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February 1, 2022

The Honorable Xavier Becerra

Secretary

U.S. Department of Health & Human Services

200 Independence Avenue, S.W.

Washington, DC 20201

The Honorable Chiquita Brooks-LaSure

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human 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:

The American Kidney Fund (AKF) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Request for Information (RFI) referenced above.

AKF fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation, and advocacy, no kidney organization impacts more lives directly than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds has held the highest 4-Star rating from Charity Navigator Platinum Seal of Transparency from GuideStar.

AKF appreciates that CMS is requesting information on how it can take steps enhance the lives of kidney patients by improving organ donation, organ transplantation, quality of care in dialysis facilities, and improved access to dialysis services. [More than 780,000](#) people in the United States, or 2 in every 1,000 people, are currently living with end-stage renal disease (ESRD, or kidney failure).<sup>1</sup> The numbers are growing. Studies project that 971,000 to 1,259,000 individuals will be living with ESRD in 2030.<sup>2</sup> As a patient

<sup>1</sup> Centers for Disease Control and Prevention. Chronic Kidney Disease Surveillance System website. <https://nccd.cdc.gov/CKD>. Accessed 2/19/2021. <https://www.cdc.gov/kidneydisease/pdf/Chronic-Kidney-Disease-in-the-US-2021-h.pdf>

<sup>2</sup> Keith P. McCullough, Hal Morgenstern, Rajiv Saran, William H. Herman, & Bruce M. Robinson(2019). Projecting ESRD Incidence and Prevalence in the United States through 2030. JASN, 30 (1) 127-135. <https://jasn.asnjournals.org/content/30/1/127>

advocacy organization, AKF's comments will focus on the patient experience and what our organization does to help kidney patients.

AKF is especially appreciative of your request for information concerning health equity and addressing health disparities in kidney disease and kidney failure. Kidney failure has a disproportionate impact on people of color, and fighting health disparities has long been an integral part of AKF's mission.

Black Americans make up just 13% of the U.S. population, but they account for 35% of Americans on dialysis. Compared to white Americans, Black Americans are 3.4 times more likely to develop kidney failure. Native Americans are 1.9 times, and Asian Americans are 1.3 times, more likely than white Americans to develop kidney failure. People of Hispanic ethnicity are 1.5 times more likely to develop kidney failure than non-Hispanics.<sup>3</sup>

Data has shown that individuals from communities of color have lower rates of kidney transplantation. Kidney transplantation is considered the best treatment option for most people with kidney failure because it increases a patient's chances of living a longer, healthier life. There are more than 105,000 Americans on the organ transplant waiting list, with 92,000 of them—86%—waiting for a kidney. In 2021 42% of all kidney transplant recipients in the U.S. were white, while 29% were Black and 20% were Hispanic.<sup>4</sup>

AKF is also a member of Kidney Care Partners (KCP), an alliance of members of the kidney care community. In addition to our comments below, we support the comments that KCP has submitted.

## **A. Transplant Programs**

### **3. Transplant Recipient Patient Rights**

#### **Question 1: 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?**

Patients commonly experience challenges in getting information to and from transplant coordinators, and many do not understand the various steps in the evaluation process. The volume of communications—especially at large transplant centers—can make it difficult for coordinators to be responsive to patients with their questions. The current transplant evaluation process should be easier for patients to navigate.

- CMS can work with patient and provider groups to lay out a framework or a start-to-finish set of expectations for patients. For example, it should include a list of needed tests to be done by their primary care provider and to whom they need to send the results. The framework will let patients know where they are in the process. It can be written, but also made into a video or podcast. Both written and oral education needs to be provided in easy-to-understand language and provided in the primary language of the patient. The educational materials should also include information on the organ procurement process and organ allocation system.
- Peer mentors and care navigators can be utilized to a greater degree to assist new patients with the process.

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<sup>3</sup> National Institutes of Health, National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK) website. <https://www.niddk.nih.gov/health-information/kidney-disease/race-ethnicity>

<sup>4</sup> Data from Organ Procurement and Transplantation Network: <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#>

- Education should also be provided early in the process so more patients can be placed on the transplant list preemptively or soon after beginning dialysis. A focus on getting appropriate patients waitlisted or receiving living donor transplants earlier in their dialysis treatments is a strategy that both the community and CMS could adopt. It is regrettable when a patient has access to a living donor and could have been transplanted in the first or second year of dialysis, but could not get the transplant until the fourth or fifth year because of the transplant process.
- The cohort of people who get preemptive transplants have higher education levels and have a higher socioeconomic status. Those with lower socioeconomic status, inadequate insurance, or who live in underserved areas can face barriers to kidney transplantation.<sup>5</sup> Education and assistance should be provided to people from communities of color, underserved communities and rural communities earlier in process.
- Once individuals are on the waitlist, access to transplantation is generally equalized. However, there is potential in bias in the decisions to refer patients to the waiting list and in the timing of the physician assessment of appropriateness for transplant. Data shows that there are racial disparities in that process. There can also be a lack of knowledge at both the dialysis center and referring physician levels about the organ allocation system, which can lead to less timely referrals.

#### **A. Transplant Programs**

#### **4. Equity in Organ Transplantation and Organ Donation**

#### **Question 1: Are there revisions that can be made to the transplant program or OPO requirements to reduce disparities in organ transplantation?**

Suggested revisions to the transplant program or OPO requirements include:

- Create outreach programs to contact dialysis patients who are in communities of color. For example, Northwestern University and George Washington University have outreach programs to specifically assist kidney patients from communities of color to educate them on kidney transplantation.
- CMS could require transplant programs or OPOs to conduct an organizational literacy audit and create documents for patients to show how to interact with the transplant program.
- Kidney patients all over the country set up “GoFundMe” or other fundraisers to get the cash needed to be accepted onto a waitlist. The required amount of cash on hand can be a barrier to kidney transplantation for low-income people. Transplant programs can reduce the amount of money that patients need to have in a bank account prior to being accepting to the transplant waiting list.
- HHS can work to align two seemingly opposing incentives due to metrics from two agencies within the department. The first metric is part of the Scientific Registry of Transplant Recipients (SRTR) “Getting a Transplant Faster” reported by the Health Resources and Services Administration (HRSA), which is used to compare transplant programs. It provides publicly available program-specific reports, which include rates of transplantation, deceased donor transplantation, waitlist mortality, and time to transplant. The information provides a comparison between transplant programs within its donor service area, region and the nation as a whole. The metric incentivizes waitlisting fewer patients because the number of deceased donor kidneys available to each center

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<sup>5</sup> David A. Axelrod, Mary K. Guidinger, Samuel Finlayson (2008). Rates of Solid-Organ Wait-listing, Transplantation, and Survival Among Residents of Rural and Urban Areas. *JAMA*, 299(2):202–207. <https://jamanetwork.com/journals/jama/fullarticle/1149365>

for transplantation increases slowly, if at all. Hence, the most expedient strategy a transplant center can use to improve those metrics related to transplantation rates is to waitlist fewer patients. The second metric is required by CMS. Dialysis facilities must report the percentage of patients at their facility who are on the kidney or kidney-pancreas transplant waitlist, averaged across patients prevalent. Therefore, dialysis facilities are incentivized to help more patients get on the waitlist. Revising these transplant center metrics to encourage waitlisting more patients may improve access.

- Medigap insurers should be required to offer all Medigap plans to all Medicare beneficiaries regardless of state. Currently, Medigap insurance for those under age 65 is regulated by the states, and there are 20 states that do not require insurers to offer Medicare ESRD beneficiaries under age 65 a Medigap plan. Medicare coverage alone is not sufficient for a patient to be eligible to be placed on the transplant waiting list.
- Insurance companies should be required to accept direct payments from the American Kidney Fund. AKF helped nearly 1,800 people—or 7% of all the 25,489 Americans who received a kidney transplant in 2021—pay for their insurance and get a life-saving transplant. And of those nearly 1,800 people, 34% were Black and 23% were Hispanic, which is higher than the national average.

## **A. Transplant Programs**

### **4. Equity in Organ Transplantation and Organ Donation**

**Question 2: 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?**

Transplant programs and OPOs should be aware of social determinants of health (SDOH) in their policies, but it needs to be very clear that the SDOH should not disqualify a kidney patient from being listed on the transplant waiting list or being asked to be a living organ donor.

Suggestions for how transplant programs or OPOs could or should consider social determinants of health in their policies include:

- Transplant centers and OPOs should be cognizant that people have been denied treatment due to race, but also based on their income level, where they live and whether decision makers think that their living environment is going to be conducive for them to maintain their transplant. We should ensure that data around SDOH should not be used to discriminate against patients.
- Transplant centers and OPOs should focus on equity in-and-of itself. When transplant centers and OPOs focus solely on the outcome, all the SDOH creating the disparities that get patients to dialysis are reenacted in transplant patients.
- CMS can study how economic factors are being used to evaluate patients to be admitted to the waitlist site to understand if the economic factors being used really determines the outcomes of the transplant. As stated above, AKF pays for the health insurance of low-income and financially struggling kidney patients. The people AKF help have an average annual income of just over \$25,000, so their outcomes might have been assumed to be worse than people with a higher socioeconomic status. We believe that the people we help have the same outcomes. We are conducting a study now to challenge the assumption that low socioeconomic status has a more adverse impact on outcomes and therefore they are significant for the decision about whether or not a person is on the list.

- Investigate changing the kidney allocation system that favors patient survival over graft survival. There are two studies<sup>6 7</sup> that surveyed post-transplant expectations. Patients and providers had different expectations about quality of life, capabilities and health after transplant. Also, cost and financial questions were big concerns about post-transplant care for providers, but patients were more concerned about their lives and health. These studies were about post-transplant patients, but it is possible that these documented disparities in attitudes of providers and patients in post-transplant care could also influence pre-transplant care.

## A. Transplant Programs

### 4. Equity in Organ Transplantation and Organ Donation

#### **Question 6: What changes can be made to the current [transplant program and OPO] 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?**

Decisions need to be informed by evidence and the individual's personal attributes must be considered. Current measures are linked to evidence and measures should be used to support patients in getting good outcomes, but not limiting them.

Suggestions to transplant centers and OPOs are:

- Focusing on cultural competency can better ensure that transplant centers are aware of individual organ recipient's unique support systems post-transplant. They need to be aware of possible implicit bias when assumptions are made about a patient's ability to follow transplant instructions, a patient's unique support system, and the patient's financial challenges.
- The U.S. House of Representatives Ways and Means Committee released a report in October 2021 entitled [\*Fact versus Fiction: Clinical Decision Support Tools and the \(Mis\)Use of Race\*](#). The report discussed two clinical support tools (CST) that could have resulted in poorer health outcomes for Black Americans. The first CST was estimated glomerular filtration rate (eGFR). The Committee flagged this measure because it specifically had a different result for Black Americans. Recommendations to change the measure were put forth in September 2021 by the NKF-ASN Task Force on Reassessing the Inclusion of Race in Diagnosing Kidney Disease to no longer include race, and the measure is now being incorporated into some medical practices and labs across the country. The Ways and Means Committee pointed to another CST related to Black Americans and access to kidney transplants called the Kidney Donor Risk Index (KDRI). The report states that KDRI measure can result in kidneys from Black donors appearing are riskier than others, and thus diminishing the number of Black kidney donors. It is important the transplant centers and OPO are aware of these measures.

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<sup>6</sup> Maass KL, Smith AR, Tucker EL, Schapiro H, Cottrell SM, Gendron E, Hill-Callahan P, Gill SJ, Daskin MS, Merion RM, **Leichtman AB**. Patient Educ Couns. 2019 May;102(5):990-997. doi: 10.1016/j.pec.2018.12.010. Epub 2018 Dec 13. PMID: 30591284 [Comparison of patient and provider goals, expectations, and experiences following kidney transplantation.](#)

<sup>7</sup> Tucker EL, Smith AR, Daskin MS, Schapiro H, Cottrell SM, Gendron ES, Hill-Callahan P, **Leichtman AB**, Merion RM, Gill SJ, Maass KL. BMC Nephrol. 2019 May 16;20(1):175. doi: 10.1186/s12882-019-1368-0. PMID: 31096942 [Free PMC article. Life and expectations post-kidney transplant: a qualitative analysis of patient responses.](#)

## B. Kidney Health and End-Stage Renal Disease Facilities

### 1. Background

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

Seventy-five percent of new kidney failure cases are due to diabetes and hypertension. Management of those underlying diseases is vital to controlling kidney failure. We have seen that when insurance is provided to at-risk populations, their health improves. Control measures for blood pressure and glucose (diabetes) have improved in Medicaid expansion states compared with non-expansion states. The improvements in blood pressure and glucose control are greatest for Black and Hispanic Americans.<sup>8</sup> Compared to states that did not expand Medicaid, people living in states that expanded the program had lower mortality rates after going on dialysis and more patients were preemptively placed on the transplant list so they could be on dialysis for a shorter time.<sup>9, 10</sup>

Nutritional, lifestyle and medical management interventions are generally more available to those with health insurance. Expanding health insurance will provide access to these services that play a critical role in addressing chronic kidney disease (CKD). No doubt the racial disparities in ESRD can be explained, in part, by the lack of preventive care and early interventions that people with limited access to affordable and high-quality health care have.

The lack of affordable and high-quality insurance in many at-risk communities needs to be addressed. One focus is to expand Medicaid in the non-expansion states. Over 2.2 million people fall into the Medicaid “coverage gap:” they don’t qualify for Medicaid or ACA premium tax credits.<sup>11</sup> Over three-quarters of people in the coverage gap live in just 4 states: Florida, Georgia, North Carolina and Texas.<sup>12</sup> Fifty-eight percent of those in the Medicaid coverage gap are racial and ethnic minorities: 28% African American/Black, 28% Hispanic/Latino, 1% American Indian or Alaska Native, 1% Asian or Pacific Islander.<sup>13</sup>

The Build Back Better Act included provisions that would have provided access to ACA coverage to individuals who live in states where there is a coverage gap because the state did not expand Medicaid. The Medicaid provision in Build Back Better is an important tool for battling kidney disease in the United

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<sup>8</sup> Berman, Robby. “Medicaid expansion improves hypertension and diabetes control,” *Medical News Today*, 20 September 2021. <https://www.medicalnewstoday.com/articles/medicaid-expansion-improves-hypertension-and-diabetes-control>

<sup>9</sup> Shailender Swaminathan, Benjamin D. Sommers, Rebecca Thorsness (2018). Association of Medicaid Expansion With 1-Year Mortality Among Patients With End-Stage Renal Disease. *JAMA*, 2018;320(21):2242-2250. <https://jamanetwork.com/journals/jama/fullarticle/2710505>

<sup>10</sup> Weiner, Janet. “Addressing Kidney Transplant Waiting List Disparities Through Medicaid Expansion,” *University of Pennsylvania Leonard Davis Institute of Health Economics, Health Care Access & Coverage, Health Equity, Blog Post*, 18 June 2018 <https://ldi.upenn.edu/our-work/research-updates/addressing-kidney-transplant-waiting-list-disparities-through-medicaid-expansion/>

<sup>11</sup> Rudowitz R, Garfield R, Levitt L. “Filling the Coverage Gap: Policy Options and Considerations,” Kaiser Family Foundation, 22 April 2021. <https://www.kff.org/medicaid/issue-brief/filling-the-coverage-gap-policy-options-and-considerations/>

<sup>12</sup> Larry Levitt (2021). The Inequity of the Medicaid Coverage Gap and Why It Is Hard to Fix It. *JAMA Health Forum*. 2021;2(10):e213905. <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785323>

<sup>13</sup> Lukens G, Sharer B. “Closing Medicaid Coverage Gap Would Help Diverse Group and Narrow Racial Disparities,” Center on Budget and Policy Priorities (CBPP), 14 June 2021. <https://www.cbpp.org/research/health/closing-medicaid-coverage-gap-would-help-diverse-group-and-narrow-racial>



States. Although the provision needs to be enacted through legislation, AKF suggests CMS investigating if they can contract with Medicaid Managed Care Organizations in non-expansion states to provide coverage for these individuals.

### **AKF's Charitable Premium Assistance Program**

Providing people of color with full health insurance will assist in increasing the number of transplants. AKF's federally recognized financial premium assistance program for people with ESRD, the Health Insurance Premium Program (HIPP), is governed by Advisory Opinion (AO) 97-1, issued by the HHS Inspector General in 1997. HIPP assists more than 70,000 low-income or financially struggling people on dialysis or with a recent kidney transplant pay for their health insurance premiums every year.

HIPP pays for all types of insurance, including Medicare Part B, Medigap, Medicare Advantage, employer group health plans, COBRA and Affordable Care Act (ACA) Marketplace plans. As most dialysis patients are eligible for Medicare due to their ESRD status, over 69% of the premiums we pay are for Medigap plans, Medicare Part B and Medicare Advantage. About 21% are employer-sponsored plans and COBRA, about 3% are for ACA Marketplace plans and the remaining 7% are primarily for off-exchange plans. It is important to note that Medicare alone—without supplemental coverage—can be unaffordable for most patients and is not considered full coverage for purposes of being put on a transplant waiting list. Medicare does not have an out-of-pocket cap, and dialysis patients can face out-of-pocket costs upwards of \$10,000 per year. At the same time, over 80% of ESRD patients on dialysis are unable to work because of the burdens of the disease and because they must receive life-sustaining dialysis treatments, which are typically four hours per treatment at least three times per week.

As described above, kidney disease disproportionately affects people of color. Because Black Americans and Hispanics are more likely to have their kidney disease progress to kidney failure, over 60% of AKF HIPP grant recipients are individuals from communities of color: 34% are Black, 23% are Hispanic, and 6% are Asian, Pacific Islander, Alaskan Native or Native American.

Health insurers have taken steps to make it difficult for dialysis patients to accept assistance from AKF by rejecting direct payments, or by requiring patients to sign attestations that they will not accept help from a charity. Driving this policy is the misguided belief that because most ESRD patients are eligible for Medicare, those receiving premium assistance should not have the option of private insurance, especially ACA Marketplace plans. However, the choice of insurance plan is an individual decision based on individual needs. The ACA and Medicare statutes affirm that patients have choice of insurance coverage.

Insurance company policies that make it difficult for patients to receive charitable premium assistance disproportionately impact people of color. By implementing these policies, insurers are targeting populations that have historically been marginalized by the health care system and the health insurance industry. It is important to note that if you can afford to pay your own premiums, insurance companies must take your premium payments; it is only if you cannot afford the premiums and rely on a private charity for assistance that an insurance company can discriminate against you.

To advance health equity and protect patients with high-cost chronic conditions, AKF urges HHS to require health insurers to accept financial assistance from non-profits like AKF that operate their programs with certain guardrails that ensure program integrity. AO 97-1 requires strict firewalls and safeguards to protect and ensure patient choice of provider and insurance coverage, providing a safe harbor from federal

beneficiary inducement laws. This protocol has set the standard for dozens of similar national charity care programs for more than two decades. Protecting access to financial assistance programs like AKF's HIPP helps advance health equity for low-income people with high-cost chronic conditions who are disproportionately from underserved communities.

## **B. Kidney Health and End-Stage Renal Disease Facilities**

### **1. Background**

**Question 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?**

A main barrier to access for routine and preventive care is most people with kidney disease do not know that they have it. Almost half of people who start dialysis do not even know they had kidney disease. One way to address a barrier to care is expanding kidney screenings as part of the yearly wellness physical, at least for higher risk populations. The United States Preventive Services Task Force last looked at the issue in 2012 and did not recommend yearly screenings for all people. AKF supports screening targeted populations, such as people with diabetes and hypertension.

The American Diabetes Association recommends annual kidney screenings for people with diabetes using urine albumin and serum creatinine testing<sup>14</sup>. The National Institutes of Health's Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends that people with hypertension should have urinalysis and serum creatinine testing<sup>15</sup>.

## **B. Kidney Health and End-Stage Renal Disease Facilities**

### **1. Background**

**Question 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 predialysis education and prevention programs be improved?**

**Question 4: How can we increase awareness of known racial, ethnic, gender, sexual orientation, and economic disparities in care for CKD?**

**Question 6: How can we improve health literacy among the general population, and individuals at higher risk about the prevention of CKD?**

AKF conducts numerous public awareness campaigns aimed at educating the public about kidney disease and kidney disease prevention, such as *Know Your Kidneys™*, *Kidney Kitchen™*, *Kidney Health Coach* and our annual *Kidney Action Week*. We are beginning a public awareness campaign to specifically reach communities of color about prevention and early interventions for kidney disease. CMS can partner with patient groups like AKF to enhance and further spread these efforts.

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<sup>14</sup> American Diabetes Association. Executive summary: standards of medical care in diabetes—2012. *Diabetes Care*. 2012;35(Suppl 1):S4-10.

<sup>15</sup> Chobanian AV, Bakris GL, Black HR, et al; Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. National Heart, Lung, and Blood Institute. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Hypertension*. 2003;42:1206-52.



## **B. Kidney Health and End-Stage Renal Disease Facilities**

### **1. Background**

**Question 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?**

There are a number of ways that PCPs can better support their patients in prevention and slowing the progression of CKD:

- One unique opportunity is informing primary care physicians that we now have a different standard of eGFR with the recent suggested elimination of the race component. Outreach and education to PCPs about this change is an opportunity to discuss kidney disease and educate PCPs about who is at-risk for kidney disease.
- The care of vulnerable groups with high rates of kidney failure are concentrated amongst relatively few providers. These individuals are dependent on the health care safety net such as Federally Qualified Health Centers (FQHCs) as well as other safety net providers. FQHCs monitor and report on indicators, including diabetes and hypertension., and they and other safety net providers could also monitor kidney function as they are often in communities of color and in underserved and rural communities.
- For individuals who are not reliant on the safety net, individual PCPs are consolidating into bigger practices. Educating the large practices and urging them to include screenings for at-risk individuals, including those with hypertension and diabetes, should prove easier due to the streamlined systems that large practices use. Their utilization of systems and electronic medical records make it easier to incorporate kidney screening tests to be included in their yearly physicals.

## **B. Kidney Health and End-Stage Renal Disease Facilities**

### **1. Background**

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

CMS can partner and utilize information created by patient groups. AKF has a program called the “FIRST30,” which is an integrated public and professional education campaign that provides vital information for people newly diagnosed with kidney failure, their caregivers and the professionals involved in their treatment. The campaign focuses on the first 30 days of dialysis treatment, a crucial period of adjustment for patients. The FIRST30 campaign provides easy-to-understand, supportive resources that make navigating the process of dialysis easier for those feeling overwhelmed by their new situation. The information includes a checklist that breaks down the priority items to consider week-by-week such as coping with the diagnosis, diet adjustments, understanding dialysis treatment and where to turn with specific questions. It also includes a series of videos featuring kidney patients and renal professionals talking about adjusting to life as a dialysis patient.

## **B. Kidney Health and End-Stage Renal Disease Facilities**

### **2. Home Dialysis**

**Question 2: 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?**

Home dialysis has traditionally seen low rates of utilization in the United States, with 13.1% of all dialysis patients using home dialysis in 2019.<sup>16</sup> With studies showing that home dialysis for certain patients can lead to better health outcomes,<sup>17</sup> there is clearly an opportunity and a need to increase its utilization, and AKF has been supportive of federal efforts to do so. Increasing access to home dialysis is particularly important for communities of color, who see disproportionately lower rates of its use. For example, 58% of all dialysis patients (both in-center and home dialysis) in 2018 were White, 33% were Black, and 19% were Hispanic.<sup>18</sup> However, 66% of peritoneal dialysis (PD) patients were White, 24% were Black, and 16% were Hispanic.<sup>19</sup>

For home hemodialysis (HHD), 50.8% of HHD patients were white, 24.2% were Black, and 16% were Hispanic.<sup>20</sup> A study has also found that Blacks and Hispanics were 30% and 19% less likely, respectively, than whites to start on PD.<sup>21</sup> Additionally, the study found communities of color (particularly Hispanic and Asian patients) were 7% to 35% less likely to initiate HHD compared with white patients, though the difference for Black patients was not statistically significant.<sup>22</sup>

For these disparities in home dialysis initiation, the study found socioeconomic factors played a significant role.<sup>23</sup> Another study examining the reasons why patients start but then exit from a HHD program found that the primary reasons included lack of caregiver support and housing insecurity due to losing a home or being evicted.<sup>24</sup>

As with transplantation, there are various policy tools that could be used to address the low rate of home dialysis in communities of color, one we want to highlight in this letter is expanding the use of the Medicare Kidney Disease Education (KDE) benefit. While we support CMS granting these KDE flexibilities within the ESRD Treatment Choices Model, we believe it should be implemented throughout the Medicare program. Additionally, we believe it would be beneficial to extend the KDE benefit to beneficiaries with stage 3b CKD, so that more patients would be able to learn about future treatment modality options and interventions that can help slow their disease progression.

In talking to ESRD patients, AKF has heard numerous accounts where patients were not adequately educated on their treatment options and were not aware that home dialysis or a preemptive transplant might be a good option for them until they researched it themselves or went to a different clinician. Given the importance of patient education in empowering patients to make the right modality choice for them,

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<sup>16</sup> United States Renal Data System, Annual Data Report, 2020. Volume 2, Chapter 1, Incidence, Prevalence, Patient Characteristics, and Treatment Modalities: <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities>

<sup>17</sup> Rivara, M. B., & Mehrotra, R. (2014). The changing landscape of home dialysis in the United States. *Current opinion in nephrology and hypertension*, 23(6), 586–591. doi:10.1097/MNH.0000000000000066

<sup>18</sup> United States Renal Data System (USRDS): <https://usrds.org/data-query-tools/esrd-prevalent-count/>

<sup>19</sup> Ibid.

<sup>20</sup> Shen, Jenni I. et al. Socioeconomic Factors and Racial and Ethnic Differences in the Initiation of Home Dialysis, *Kidney Med.* 2(2):105-115. Published online February 11, 2020. DOI: <https://doi.org/10.1016/j.xkme.2019.11.006>

<sup>21</sup> Ibid.

<sup>22</sup> Ibid.

<sup>23</sup> Ibid.

<sup>24</sup> Paterson B, Fox DE, Lee CH, et al. Understanding Home Hemodialysis Patient Attrition: A Cohort Study. *Canadian Journal of Kidney Health and Disease.* January 2021. doi:10.1177/20543581211022195

eliminating barriers to the Medicare KDE benefit is an important step in increasing the rate of home dialysis and transplantation, especially in communities of color.

Another policy tool that we urge Congress and CMS to support is including kidney disease screening in the “Welcome to Medicare” preventive visit. For many patients with kidney failure, they were not aware of their CKD until they “crashed” into dialysis. Because a person with CKD usually does not have any symptoms until their kidneys are badly damaged, having access to a kidney disease screening is critical for early detection. By detecting their CKD earlier on in the process, before they reach ESRD, patients and their providers can work together on ways to slow the progression and discuss treatment modalities, including preemptive transplantation.

## **B. Kidney Health and End-Stage Renal Disease Facilities**

### **3. Dialysis in Alternative Settings**

#### **c. Alternate Models of Care**

We want to note that although the RFI states “We have received significant public interest and questions related to staff assisted home dialysis, which is not a separately paid service, but is covered as part of the ESRD Prospective Payment System (PPS) bundled payment,” this is actually not the case. Staff-assisted home dialysis is not a Medicare-covered service. As seen in the Medicare Benefit Policy Manual, “Staff-assisted home dialysis using nurses to assist ESRD beneficiaries is not included in the ESRD PPS and is not a Medicare covered service.”<sup>25</sup> AKF is supportive of the concept of staff-assisted dialysis and is eager to work with CMS and other key stakeholders to begin to address this complex issue.

Thank you for the opportunity to provide comments on this RFI. If you have questions on our response or would like to further discuss these issues, please contact Holly Bode, Vice President of Government Affairs, at [hbode@kidneyfund.org](mailto:hbode@kidneyfund.org).

Sincerely,



LaVarne A. Burton  
President and CEO

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<sup>25</sup> Center for Medicare & Medicaid Services, Publication No. 100-02, *Medicare Benefits Policy Manual, Chapter 11 End Stage Renal Disease (ESRD)*, Sections 30.1(C). <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf>