who experience kidney disease, as well as those with low SES, efforts should focus working with trusted voices in communities of color to develop the messages and outreach, as noted already. It is also important to address the barriers to accessing reliable primary care services that screen for kidney disease on a regular basis. Once patients are diagnosed with CKD, they need to have support from a group of clinicians to manage depression as well as nutrition and other healthy behaviors.

In addition to covering the costs of these services, patients may need additional financial support or assistance to effectuate the behavior changes about which they are being educated. For example, nutritional education services will not change behavior if a person is living in a food desert without access to fresh, nutritious food options. Similarly, employment or family commitments, as well as SES issues such as inadequate housing, can be overwhelming and present challenges that have an enormous impact whether individuals are able to make the recommended behavior changes. The federal government should work across the departmental silos to make sure that individuals with CKD know about and can access social support programs.

4. Improving PCP Support of Patients

The response below addresses the following question set out in the opening section of the RFI related to improving PCP support for patients to slow the progression of CKD:

5. How can primary care providers (PCPs) better support their patients in prevention and slowing progression of CKD? What can be done to increase screening of at-risk individuals and how can we ensure that PCPs provide timely referrals to nephrologists for individuals with poor or declining kidney function?

As noted above, the first step is to increase the number of PCPs available for patients to access in a timely manner. Second, medical schools need to do a better job of incorporating CKD screening and management into their curricula. Reimbursement for screening test and management services should incentivize providing these services. Once a patient is diagnosed with CKD, referral to a nephrologist is critically important. For that to work, the number of nephrologists also needs to grow.

5. Informing and Empowering Patients with CKD Progressing to Kidney Failure

The response below addresses the following question set out in the opening section of the RFI related to improving education for patients to slow the progression of CKD:

7. How can individuals facing complete kidney failure be informed and empowered to make choices about their care?

Many of the recommendations suggested with regard to educating earlier stage CKD patients are equally relevant to informing and empowering individuals facing kidney failure, and KCP asks that they be considered with regard to this question as well.

In addition to those recommendations, we want to emphasize that one of the most significant barriers to patient empowerment occurs when an individual “crashes” into dialysis.³² The unplanned initiation of dialysis greatly diminishes a patient’s ability to receive education, consider it, and make informed decisions based on it. Simply put, once a patient gets to the dialysis facility with complete kidney failure, while some choices can be made and outcomes improved, the ability of their care team and the patients to address their health problems becomes extremely limited.

As noted in the earlier questions, KCP strongly recommends that Medicare, Medicaid, and commercial payers incentivize screening programs and early intervention that includes not only education but access to nephrologist, social workers, dieticians, mental health providers, and other health care professional to help them slow the progression of the disease. These payers should provide adequate reimbursement for the services provided in these early stages to incentive their use.

³²Molnar, Amber O et al. “Risk factors for unplanned and crash dialysis starts: a protocol for a systematic review and meta-analysis.” 5 *Systematic reviews* 117 (2016).

Accessing social services is also critically important. Patient advocates report that some patients fear the loss of disability payments or other low-income subsidies if they were to pursue a transplant. For others, the lack of adequate housing and/or caregiver support can make home dialysis a less attractive option. These are only a few examples of the SES factors that the Government Accountability Offices (GAO) and others have identified as making it difficult for patients to feel truly empowered. Other individuals experience depression but may not have access to mental health resources in their communities, or fear the stigma attached to it. We encourage CMS and HHS to think beyond the health care context to help address the social and economic challenges these patients face. These are problems that nephrologists, dialysis facilities, and care teams cannot solve.

B. Considering Transitional Care Units

The responses below address the following questions set out in the Kidney Health and ESRD Facilities section of the RFI in relation to transitional care units:

9. For people beginning dialysis, how can CMS support a safe transition?
10. Are there concerns regarding the location or quality of care of the transitional care units?
11. How can these care transitions be equitably provided?

KCP supports efforts to address the needs of patients transitioning to dialysis. The first year of dialysis is often the most difficult for patients and presents a significant risk of mortality.³³ We have a long history of working with the federal government and within the community to find ways to improve patients' transition onto dialysis, regardless of modality.

In KCP's Performance, Excellent, and Accountability in Kidney Care (PEAK) Campaign, we worked with patients, clinicians, researchers, and other experts in the kidney care community and partnered with Dr. Vincent Mor, Professor of Health Services, Policy & Practice and the Florence Pierce Grant University Health in the Brown University School of Public Health to reduce 120-day and first year mortality. Brown University was tasked with monitoring the data in consultation with a Data/Results Expert Panel. KCP also worked with Quality Partners of Rhode Island to manage the Expert Panels who identified both clinical and patient and family engagement best practices to improve survival rates. KCP greatly appreciates the significant time, effort, and expertise of the Expert Panel members, whose contributions were invaluable. During the time period of the PEAK campaign, data showed successful reduction in the one-year mortality rate for dialysis

³³*Supra*, note 9.

patients by 13.6 percent and the 90-day mortality rate by 25 percent.³⁴ This work remains relevant today.

PEAK showed through the best practices it developed that taking certain steps and increasing attention on patients initiating dialysis who have a high-risk of mortality is effective in improving patient outcomes and reducing mortality. Transitional Care Units (TCUs) are one way that some facilities have applied these principles after PEAK to reduce mortality during that first year. TCUs typically offer a higher staff to patient ratio and seek to ensure patients have a smoother transition to dialysis with a heavy focus on medical and emotional stabilization and early education on managing their disease. While TCUs are not typically modality specific, one goal is to provide more intensive education on modality options, including home modalities.

Because TCUs are incorporated into within existing facilities, they are subject to and comply with the health and safety patient protections of CfCs.

We are not aware of concerns about the equity in the context of TCUs. As the USRDS data indicate, Black patients are more likely to be at high risk during the first year being on dialysis. By initiating programs to increase support for the transition to in-center and home dialysis, these individuals receive services to assist with activities of daily living and that improve their outcomes. If there are specific concerns that CMS has identified, KCP would welcome the opportunity to discuss them.

In addition and outside the scope of TCUs, CMS may also want to consider ways to incorporate pharmacy management services when appropriate by incentivizing pharmacists to work with dialysis facilities during this time, especially the first 90 days of dialysis. Medicare Part D provides some medication management services and reimbursement for pharmacists, but not all ESRD beneficiaries have access to these services.

C. Accessing Home Dialysis

The response below addresses the following question set out in the Kidney Health and ESRD Facilities section of the RFI in relation to patient selection of home dialysis modalities:

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

³⁴Kidney Care Partners. *PEAK Final Report*. (Sept. 2013). <https://kidneycarepartners.org/files/final-report.pdf>.

As noted throughout this paper, KCP believes the community and the federal government need to address the barriers patients with kidney disease experience and that reduce or eliminate their ability to select the modality they prefer. We address aspects of the Medicare physician and facility payment programs, as well as the organ transplant program, elsewhere.

We highlighted in the discussion about the inequities in the transplant section of this letter that a major barrier for patients making informed choices is knowing they have kidney disease earlier in the disease state. That lack of awareness is also a barrier for patients who may want to select a home dialysis modality. While USRDS reports that awareness has increased from 7.2 percent of people with kidney disease being aware of their status between 2003 and 2006 to 12.1 percent between 2015 and 2018, that percentage remains unacceptably low.³⁵ Today, there are meaningful interventions that nephrologists can prescribe to slow the progression of the disease to complete kidney failure, yet the vast majority of the patients who could benefit from these interventions do not even know they have the disease. Of those that do know they have kidney disease, only a small fraction receives nephrology care prior to starting dialysis. Patients aged 18-44 years were least likely to receive pre-ESRD nephrology care. Incident patients without pre-ESRD nephrology care had a greater than 80 percent probability of initiating hemodialysis with a catheter.³⁶

It is critically important that HHS take steps to increase awareness and early diagnosis. As recommended throughout this letter, we encourage CMS to work with the Congress to expand the Medicare annual visits to include CKD screening for all beneficiaries. We also recommend that HHS urge commercial insurers and Medicaid programs to provide annual screening as well because more than half of those patients eligible for Medicare because of their ESRD status are under the age of 65 and become beneficiaries through the diagnosis of ESRD. We also suggest that CMS expand the KDE benefit in terms of eligible beneficiaries and eligible providers and increase the reimbursement rate for the benefit to incentivize its greater utilization. In the Senate, Senators Ben Cardin (D-MD) and Roy Blunt (R-MO) have introduced the legislation as S. 1971, while in the House Representatives Terri Sewell (D-AL) and Vern Buchanan (R-FL) have introduced it as H.R. 4065. Both bills would require these important changes.

Additionally, it is important that CMS communicate with surveyors to ensure that they do not construct barriers to urgent start PD through the survey process. KCP asks that CMS enforce the current language in the survey guidelines that indicates that separate approval is not required.³⁷

³⁵*Supra*, note 9.

³⁶*Id.*

³⁷CMS. "Revisions to the State Operations Manual (SOM), Chapter 2, End Stage Renal Disease (ESRD) Program. (Aug. 10, 2018). <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-22-ESRD.pdf>.

Patients with kidney disease face a series of practical barriers to slowing the progression of the disease and getting treatment. For many patients, unless they can address these barriers, they will not be able to select home dialysis. These include the lack of a care partner, inadequate space for the home dialysis equipment and supplies, problems with housing, and lack of access to nutritional food and meals. Patients also face serious mental health issues. Some patients believe their diagnosis is a death sentence, making it difficult for them to accept and understand the information shared with them. Patients may also focus on the negative stories they hear as well. Having access to mental health care professionals would help many patients address their fears and concerns to allow them to effectively receive the information about dialysis modalities and make an informed decision. 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. Managed Medicaid further complicates the relationship between kidney patients and the available resources. Coordination across all payers for the same stated outcomes must be a priority. Medicare has provided some relief for ESRD facilities to help, but it may not be enough. Addressing these patient barriers would empower many patients to consider treatment modalities outside of the in-center setting.

Currently federal and state fraud and abuse laws prohibit dialysis facilities from providing assistance to support patients. One provider shared the story that they are prohibited from giving a patient who wanted to do home dialysis a locked cabinet to protect her home dialysis supplies from children in the home. We encourage CMS to rethink these restrictions to allow providers to support their patients when such small changes could mean the difference between a patient selecting home dialysis or not.

Patients also fear being placed on home dialysis when it may not be the clinically appropriate option for them. The ESRD Treatment Choices (ETC) model has increased this fear. The Kidney Care Quality Alliance (KCQA), established by the KCP in the early 2000s, has developed a measure set that includes a home dialysis rate measure coupled with a retention measure that would incentivize clinicians to make sure that patients who are initiated on home dialysis are supported to stay on home dialysis long-term. KCP encourages CMS to support endorsement of this measure set by the National Quality Forum (NQF) so that it can be incorporated into the ESRD quality measurement programs.

Patients also need to support that goes beyond Medicare reimbursement rates to remain on dialysis. The changes patients experience when on dialysis may require financial support, for example, to allow them to hire people to assist them with setting up their dialysis or to provided assistance for activities of daily living to make it easier for the

patient to undertake the self-care necessary to dialyze at home. It may be helpful to consider “carrots” to support patients taking on the complexity of dialyzing at home as well. Another example of such barriers is housing. For many patients in densely populated urban areas inadequate housing is a barrier for home dialysis. In some instances, these patients may be able to access additional social services that improve their situation. We encourage HHS to work with social workers to provide more information with these services and how patients can access them.

1. The Effect of Race and Ethnicity on Home Dialysis Selection

The response below addresses the following question set out in the Kidney Health and ESRD Facilities section of the RFI in relation to the effect of race and ethnicity on home dialysis section:

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

Many of the concerns KCP has identified in this letter, such as lack of access to screening programs and early interventions, limited or no access to primary care physicians and nephrologists, and low socioeconomic status all play a role in the differing rates of home dialysis selection by people from communities of color. These barriers often mean that Black and Brown individuals do not realize they have kidney failure until their kidneys fail. At that point, they may feel bombarded by information as they try to understand their disease and prognosis. They may be in denial, lose hope, or become controlled by their fears.

Beyond these challenges older adults, adolescents, people with low income and educational levels, and racial and ethnic minorities are disproportionately affected by lower health literacy, as well as cross-cultural communication and language barriers. We encourage CMS working with the HHS Office for Civil Rights (OCR) and the CDC to provide meaningful assistance to clinicians, social workers, and families by creating and disseminating documents that provide information in an easy-to-understand manner and in many languages. These documents could also be designed to allow patient organizations or other trusted voices within the individuals’ communities to brand them as their own. Patients want to hear the information from trusted voices in their communities also. Providers also need financial support to provide these services in some instances as well.

In addition, HHS could work with patient advocates and community leaders to address financial concerns patients face, particularly those in Black and Brown communities. Home dialysis patients often need the support of their employer to dialyze at home, but often patients who are Black or Brown fear that lack that support and cannot afford to put their job at risk. Some patients who cannot work fear that home dialysis will

result in them losing access to disability insurance. More assistance is needed to reach out to these patients so that they understand their rights. Patients need this support outside of their dialysis providers and nephrologists as well.

2. Addressing Infection Control

The response below addresses the following question set out in the Kidney Health and ESRD Facilities section of the RFI in relation to enforcing safety standards and infection control behaviors:

14. With regard to home dialysis, how can CMS ensure adequate safety standards such as appropriate infection control behaviors and techniques are enforced?

KCP supports the application of the CfCs to all home dialysis programs to set the baseline for adequate safety standards and infection control. We are also excited by new technologies that improve the ability of providers to monitor patients in the home. Maintaining access to telehealth services can also support more frequent provider-patient interactions that support efforts to reinforce safety and infection control in the home. CMS should adjust the base rate to incentivize the use of these new technologies. As noted elsewhere, we also encourage CMS to clarify the physician codes related to monitoring patients at home so that it is clear these codes can be billed with the MCP.

In addition, it is critically important that training programs provide patients with the skills they need to be safe and limit infection in the home. We support efforts by the American Nephrology Nurses Association (ANNA) to refine and standardize home training education. It is essential that the professionals training home dialysis patients are qualified to do so and receive the necessary follow-up training as well. We also encourage HHS to address the current nephrology nursing shortage as described elsewhere in this letter by making sure that existing workforce programs within HHS prioritize nephrology services as well.

Another aspect of home dialysis training that CMS could address would be to permit more flexibility when it comes to facilities training patients. Current regulations require facilities to set aside a significant amount of space. That might not always be possible in densely populated urban areas. Permitting options requiring less space would make it easier for facilities to provide home dialysis training, and patients may find it more attractive to train in a facility that is closer to them.

3. Considering Infrastructure Needs

The response below addresses the following question set out in the Kidney Health and ESRD Facilities section of the RFI in relation to whether the current infrastructure could support an increase in the percentage of dialysis patients selecting home modalities:

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

KCP supports efforts to improve the current infrastructure to support an increase in the percentage of patients who select home dialysis. Many comments already made, such as those regarding increased screening and expanded access to the KDE benefit, require increased collaboration among providers.

To that end, we encourage CMS to review comments KCP has provided in previous Requests for Information and proposed rules that offer suggestions about improving care coordination. In particular, we recommend that CMS allow health care providers to share population health tools and predictive modeling technology to support practitioners with management of CKD patients and transplant progression. We also request that licensed health care professionals be allowed 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.

In addition, we encourage CMS to prioritize the health and safety of patients. We have read with concern previous statements suggesting that patients on home dialysis do not need access to a dialysis facility. Such suggestions ignore the reality that home dialysis patients require access to back-up in-center services from time-to-time. They also rely on dialysis facilities for monthly labs and engagement with members of interdisciplinary team. Patients deserve better than to be told they could dialyze at a hospital if they ever needed too. They need consistency and support from providers who can provide comprehensive services.

Moreover, CMS needs to address the systemic problems with the delivery of vascular access. 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. KCP supports CMMI using its authority to test alternative payment structures to address barriers to PD catheter access as part of the ETC Model. Specifically, we recommend that CMMI test a bonus incentive payment for surgeons, hospitals, and surgery centers to bring reimbursement for PD catheter placement in line with AV Fistula reimbursement. Current reimbursement rates provide little incentive for surgeons to place a PD catheter. Even when a surgeon is willing to place it, he/she may have difficulty obtaining a place at a hospital to perform the surgery. We believe that creating a bonus for physicians that is not budget neutral to the ESRD PPS or the MCP will help create an effective incentive to expand access to the procedure. We encourage CMS to work with the Dialysis Vascular Access

Coalition and the community to develop a sustainable payment system that will support the need for home dialysis access procedures.

4. Allowing for Telehealth and Remote Monitoring

The response below addresses the following question set out in the Kidney Health and ESRD Facilities section of the RFI in relation to telehealth and remote monitoring:

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

KCP strongly supports making the telehealth waivers made available during the COVID-19 public health emergency permanent and available to all dialysis patients. However, it remains clinically important that patients have at least one in-person visit each month. Physicians and clinicians have indicated that there are critical aspects of an in-person visit that simply cannot be done via telehealth visits.

In addition to making these waivers permanent, KCP urges HHS to continue to consider ways in which regulatory requirements can ensure technology and services can be provided most efficiently to patients. For example, HHS should remove fraud and abuse barriers by providing safe harbors from Stark/anti-kickback laws for providers who furnish telehealth equipment needed for home dialysis. KCP strongly supported the exceptions for telehealth for in-home dialysis under changes to the Beneficiary Inducements Civil Monetary Penalties (CMP) (at 42 C.F.R. § 1003.110) in the Final Rule addressing Revisions to Safe Harbors Under the Anti-Kickback Statute (AKS), and CMP Rules Regarding Beneficiary Inducements. We urge CMS to ensure that the fraud, waste, and abuse rules are consistent by harmonizing the Stark and AKS rules with the CMP rules.

KCP also supports efforts to incorporate remote monitoring in the Medicare ESRD program. The current base rate did not anticipate the cost of incorporating new technologies, and we recommend that CMS re-examine the ESRD PPS and adjust the rate to support their adoption. Similarly, while there are codes to support nephrologists providing remote monitoring services, CMS needs to provide clarity that these codes can be billed along with the MCP.

More work needs to be done to develop best practices with regard to telehealth visits and remote monitoring. KCP supports the efforts of the nephrology health care professional societies and dialysis facilities to take the lessons learned during the pandemic and translate them into concrete best practices and protocols. We encourage CMS to work with the community to support these efforts.

D. Addressing Dialysis in Nursing Homes

The responses below address the following questions set out in the Kidney Health and ESRD Facilities section of the RFI in relation to dialysis provided in nursing homes:

1. Should dialysis facilities have geographical limitations for distance between the certified dialysis facility and nursing homes where they provide home dialysis services? Would health and safety issues be mitigated if there were some type of geographical limitation? Are there areas where placing a geographical limitation could create access issues where there are no dialysis facilities near the nursing home? If so, why, and how could these issues be mitigated?
2. Should there be a limit to the number of agreements that a given dialysis facility can have to provide home dialysis services in nursing homes? Why or why not?
3. Should CMS enhance protections for dialysis in institutional settings in the CfCs, such as including a written agreement to outline the roles and responsibilities of the dialysis facility and nursing home when home dialysis services are provided to residents, have protections for residents incapable of self-care, including clarifying staff roles, responsibilities, safety, and supervision when the home dialysis services are not administered by the dialysis facility staff?

KCP does not believe that there should be geographic limitations for distances between the certified dialysis facilities and nursing homes. Our members have not experienced problems that would suggest geographic limitations would be necessary. Similarly, we have not heard of problems that suggest limiting agreements a dialysis facility could have with a nursing home. However, if there are individual situations where there may be an issue, we would expect the dialysis facility and the nursing facility to work together to resolve it.

KCP also believes that there should be a consistent set of health and safety rules to protect patients. Dialysis patients residing in nursing homes are complex, and it is important the requirements recognize the unique nature of this population. It is important that there is appropriate clinical oversight and infection control. We also ask that CMS provide additional clarification around the definition of self-dialysis and training requirements as well.

We also support allowing dialysis patients in nursing homes who are capable of relying upon and selected PD to be supported in their use of this modality. Given the additional staffing needs that may be associated with providing PD in nursing homes, CMS should consider creating a PD add-on that would be paid to the nursing facility.

E. Considering Mobile Dialysis and Alternative Types of Dialysis Facilities

1. Defining the Scope of Mobile Dialysis Units

The responses below address the following questions set out in the Kidney Health and ESRD Facilities section of the RFI in relation to the scope of mobile dialysis units:

1. Should the use of mobile dialysis be limited to emergency circumstances and enrollment as a Special Purpose Renal Dialysis Facility?
2. How can mobile dialysis be used? Should these units be independently certified or used as an extension to an existing facility if approved outside of emergency circumstances?
3. What are the oversight considerations of these mobile dialysis units if units do not have a brick-and-mortar location and are moving among various locations? If used outside of an emergency circumstance, should there be geographical limitations?

KCP supports efforts to promote innovative delivery of care. Our members have consistently worked to ensure that patients continue to receive life-sustaining dialysis even during the most challenging of times, including natural disasters and the COVID pandemic. The current Special Purpose Renal Dialysis Facility rules and the use of micro-clinics have proven to be effective to address emergency situations.

Mobile dialysis units are better situated to support patients in areas where they otherwise would not have access to a dialysis facility. In such situations, patients would rely upon their mobile dialysis units for services for their thrice weekly treatments. Therefore, it should be assumed that such mobile units should not be moved away from their “regular” areas of operations to provide support during an emergency. If they were relocated in that way, it would leave the patients who rely upon the units without an option for their own dialysis.

By definition, a mobile dialysis unit should be able to be moved from one location to another. A semitrailer with dialyzers that sits on cinder blocks, for example, should not be considered a mobile unit. Units without the actual ability to move should be subject to the same rules and regulations as a brick-and-mortar facility to protect patient health and safety.

Mobile dialysis units should also be required to have a viable back-up option to ensure that patients who rely upon them will be able to access dialysis if the units breakdown. To this end, these units should be owned by a dialysis facility or at least have a written agreement with a dialysis facility so that it is clear where patients can go to be dialyzed and how they will get there if there is a problem with the mobile unit. To that end,

mobile dialysis units should be within a reasonable proximity of a facility that would ensure patient access to dialysis.

2. Regulating Mobile Dialysis Units through the CfCs

The responses below address the following questions set out in the Kidney Health and ESRD Facilities section of the RFI in relation to regulating mobile dialysis units:

4. Should mobile units have separate/ different physical environment requirements compared to a brick-and-mortar building?
5. What health and safety standards are necessary to ensure a safe physical environment in mobile units?
6. What are the concerns related to equipment handling and maintenance related to mobile units that are different from brick-and-mortar facilities?
7. How can CMS ensure appropriate staffing roles, responsibilities and oversight of patient's dialysis care and needs by interdisciplinary team members for mobile units? Would these units require different staffing mix or requirements than a stationary dialysis unit?
14. What kind of emergency plans would be appropriate for mobile units or other alternative settings?

KCP believes that CMS should prioritize the health and safety of dialysis patients. To that end, we recommend that CMS apply to mobile units the CfC requirements that apply to all facilities and modalities, regardless of type. Some of these regulations would apply without change, such as those related to governance, infection control, and patient rights, among others. However, given the unique nature of mobile dialysis units, we recommend that CMS tailor other CfC requirement to mobile units in the following areas: physical environment requirements; electrical and fire safety; emergency exits and fire suppression; physical placement of nurses' stations and monitoring of patients related to line of sight; refrigeration of medications; handling of medical waste; and water systems, storage and loop disinfection – both for design and required frequency of maintenance and water testing. There should also be requirements that are unique to mobile units related to staffing and vehicle safety and, as noted above, required back-up options for patients who need to dialyze if a mobile unit fails to make it to the location. KCP would like to work with CMS as it considers developing such requirements.

3. Considering Alternative Types of Facilities

The responses below address the following questions set out in the Kidney Health and ESRD Facilities section of the RFI in relation to alternative types of dialysis facilities:

8. What other alternative types of dialysis treatment facilities should we consider?
9. What should be the appropriate use of alternative types of facilities, such as only for emergency situations?
10. How should CMS certify these alternative types of facilities?
11. Are these facilities able to meet current patient safety and equipment standards?
12. Given the importance of water quality for dialysis, how do we ensure safe water standards with facilities that do not have water treatment centers?
13. Do patients in Medicare Advantage plans have a choice whether or not to dialyze at one of these alternative facilities?

As noted, KCP supports the development of innovative care delivery. We also believe that CMS should make sure that any alternative types of facilities meet as strong health and safety requirements as those that apply to current facility types. Alternative types of facilities should not become a way for providers to avoid meeting the CfC requirements. However, we also recognize that alternative facilities may require tailoring some of the CfCs or adding new ones to address the unique aspects of such facilities. Therefore, we encourage CMS to engage in meaningful discussions with stakeholders and rely upon notice-and-comment rulemaking on a more regular basis to support innovation while protecting the health and safety of patients.

In addition, beneficiaries enrolled in Medicare Advantage and Fee for Service should be allowed to access these types of facilities as well.

F. Supporting Alternative Models of Care – Staff-Assisted Dialysis

The responses below address the following questions set out in the Kidney Health and ESRD Facilities section of the RFI in relation to staff-assisted dialysis:

1. Should there be two sets of guidelines for staff-assisted home dialysis in residential homes and staff-assisted home dialysis in alternative settings; and if so, how should they differ?

2. What factors should be taken into consideration for establishing different guidelines?

KCP supports the concept of staff-assisted dialysis, but understands that the Medicare manual indicates that staff-assisted dialysis is not a covered service, despite the language in the RFI's preamble to the contrary. "Effective January 1, 2011, renal dialysis services for patients receiving home dialysis may only be billed under Method I. Staff-assisted home dialysis using nurses to assist ESRD beneficiaries is not included in the ESRD PPS and is not a Medicare covered service."³⁸ Given that there is no funding for this type of program, CMS would need to define the scope of staff-assisted dialysis and add money to the Medicare ESRD program to support its use.

KCP would like to work with CMS to pilot a meaningful staff-assisted home dialysis program that could help define the services and quantify the cost of providing them, as well as analyze the benefit of these services. KCP believes that a limited staff-assisted home dialysis option could help those beneficiaries who may be worried about starting home dialysis overcome their doubts and fears and empower them to be able to perform home dialysis without such assistance over time. It is important that such a program avoid creating a sense of learned helplessness, as one of our patient members articulated. The length of such a program should be between the first 30-90 days a patient is receiving home dialysis.

A pilot would allow CMS to evaluate the effectiveness of increasing the number of home dialysis patients, evaluate whether such assistance improves patient outcomes, and analyze the financial impact on the Medicare program overall. It would also allow CMS to evaluate whether home dialysis may provide beneficiaries with the opportunity to return to work by creating more flexibility in their dialysis treatment schedule.

For a staff-assisted pilot to work, the shortage of nephrology nurses needs to be addressed. Dialysis facilities are currently facing a serious workforce shortage. Given this reality, it may also be worthwhile for CMS to test incentivizing patients and care partners through financial or other types of benefits. CMS could consider the New York State Consumer Directed Personal Assistance Program which currently provides assistance at home and engages with family members and care partners.

Staff-assisted dialysis, even in a pilot, should be within the scope of the ESRD facility CfCs. Physicians and clinicians agree that it is essential that home dialysis patients always have the option of receiving in-center dialysis when medically needed. Whether there is an ownership interest or other arrangement, staff-assisted home dialysis programs need to have a written agreement with an in-center facility to protect patient safety in the event a

³⁸Medicare Benefits Policy Manual, Ch. 11 § 30.1C. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c11.pdf>

patient requires in-center dialysis through the self-assisted dialysis period. We also believe that there would need to be specific staffing requirements and patient rights added to the CfCs to address the unique nature of the program. However, it is important that the overarching aspects of the CfCs apply staff-assisted home dialysis, as they would for alternative types of dialysis facilities.

KCP also asks that CMS define what it views staff-assisted dialysis to include. Once that is understood, we would welcome the chance to provide more specific details about the specific modifications to the CfCs that we anticipate being necessary.

Section IV: OPOs

A. Improving Metrics and Evaluating OPO Performance

The responses below address the following questions set out in the OPO of the RFI related to metrics and evaluating OPO performance:

1. Independent of CMS' specific outcome measures, what other metrics or attributes reflect a model or highest performing OPO?
2. What are quantitative or qualitative indicators of excellent performance and how can CMS incorporate these with outcome measures when assessing OPOs for recertification purposes?
3. Should CMS consider additional metrics, such as those that measure equity in organ donation or an OPO's success in reducing disparities in donation and transplantation?
4. Are there ways to scale, or rate, performance of other (new) factors that CMS may consider in assessing OPO performance?

KCP agrees that it is important to strengthen the performance of the OPOs, which play such a vital role in providing patients who need a life-saving transplant with access to one. With slightly more than 21,000 kidney transplants performed in 2018³⁹ and nearly 95,000 patients on currently on waitlists,⁴⁰ nephrologists and facilities face substantial limits in what they can do to increase the number of kidney transplants. Everyone agrees that we need more coordinated efforts that focuses on OPOs, living donors, and transplant center criteria and polices is needed to improve access to transplant, especially for patients living with kidney failure.

³⁹UNOS Biweekly Update (January 10, 2020).

⁴⁰National Kidney Foundation. "Organ Donation and Transplantation Statistics."

<https://www.kidney.org/news/newsroom/factsheets/Organ-Donation-and-Transplantation-Stats>.

As our history and support of value-based purchasing demonstrates, KCP understands and strongly believes in the power of performance measures to drive improved performance and accountability. We supported the revisions of the OPO measures that CMS proposed in 2021, including the donation rate of eligible donors and transplantation measures and the organ transplant rate measure.

KCP remains committed to working with CMS and the transplant community to ensure that the measures account for organs that are not appropriate to use for transplant. Such decisions and the criteria used to make them should be transparent and available publicly to promote accountability as well.

In reporting the organ transplant rate, we ask CMS to consider risk-adjusting the organ transplantation rate measure based on donor-specific information. That is, rates of organ acceptance could be benchmarked against the likelihood that a given organ would be accepted or discarded by a composite of organ acceptance behavior by transplant programs. By risk-adjusting organ acceptance rates, OPOs would be held accountable for placing organs that are likely to be accepted by transplant centers, without being held wholly responsible for organs not placed in circumstances where the vast majority of centers would not accept a particular organ. As transplant center metrics change in a manner that encourages more aggressive organ acceptance behaviors, the risk adjustment for OPOs would shift accordingly. It would be important to make sure that such an adjustment did not weaken the OPO's accountability.

KCP supports holding OPOs accountable when they do not perform adequately, but we also want to make sure that HHS minimizes any potential disruptions when an OPO is decertified. We support opening donor service areas in such instances to competition and the criteria that the competing OPO must show that it is performing significantly better than the decertified OPO. It is important that throughout this process, CMS not allow there to be a lapse in any service area that would leave a gap in the collection and provision of organs.

As noted in Section I on transplant centers, improving the transparency of data among transplant centers, OPOs, nephrologists, dialysis facilities, and patients is critically important if the Administration is to meet its goals of increasing access to transplant. KCP supports the existing requirements that OPOs providing an easy to access and understand platform for communicating with all members of the kidney care community, but especially to patients.

B. Consolidating or Expanding OPOs

The response below addresses the following question set out in the OPO of the RFI related to the consolidation or expansion of OPOs:

10. What would be the anticipated impact from consolidation or expansion of the OPO community? Would consolidation or expansion of OPOs facilitate increased competition and improved performance or have a negative impact?

KCP believes that the central question to improving access to transplant when it comes to OPOs is performance. Questions about whether consolidation or expansion is per se beneficial or harmful is tangential to improved performance. In principle, either could result in better or worse performance. Thus, rather than focus on whether there should be more or fewer OPOs, we encourage HHS to focus on ways to measure performance accurately, improve public reporting and transparency around these metrics and outcomes, and hold OPOs accountable when they do not meet performance standards.

C. Transporting Organs

The responses below address the following questions set out in the OPO of the RFI related to the transportation of organs:

12. Are there best practices regarding the arrangement of organ transportation between an OPO and a transplant program?

13. How can the tracking of organs during transport be improved? Should specific requirements be implemented to facilitate real-time tracking of organs? What additional factors should be considered to ensure organs undergoing real-time tracking arrive at their intended destination timely?

14. Can the OPO CfCs address the issue of organs that are lost during transport to a transplant program?

15. Are there other ways HHS can incentivize creation or use of additional mechanisms to reduce the likelihood organs will be lost or damaged after procurement but before transplantation?

Under the current structure, each OPO has its own system for transporting organs. Smaller OPOs struggle and may need additional assistance. The problems can begin as soon as an organ has been identified as being available. To address this fragmentation, KCP supports CMS's efforts to bring patients, transplant centers, OPOs, and nephrologists together in the ETC LC to establish a clear set of national best practices and to hold OPOs accountable for meeting them. While we want to encourage OPOs to exceed a minimum set of standards, it is also important to identify those OPOs failing to meet that minimum standard and provide ways for them to improve.

Similarly, we encourage the federal government to find solutions to transportation problems. We agree with the expectation that transportation is the responsibility of OPOs. For those not performing, we urge HHS to address such problems quickly and definitively.

Moreover, implementing a modern real-time tracking system during organ transportation is long overdue. We encourage CMS and HHS to hold its contractor responsible for the lack of a reliable and reproducible process for the electronic tracking of all organs procured for transplantation. A host of private entities (Amazon, FedEx, UPS) have extensive expertise in this area, and we recommend that a comprehensive external review of available technological solutions should be undertaken to ascertain the best solutions available to ensure no organ ever gets lost in transit. Real-time GPS tracking of all organs in transit should not be relegated to a pilot trial, it should be standard practice.

D. Addressing Organ Acceptance and Collaboration between OPOs and Transplant Centers

The responses below address the following questions set out in the OPO of the RFI related to the organ acceptance and collaboration between OPOs and Transplant Centers:

41. How has the sharing of information on organ offer and acceptance data impacted practice, including information on root causes for failure to place organs as well as organs that were declined but later
42. What is the impact to these types of information sharing in practice, and if they have been productive, how can CMS build requirements around OPO—transplant center collaboration to support best practices in reducing the number of organ discards?
43. Should this type of collaboration between OPOs and transplant programs be incorporated into quality assurance performance improvement (QAPI) requirements for OPOs and transplant centers?

KCP supports increased transparency regarding the data already collected from transplant centers about why an organ is not accepted and from OPOs about why an organ is discarded. The current codes are insufficiently detailed to offer a clear understanding of why some centers chose to decline individual organ offers. There are varying reasons for rejecting an organ. While some may be appropriate, others appear to be based on convenience, such as transplant centers refusing to accept organs after a certain time of day or during a weekend. To end the inappropriate practices, we recommend that CMS provide baseline requirements that provide direction for transplant center quality assessment and performance improvement (QAPI) programs. To increase transparency and accountability, we suggest formal after-action reviews of organ decline decisions be included in the requirement.

We also encourage HHS to modify the transplant center COPs to require the centers to inform patients when an organ has been offered for the patient and why the transplant center rejected it. Given the time-sensitive nature of organ acceptance procedures, we do not believe this disclosure has to be offered in real time. But it is inappropriately paternalistic to withhold this information from patients. In addition to communication with patients, the transplant centers' performance on this metric should also be publicly available. Current websites that contain this information can be difficult to use and often are unintelligible to patients and care partners who are not health care professionals.

Greater transparency is also needed when it comes to donor hospitals coordinating with OPOs. In particular, we believe the CfCs for donor hospitals should be modified to include required reporting to CMS all eligible donors and evidence of timely notification of the donor hospital's OPO, after the donor hospital has become aware of an eligible donor, with evidence of process improvement plans in place when and where suboptimal rates of eligible donor identification and/or timely notification metrics are below designated thresholds. Donor hospitals with suboptimal performance on timely notification of the OPO should be subject to additional scrutiny. We also recommend that CMS revise the hospital COPs to require them to report eligible deaths to OPOs and CMS. These COPs should also be updated to include the definition of "eligible donor" in the OPO CfCs.

In addition, we believe that evidence of racial/ethnic disparities in rates of donor authorization, donation, and organ transplant rates in individual OPOs should be cause for requiring additional QAPI interventions on the part of these OPOs. There are plenty of well-performing OPOs which have reduced these disparities, and OPOs which have not reduced these disparities should either work to correct them, or those donation service area (DSA) contracts should ultimately be awarded to OPOs which have successfully do so.

E. Reducing Discard Rates

The responses below address the following questions set out in the OPO of the RFI related to discard rates:

44. We are interested in ways information on organ discard rates and organ acceptance practices can become more available and whether CMS should track and evaluate this information more closely and consider it for recertification purposes.

45. We are also interested in ways in which it may be possible to determine an "acceptable" baseline rate of organ discards based on medically disqualifying factors and how this should be assessed.

Discard rates in the United States are unacceptably high. In 2021, the discard rate for kidneys was 24 percent, which is three to four time the rate experienced in other

countries, such as the United Kingdom and France, where discard rates were between eight and ten percent. It is important to monitor OPO's discard rate, which are already required to be reported. We support existing requirement for transplant centers to report their organ acceptance rate, as noted in the previous section. It is also important to identify standards and best practices for procurement surgeons to avoid errors made at that stage. Similarly, transplant surgeon training should be target ways to use less than perfect organs, which some surgeons are able to use with great success already today. Moreover, KCP recommends eliminating the ranking of kidney against each other and using instead a metric that relates to the value the organ will provide to the patient.

F. Addressing Disincentives in Payment Policy for Donor Management

We believe the Medicare organ ratio calculation for transplant centers should eliminate any disincentive for transplant hospitals to relinquish donation after brain death (DBD) donors to organ recovery facilities. For the purposes of the Medicare organ ratio calculation, DBD donors diagnosed with brain death in a transplant hospital should count toward the transplant hospital's Medicare organ ratio. The donor transportation costs from a transplant hospital to an organ recovery center should be covered by Medicare in all circumstances where kidneys are procured and transplanted into Medicare beneficiaries. The OPO should be able to include donor transportation costs in its Medicare Cost Report and reconcile qualified donor transportation costs with the OPO's Medicare contractor. We appreciate that there is an existing MS-DRG for this area, we are concerned that the rate does not cover the cost of providing these services.

Section V: Nephrology Joint Ventures

The responses below address the following questions set out in the Nephrology Joint Ventures section of the RFI:

1. Would it be helpful for CMS to collect information on joint venture arrangements as part of Medicare enrollment in order to support analysis of the impact of these arrangements on the quality of care furnished to Medicare beneficiaries?
2. Should a dialysis facility or nephrologist be required to disclose information on joint venture arrangements to patients for improved transparency?
3. Do joint ventures between nephrologists and dialysis facilities have an impact on resource use, patient care, and/or choice of modality? If so, please describe how joint venture arrangements affect resource use, patient care, or choice of modality.

Consistent with our previous comments, KCP support transparency across the health care system. CMS already collects information on joint venture arrangements and both facilities and nephrologists report this information already through the PECOS

system. We appreciate that it may have been difficult for stakeholders to access this information and support sharing the percentage of ownership data in a more user-friendly manner, but CMS should not impose a duplicative reporting on nephrologists or facilities requirement. We believe that patients and researchers have an interest in knowing about the existence of joint venture arrangements. In general, we support disclosure requirements which include: (a) the fact that a facility or service is in a joint venture relationship, and (b) the names of the owners of the joint venture entity. We do not support additional disclosure requirements of the detailed financial arrangements of joint ventures agreements, as these additional requirements may unintentionally create impediments to the negotiation of new joint venture agreements.

While we support transparency, KCP also wants to emphasize that CMS has relied upon expansive joint venture arrangements between dialysis providers and nephrologists in previous Innovation Center models to improve patient outcomes and the quality of care provided, namely the ESRD Seamless Care Organization (ESCO) model. At the time, ESCO agreements included a requirement to disclose to patients the fact that they were enrolled in an ESCO, as well as the ESCO participants, but did not permit disclosure of the financial structures of individual ESCOs. Significantly, CMMI's ESCO joint venture pilot project demonstrated significant decreases in hospitalizations and readmissions and a statistically significant savings of \$114 per beneficiary per month due to improvements in care coordination.⁴¹ CMS is also relying on nephrology joint ventures in the Kidney Care Choices (CKCC) model that just launched January 1. The goals of this model are to increase home dialysis utilization and transplants among beneficiaries with kidney failure. As the reliance on joint ventures in these models suggests, joint ventures can allow for improved care coordination and patient outcomes. It is important that these impacts and outcomes be reported and considered as part of the policy efforts contemplated by this RFI.

VI. Conclusion

KCP appreciates the opportunity to provide comments on the RFI. In the coming weeks, we will follow-up on the recommendations outlined in this letter with the appropriate agencies, as well as share them with Members of Congress. We look forward to working closely with the Administration as it develops and implements policies to improve the organ and transplantation ecosystem, as well as the delivery of care to individuals with CKD and ESRD.

⁴¹Marrufo G, Colligan EM, Negrusa B, Ullman D, Messana J, Shah A, Duvall T, Hirth RA. "Association of the Comprehensive End-Stage Renal Disease Care Model With Medicare Payments and Quality of Care for Beneficiaries With End-Stage Renal Disease." 180 *JAMA Intern Med.* 852-860 (2020).

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The Honorable Chiquita Brooks-LaSure
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In the meantime, please do not hesitate to reach out to our counsel in Washington Kathy Lester if you have any questions or would like to coordinate a meeting. She can be reached at 202-534-1773 or klester@lesterhealthlaw.com. Again, thank you for the opportunity to provide comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'J Butler', with a stylized flourish extending to the right.

John Butler
Chairman

Appendix: KCP Members

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