



February 1, 2022

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 Administrator Brooks-LaSure,

On behalf of the Nonprofit Kidney Care Alliance (NKCA), I write to offer our comments and recommendations on the Centers for Medicare & Medicaid Services (CMS) “Request for Information: Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities.” NKCA represents eight nonprofit dialysis providers: Centers for Dialysis Care; Central Florida Kidney Centers, Inc.; Dialysis Center of Lincoln, Inc.; Dialysis Clinic, Inc.; Independent Dialysis Foundation, Inc.; Northwest Kidney Centers; Puget Sound Kidney Centers; and The Rogosin Institute. Collectively, we serve more than 22,500 patients at more than 326 facilities in 32 states. In an effort to keep patients off dialysis, we also serve more than 10,000 patients with chronic kidney disease (CKD), with the goal of avoiding, or at least delaying, the onset of end-stage renal disease (ESRD). Approximately 85 percent of our patients are covered by Medicare, including Medicare Advantage (MA) plans.

Avoiding or Delaying ESRD and Transplants

Before commenting on some of the questions CMS raises in the RFI, we urge CMS, as well as the Department and the Administration to broaden the scope of this inquiry beyond transplantation to encompass the broader kidney care ecosystem. By doing so, policy can better address the unmet needs and missed opportunities affecting patients with chronic kidney disease (CKD) that lead to renal failure and the need for transplant and dialysis care in the first place. In short, we urge CMS and the Department to “go upstream” in a coordinated campaign that bridges the various missions and authorities to pursue better outcomes for patients along the continuum of kidney care.

Indeed, in Section B, “Kidney Health and End-Stage Renal Disease Facilities,” CMS addresses this very point, in describing “interventions that can slow progression of CKD” and in the several questions that follow, which we address below. Nevertheless, more can be gained from a greater emphasis on this broader perspective. While effective coordination across departments can be cumbersome, the opportunity to improve the lives of those living with CKD, institute reforms

that delay progression of CKD, promote a broader array of treatment modalities, and reduce the demand for costly healthcare services for these patients justifies the required effort.

In the remainder of this comment letter, we address specific questions raised by CMS in the RFI.

Transplant Programs

Among the issues and questions CMS raises regarding transplant programs are the inter-related issues of the high discard rate of so-called marginal organs and the notification and involvement of potential recipients of the availability of such organs, particularly kidneys. A few years ago, CMS did address the problem of Conditions of Participation (CoPs) having the unintended effect of incentivizing organ discards, but more needs to be done. Moreover, as CMS also acknowledges, patients who may have waited years on a transplant list are often unaware that a potential organ is available and have no voice, in consultation with their physician and family, about whether they would accept a less-than-optimal organ.

We urge CMS to propose changes to Section 482.102, “Patient and living donor rights,” to require that both a patient who would otherwise be an acceptable recipient and their physician be informed of the availability of a kidney even if that organ has a high Kidney Donor Profile Index (KDPI).

CMS asks (Transplant Recipient Patient Rights, question 1) how the worthy objective of increased transparency and accountability regarding the potential availability of kidneys can be achieved without undue delay and undue anxiety on the part of patients. We believe that these concerns could be addressed with an early-intervention education effort for patients as they first enter the transplant system. In other words, patients need clear information on the risks and benefits of a high KDPI kidney early on, rather than at the last moment when a high KDPI kidney becomes available.

Equity in Organ Transplantation and Organ Donation

Racial and ethnic disparities in access to transplantation are readily apparent and efforts to address them are long overdue. There are many reasons for these disparities, beginning with underlying disparities in healthcare coverage; access to care; and social factors—social determinants of healthcare (SDOH)—that include community factors, education, housing and transportation, nutrition, and other related factors.

CMS asks for comment on the Chronic Kidney Disease Epidemiology (CKD-EPI) equation used to measure kidney function, which includes an adjustment for race (specifically Black/African American) that has had the unintended effect of under-identifying CKD among Black/African American patients. One consequence of this effect is a longer time on transplant waitlists. Fortunately, there have been efforts across the kidney community to address the CKD-EPI equation. Recently, the National Kidney Foundation and the American Society of Nephrology have offered a recommendation to use a new “race-free” index of kidney function. Their report was published in the *American Journal of Kidney Disease* ([Delgado et al., 2021a](#)) and the *Journal of the American Society of Nephrology* ([Delgado et al. 2021b](#)).

In addition, research published recently in the *New England Journal of Medicine* ([Inker et al., 2021](#)) proposes new glomerular filtration rate (eGFR) equations, which incorporate creatinine and cystatin C while omitting race, that the authors find more accurate than those that omit race only from the current creatinine equation.

The important point is that there is widespread agreement among stakeholders that the equations that have been used for many years to measure kidney function and glomerular filtration rate have had an unintended discriminatory effect and should be modified or replaced. As the largest payor in the US for the treatment of patients with kidney disease, CMS, and HHS more generally, should use their regulatory authorities to address this racial bias at the earliest opportunity.

CMS also asks two inter-related questions revolving around SDOH and efforts to connect with communities of color and diverse cultures. With respect to the former, the first place to start should be for CMS to require, or at least incentivize, SDOH assessment of new and existing patients. Through its authority over the Medicare Advantage program, Medicaid MCOs and plans in the Marketplace, CMS can promote risk stratification that incorporates SDOH metrics. The Center for Medicare and Medicaid Innovation (CCMI) has already developed an instrument as a product of its [Accountable Health Communities](#) initiative.

With respect to connecting with communities of color and diverse cultures, CMS should consider launching an education campaign, as part of its health equity initiative, that puts a spotlight on successful efforts to reach communities of color and diverse cultures. For example, one of our members has worked with religious and other groups in communities to educate, and listen to the concerns of, residents regarding kidney disease, transplant—including living donor—and home dialysis. Another of our members partners with their local safety net hospital to share “cultural mediators,” who not only provide routine interpreter services, but, equally important bring their understanding of particular cultures in the community to build support and confidence with patients to bridge cultural differences.

Another means of bridging the current disparities in transplant is to address the lack of dental care, which can delay entry to transplant waitlists or even preclude access to transplant. Good oral hygiene is necessary to be active on a transplant list. Without proper oral hygiene, transplants are delayed. The reasoning behind this requirement is that post-transplant medications used to prevent organ rejection weaken the immune system and therefore a common periodontal infection may lead to much broader health complications for a transplant patient. According to the National Institute of Dental and Craniofacial Research, “Whenever possible, all active dental disease should be aggressively treated before transplantation, since post-operative immunosuppression decreases a patient’s ability to resist systemic infection.”

However, in the same way that Black and Hispanic Americans are more likely to suffer from kidney failure or wait longer on transplant lists than their white counterparts, they also are more likely to have periodontal disease and cavities. Black and Hispanic Americans are also less likely to have dental insurance coverage, which is vital to ensure continuing access to oral health treatment. Currently, Medicare only covers the final oral exam before transplant surgery at a hospital. All other dental care for CKD patients before their transplant surgery and before they

are even accepted onto an organ waitlist must be handled outside of Medicare. Most turn to the private individual market for a stand-alone dental plan (SADP) to pair with their healthcare or Medicare coverage. If not addressed, disparities in oral health treatment and coverage will continue to impact the transplant care process, disproportionately limiting the eligibility of Black and Hispanic Americans to receive transplants.

To increase access to dental care for patients with CKD and increase the ability of patients with kidney disease to be eligible for transplant, we request that the Center for Consumer Information & Insurance Oversight (CCIIO) provide the option of purchasing dental coverage independent of medical coverage on the federal health insurance Marketplace. The insurance Marketplace provides a centralized platform for individuals to purchase affordable dental coverage while they are wanting, awaiting, or recovering from an organ transplant. Currently, an individual looking to purchase an SADP on the Marketplace must first buy a medical plan, which limits the availability of dental plans for transplant patients already enrolled in Medicare or other health coverage.

Kidney Health and End-Stage Renal Disease Facilities

As we noted in the introduction of this comment, the ecosystem that should be—and to some extent is—the focus of this RFI is the broader kidney care ecosystem, not just the triad of transplant, organ procurement organizations, and ESRD facilities. Indeed, while much can be gained by improving each element of the triad, the broader objective must be to address CKD at earlier stages, by going “upstream” in the continuum of kidney disease. If this is successful, fewer patients will need renal replacement therapy, and those who do will be better informed and better prepared medically.

In this section of the RFI, CMS asks several important questions that speak to going upstream, among them:

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

For many, a gradual decline in kidney function is associated with normal aging and does not pose a significant threat to health or wellbeing. However, for patients with one or more medical conditions, such as diabetes or hypertension, the damage to kidney function can, if not addressed, lead to kidney failure. As CMS notes, many patients are unaware that they have kidney disease until it is far advanced and, in too many cases, patients are on a gurney in a hospital emergency room.

We believe that the primary care provider (PCP) of a patient with kidney disease should closely follow and manage the comorbidities that contribute to disease progression, including diabetes and hypertension. In addition, PCPs should routinely order lab work to measure GFR as well as hemoglobin A1C and protein in urine for at-risk patients. We do not believe it is necessary for a PCP to refer a patient to a nephrologist until they have a GFR less than 30. At that point,

nephrologists have actionable steps they can take to manage the disease and, if necessary, prepare patients for any care transition.

We do not recommend including stage 3 CKD in the evaluation of the kidney health ecosystem. The vast majority of individuals with stage 3 CKD will never need dialysis or a transplant. In addition, in our opinion CMS is already effectively addressing the primary causes of stage 3 CKD—diabetes and hypertension—with accountable care organizations and other value-based arrangements with PCPs.

In this regard, as CMS notes in the RFI (pg. 68596), there are potential gains from greater “harmonization policies across the primary HHS agencies.” In our view, HRSA’s support of community and rural health centers is an opportunity to do more to identify patients at risk of CKD—not least of which in communities of color and others who are chronically underserved. We also believe that CMS should consider the role of other health care professionals and social workers in helping identify at-risk patients and, once they are identified, work with them to help reduce CKD risk factors. For example, pharmacists, whether working independently, as part of practices and clinics, or through MA-PDs and PDPs, can play an important role in screening, medication reconciliation, and medication coordination—all functions that they are educated to perform, and that PCPs and others lack time or expertise to do. See, for example, work being done by the [Advancing Kidney Health Initiative](#), based at the University of Minnesota.

Currently MA/PDP plans have the responsibility to identify plan members who can benefit from Medication Therapy Management (MTM), but much more can and should be done. Plans—particularly MA-PDs, can identify patients at risk of CKD, by virtue of their medical and drug claims history, and ensure that they are offered screening, medication reconciliation, and care coordination to help stem the progression of their CKD.

Alternative Dialysis Sites

CMS poses a series of questions related to health and safety standards in mobile dialysis units, which also have a bearing on any type of alternative site, such as neighborhood drop-in clinics, among them:

- 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?;
- Should mobile units have separate/different physical environment requirements compared to a brick and mortar building?; and
- What health and safety standards are necessary to ensure a safe physical environment in mobile units?

Alternative sites can provide a valuable option for patients, who can benefit from flexibility of location and time, as well as support when travelling. But such flexibility should not come at the expense of patient safety and quality of care. Alternative sites are not equivalent to home dialysis, and health and safety standards should recognize the unique risks posed by care delivered in this setting. For example, mobile sites and dialysis in a nursing home involve multiple users. The risk of infection is no less than in any clinic or “congregate” site. Moreover, the equipment that is used in an alternative site may be less familiar to a user, which could affect dialysis adequacy.

While current conditions for coverage (CfC) requirements for ESRD clinics may not be appropriate in every regard, there should be specific criteria for each alternative site type analogous to ESRD CfCs. We recommend that CMS convene appropriate stakeholders, perhaps through a Technical Expert Panel, to consider such criteria and then provide an opportunity for comment on a proposed set of criteria.

Nephrology Joint Ventures

CMS asks a series of questions regarding joint ventures, including:

- 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?; and
- Should a dialysis facility or nephrologist be required to disclose information on joint venture arrangements to patients?

We firmly believe that joint venture arrangements are not inherently positive or negative to the healthcare system. They can bring additional financing to bear to provide care, as well as share risk. We also acknowledge that there are examples of such arrangements resulting in significant change that may not always center on patient care objectives. We support CMS data collection requirements at the time of provider enrollment and periodically thereafter with regard to basic information related to the existence and structure of joint venture arrangements in nephrology. We also believe that such financial arrangements should be publicly disclosed to patients. Indeed, rather than have a chilling effect, such disclosure can enhance patient trust.

In closing, we appreciate the opportunity to comment on this important RFI and thank the agency for its interest and commitment to patients with CKD. We believe a broad framework that recognizes the full continuum of care associated with kidney disease, in conjunction with an array of specific and targeted strategies to increase organ transplant, slow progression of CKD for patients, and improve access and quality of care across all modalities, can lead to improved health outcomes for the 37 million patients with CKD and nearly 800,000 patients on dialysis in the United States.

We look forward to the opportunity to continue to engage with the agency on these important issues and would be pleased to discuss these comments and suggestions in greater detail at any time. If you have any questions, please feel free to contact me at 202-580-7707 or info@nonprofitkidneycare.org.

Sincerely,



Martin Corry
Executive Director