

Centers for Medicare and Medicaid Services (CMS) Request for Information [CMS-3409-NC]

Executive Summary

Addressing a Critical Health Crisis

Chronic kidney disease (CKD) is an underrecognized public health emergency, and access to its optimal treatment, a health crisis. According to the Organ Procurement and Transplant Network (OPTN), more than 90,000 individuals are waiting for a kidney transplant. These data are more dire when taken in the context of the growing kidney disease emergency. 37 million people, 1 in 7 adults, are estimated to already have CKD.¹ The prevalence of kidney failure is expected to dramatically increase, possibly exceeding one million people who may need access to the transplant waitlist by 2030.²

Most importantly, and of the utmost urgency, there are not enough deceased or living donor organs to meet current or future needs. 2021 was a record-breaking year for kidney transplantation; 24,669 people received a kidney transplant. However, too many people are still waiting, never access the transplant waitlist or never learn that transplant is option. The National Kidney Foundation (NKF) champions the following efforts to increase access to transplantation, giving hope to those in need of the gold standard in kidney replacement therapy.

Roadmap to Increasing Kidneys for Transplant

- Reducing organ discards
- Increasing deceased and living donation
- Expanding access to the transplant waiting list
- Promoting system-wide performance of the agencies overseeing the transplant ecosystem
- Creating a transparent and patient-centered transplant experience

Improving Organ Procurement and Transplantation



CMS must maximize every opportunity to increase the organ supply and save lives through organ donation and transplantation. NKF calls on CMS to implement policies that remove silos, improve how the fractured transplant ecosystem (dialysis facilities, organ procurement organizations (OPOs), donor hospitals and transplant centers) operates, drive system-level performance, and increase equity.

Risk aversion in the transplant system is a significant contributor to kidney discards and devastating for patients depending on a live-saving kidney transplant. NKF urges CMS to develop new reimbursement mechanisms that incentivize transplant centers to list high-risk patients, accept less-than-perfect organs for transplant, and adopt innovative therapies and technologies. New measures of transplant center performance should be designed with reducing risk-aversion as a goal.

NKF supports *the Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs*. OPOs have the privilege and responsibility of recognizing each opportunity for organ donation and procuring organs for transplant. CMS should hold OPOs to the aggressive performance standards defined in the final rule. We urge CMS to require OPO data transparency to monitor organ donation process efficiency. Donor hospitals have an essential role in recognizing opportunities for donation. We support the decertification of OPOs and regulatory consequences for donor hospitals that fail to comply with regulatory requirements designed to drive performance, the recognition of every opportunity for donation, and equity.

NKF supports *the Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs and Removing Financial Disincentives to Living Organ Donation* final rule as significant steps in increasing organ supply. The Department of Health and Human Services (HHS) should continue to expand the income eligibility threshold for assistance from the National Living Donor Assistance Center (NLDAC) and consider other policies to increase the transplantation of living donor organs, such as greater investment in kidney paired donation (KPD).

Access to kidney transplantation is highly inequitable, beginning far downstream with the factors that place structurally disadvantaged populations at higher risk for CKD. Broadly speaking, policies that serve kidney patients are inherently policies that improve health equity.

Nevertheless, specific actions are needed to ensure that organ donation and transplantation stakeholders are meeting their obligations to patients from structurally disadvantaged groups.

NKF Health Equity Priorities

- Ensuring that OPO performance measures are **not** adjusted for race
- Providing transplant centers with resources and partnerships to increasing community outreach/education
- Implementing incentives that drive OPOs to diversify staff to reflect communities in their DSA for improved donation consent rates
- Increasing data collection from transplant centers to better understand and close gaps in transplant referral, evaluation, and waitlisting.

Kidney Health Advocacy

As the founding member of the Coalition for Kidney Health, NKF advocates for prevention, detection, and management of CKD to slow or stop its progression of kidney disease and reduce related complications (e.g., cardiovascular disease). NKF asks CMS to support a United States Preventive Services Task Force (USPSTF) screening recommendation for CKD. We further recommend that CMS works with NKF to undertake an effort to locate at-risk patients in the Medicare population and assure these Medicare beneficiaries are receiving guideline-concordant eGFR and uACR assessment.

NKF Proposals for CMS to Improve Kidney Health

- Implement quality measures that increase CKD screening in at-risk patients
- Assure access to highly efficacious drug therapies
- Increase opportunities for high-quality, multi-modal kidney disease education
- Incorporate CKD prevention, detection, and management into CMS/CMMI primary care initiatives

Promoting Home Dialysis and Other Dialysis Modalities

NKF champions a patient’s free choice of the treatment options for kidney failure that aligns with his or her values and preferences for care. Home modalities and palliative care are underutilized, and alternative modes of dialysis delivery are either just beginning to grow or have not been explicitly allowed by regulation. NKF supports efforts to increase diverse, flexible, high-quality options for people to live their lives on their own terms while continuing to receive dialysis treatments.

Dialysis Considerations for CMS

- Modernize the dialysis Conditions for Coverage to support the growth of home and alternative dialysis modalities
- Provide an add-on to the ESRD bundle to support staff assistance
- Increase transparency into the financial arrangements between dialysis facilities and other entities
- Increase capacity for early modality education and high-quality home training

Conclusion

The National Kidney Foundation has been fighting kidney disease for over 50 years. We appreciate the opportunity to collaborate with CMS and other government health agencies to improve outcomes for kidney patients and patients at-risk by emphasizing prevention, early detection, and CKD management to slow or stop the progression of kidney disease, increasing access to kidney transplantation, and improving patient choice of high-quality, patient-centered options to treat kidney failure. Kidney care is fraught with disparities. We will continue to advocate for policies that barriers, biases, and prejudices that prevent all patients from receiving the care they rightly deserve.



February 1, 2022

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services (CMS)
Hubert H. Humphrey Building
Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

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,

The National Kidney Foundation (NKF) sincerely appreciates the ongoing attention by the Centers for Medicare and Medicaid (CMS) to kidney disease, particularly through the lens of health equity. As CMS is undoubtedly aware, kidney disease is a preeminent example of the impact of racism and injustice on health. Type 2 diabetes (T2DM), one of the leading causes of kidney disease, is mediated by poverty.³ American Indian/Alaska Native, Black, and Hispanic populations have 168%, 136%, and 91% higher poverty rates than White populations.⁴ When taken with other factors, the result is higher percentages of adults with diabetes in American Indian/Alaska Native, Hispanic, Black, and Asian populations.⁵ The burden of CKD disproportionately falls on the poor. People from systematically disadvantaged racial and ethnic minority populations progress to end-stage renal disease (ESRD)¹ more quickly and are more likely to die prior to the need for dialysis. A kidney transplant is the optimal treatment for ESRD, but Black/African American people are disadvantaged at every step of the transplant process and have poorer graft outcomes.⁶

Policies that improve outcomes for kidney patients and people at-risk of kidney disease *are fundamentally health equity policies*. With that lens in mind, in this response, we articulate policy

¹ Though the preferred terminology is end-stage kidney disease (ESKD), in this response, we use the term end-stage renal disease (ESRD) to align with its use by the Department of Health and Human Services (HHS) in the context of the ESRD benefit. ESRD and ESKD are synonymous.

recommendations that stem from NKF's agenda for the Administration:

- Prevent CKD whenever possible
- Detect and manage CKD early on to slow or stop progression
- Give every patient the opportunity to freely choose the full spectrum of high-quality treatments that align with their goals, preferences, and values for care
- Increase emphasis on and access to kidney transplantation, the optimal treatment for kidney failure for many patients

Our comments broadly follow the general outline of the RFI, though we have consolidated our general comments and specific responses regarding transplantation and organ procurement, which we offer in section I of this letter. In section II, we provide our perspective, in the form of general comments and specific responses, on enhancing kidney health. In section III, we comment on home dialysis and dialysis in alternative settings.

We thank the Administration for endeavoring to better understand how CMS can improve the lives of kidney patients living in the United States. We look forward to partnering with HHS to move meaningful policies forward in order to have the greatest impact on the lives of the people we mutually serve.

Section I. Kidney Transplantation and Organ Procurement

General Comments

NKF is fueled by our desire to provide long-lasting kidney transplants for all individuals who need one. Accordingly, NKF's transplant and organ procurement priorities are:

- Reducing deceased donor kidney discards
- Increasing living and deceased organ donation
- Expanding access to the deceased donor kidney transplant waitlist
- Making the transplant evaluation process and experience more transparent and patient-centered
- Promoting system-wide performance

The current transplant system infrastructure has numerous opportunities for improvement to better serve individuals who can benefit from a kidney transplant. As CMS has acknowledged, the transplant center Conditions of Participation (CoPs) and Organ Procurement Organization (OPO) Conditions of Coverage (CfCs), are powerful policy levers by which to increase kidney transplant in an equitable manner. Additionally, modifications to the dialysis facility CfCs could also enhance patient awareness about, access to, and success securing a transplant. We further strenuously encourage CMS to use payment policy to incentivize and align behaviors among nephrologists, dialysis facilities, donor hospitals, OPOs, and transplant centers to better serve patients.

Kidney transplants provide significant benefits to patients, as well as to the Medicare program. In 2019, the Assistant Secretary for Planning and Evaluation (ASPE) found that extending Medicare coverage of immunosuppressive drugs beyond three years post-transplant, when Medicare eligibility under the ESRD benefit ends, would result in ten-year accumulated savings to CMS of approximately \$73 million.⁷ Over a 10 year period, all types of kidney transplants improve survival and are cost effective when compared to dialysis, for which Medicare remains the primary payer.⁸ Kidney transplants offer improved quality of life when compared to dialysis over a 10-year period of assessment.⁸ Historically, Medicare accounting has not directly compared expenditures in Part A, the payer for the kidney transplant procedure, and Part B, the payer for expenditures in the dialysis bundle. We ask CMS to keep HHS' own analyses that have found cost savings from investing in transplantation in mind when considering how to resource the recommendations we outline in this section.

1. Reduce Deceased Donor Kidney Discards

NKF shares CMS' frustration over kidney discards. Kidney discards are *rising*, even as nearly 100,00 people are on the national kidney transplant waitlist, and approximately 12 people die each day awaiting a kidney transplant. Yet for over a decade, about 20% of recovered kidneys have been discarded. In 2018, 3755 recovered kidneys went untransplanted.⁹ In 2019, 4460 kidneys were discarded, even more than the year before.⁹ Policy solutions to improve the utilization of kidneys that are procured for transplant but that end up in the trash despite their clinical value to patients are urgently needed.

In 2017, NKF convened a Consensus Conference on Decreasing Kidney Discards which resulted in a series of recommendations for transplant centers, OPOs, the United Network for Organ Sharing

(UNOS), and CMS to improve procurement by OPOs and utilization by transplant centers.¹⁰ Recommendations from the consensus conference included the creation of risk adjusted payments under the Inpatient Payment System (IPPS) that account for the higher costs of transplanting kidneys at high risk of discard. Transplant centers do not receive adequate reimbursement to care for complex cases, disincentivizing them from accepting imperfect organs. A payment structure that incentivizes greater utilization of imperfect kidneys is necessary.

The discard conference recommendations also highlighted the one-year patient and graft survival metric as a disincentive to accept less than perfect organs. Though CMS and UNOS have both moved away from the use of the one-year patient and graft survival metric for purposes of recertification and for other performance monitoring, commercial payers still rely on the one-year patient and graft survival metric when developing highly lucrative contracts with hospitals and transplant centers. As CMS' transplant metrics evolve, we expect the commercial payers will follow suit. **NKF's priority, one that we encourage CMS to share, is the adoption of payment and regulatory policies that incentivize risk taking in organ acceptance and transplant.**

2. Increase Living and Deceased Organ Donation

Reducing kidney discards is of the utmost importance, however, should not be the only policy goal with regards to improving the supply of organs. Increasing living donation and deceased donation are also of vital consequence, as eliminating discards will not alone close the gap between the supply of kidneys and the demand for them. NKF supports both the *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs* and *Removing Financial Disincentives to Living Organ Donation* final rule as significant steps in increasing the organ supply. We encourage CMS to iterate on the OPO final rule through subregulatory guidance and further regulatory action if needed, to continue to incentivize the adoption of consistently high-quality organ procurement practices. HRSA must maximize its authority under the Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation Program, administered by the National Living Donor Assistance Center (NLDAC) to raise the income eligibility threshold for assistance to, at minimum, 500% of HHS Federal Poverty Guidelines.

The Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation Program is limited by its statutory design that links the donor's ability to receive assistance to the

potential recipient's income. NKF is working with Congress to restructure the benefit to allow for a greater number of donors to receive reimbursement for the expenses associated with living donation. The recipient's income level has little to do with the donor's needs, especially because people with chronic illnesses, as a recipient would have, often face significant out of pocket expenses. This illustrates why even an income eligibility threshold of 500% of HHS Federal Poverty Guidelines is still, ultimately, arbitrary.

In addition to using traditional methods to increase living and deceased donation, NKF encourages CMS to work with HRSA and UNOS to improve kidney paired donation (KPD) to address the organ shortage and maximize the benefit of each living donor organ. Relatively little has been done to facilitate KPD. At minimum, further investment in, evolution of, and policymaking around the UNOS Kidney Paired Donation Pilot Project is warranted.

3. Expand Access to the Transplant Waitlist

Despite that transplant is the optimal treatment modality for an expanding group of ESRD patients, there are relatively few incentives to encourage it on the demand side. Value-based purchasing programs for nephrologists, i.e., the Merit-Based Incentive Payment System (MIPS), and dialysis facilities, i.e., the Quality Incentive Program (QIP), do relatively little to incentivize transplantation. Dialysis facilities are required by CMS regulations at § 494.90(d) to educate dialysis patients about transplantation and the Quality Incentive Program ties 2% of Medicare reimbursement to dialysis facility performance on a set of quality measures, one of which is Percent of Prevalent Patients Waitlisted (PPPW). The ESRD Treatment Choices (ETC) model now holds 30% of Medicare enrolled nephrologists and dialysis facilities accountable for improvements on historic performance and performance relative to comparison providers in transplant waitlisting.

Despite these efforts, patient access to the deceased donor waitlist has not increased in two decades and has actually fallen in socially vulnerable populations.¹¹ Access to the transplant waitlist is an issue of health equity. From the patient perspective, access to the waitlist also represents that transplant is a possibility, if not a guarantee. When patients are brought into the transplant system, they often receive more support in finding a living donor and participating in kidney paired donation (KPD). It is a disservice to patients to claim that because organ supply cannot meet demand that patients should not be educated on and encouraged to pursue kidney

transplantation and that incentives that encourage these behaviors among providers and clinicians are purposeless. It is no fault of patients that we have not done everything possible to maximize the organ supply. We do note that flooding the transplant system with referrals with no concomitant change to transplant policies and reimbursement to build capacity for pre-transplant evaluation processes is not productive.

4. Improve Transparency, Patient-Centricity, and System Performance

Lastly, NKF is invested in understanding and improving the performance of the transplant system as a whole, particularly with regards to patient-centricity. NKF's position is that every entity in the transplant system from donor hospitals to transplant centers must be high performers on metrics that are meaningful to patients. Donation and transplant are marked by missed opportunities that are not identified, reported, or understood, and for which nobody is responsible. Data that are collected from OPOs and transplant centers are out of date, unaudited, incomplete, and self-reported, making it impossible to develop modern quality measures, particularly for early steps in the transplant and pre-transplant processes. There are no regulatory requirements for either dialysis facilities or transplant centers to implement application programming interfaces (APIs) to facilitate data transfer across entities or to CMS.

Of grave concern to NKF is that this lack of transparency extends to patients and impacts their ability to make decisions about their health. As CMS is aware, patients on the waitlist receive many offers that are turned down by the center on their behalf without their knowledge or consent.¹² Unlike other facets of the donation and transplant ecosystem, organ offer data are readily available and could be presented to patients with little additional burden. The Scientific Registry of Transplant Recipients (SRTR) could produce reports quarterly on the number of organs declined by the center to be shared with the waitlisted patient. The greater challenge is developing an infrastructure where patients can discuss these data and engage in shared decision-making with their care team. Transplant education is generally poor with dialysis facilities lacking expertise in transplantation and transplant centers lacking time and resources for it.¹³

Overall, the fragmented nature of transplant oversight contributes to a generally poor understanding of system performance. In this RFI, CMS requests information about harmonizing regulatory requirements. Harmonization is a laudable goal, however **NKF supports the more**

straightforward approach of creating a Health and Human Services (HHS) level Office of Transplantation that would be responsible for monitoring and improving overall system performance.

Specific Comments: Transplant Center Conditions of Participation (CoPs)

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

Code of Federal Regulation (CFR) Citation	Comment	Outcome Seeking	Recommendation
§ 482.80: Condition of participation: Data submission, clinical experience, and outcome requirements for initial approval of transplant centers.	NKF thanks CMS for removing the one-year patient and graft survival metric for the purposes of transplant program recertification.	Increase organ supply by increasing risk tolerance for the transplant of imperfect organs.	NKF recommends either a composite metric of pre-transplant measures and outcome measures or multiple metrics including an outcome measure of survival compared to dialysis (Figure 1). Outcome measures must incentivize risk taking and be paired with other policies that support long-lasting transplants in order to achieve seemingly contradictory goals of transplanting more imperfect organs while reducing the number of times a patient needs to be retransplanted.
§ 482.82: Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.		Increase access to transplant by improving higher risk recipients' ability to be listed. Incentivize longer lasting transplants	

<p>§ 482.92: Condition of participation: Organ Recovery and receipt.</p>	<p>Some transplant centers do not accept organ offers on weekends or after standard business hours, limiting high-mortality dialysis patients the opportunity to improve survival with transplantation.</p>	<p>Increase organ supply by improving acceptance of organ offers</p>	<p>Transplant centers should be available every day for as many hours as reasonably possible to accept organ offers from OPOs for patients on their transplant waitlist</p>
<p>§ 482.94: Condition of participation: Patient and living donor management.</p>	<p>Deceased patients remain on the transplant waitlist, receiving organ offers instead of offers going to patients who are alive. In one study, 17% of transplanted deceased donor organs were offered to one or more deceased donor candidate.¹² Each offer to a deceased candidate increases cold time and contributes to</p>	<p>Increasing organ supply by improving the efficiency of organ allocation</p>	<p>Immediate removal of deceased patients from the waitlist is needed to promptly stop all organ offers for someone who has died, which increases morbidity and mortality of people waiting for a transplant¹⁴</p>



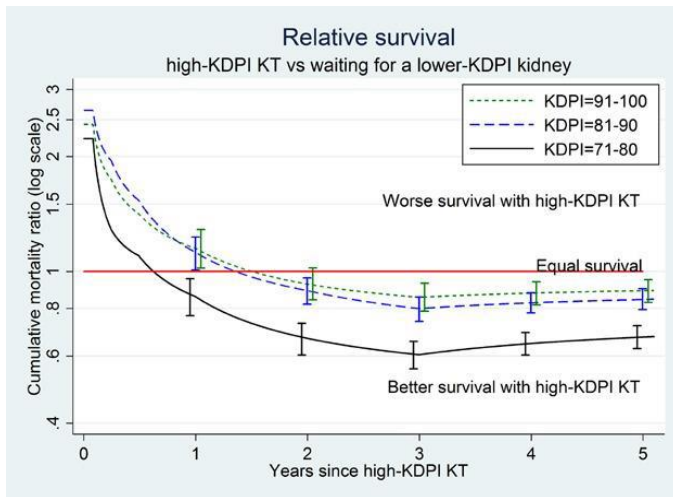
	declining organ quality and overall process inefficiency.		
§ 482.96: Condition of participation: Quality assessment and performance improvement (QAPI)	CMS should hold transplant centers and OPOs accountable for maximizing the use of recovered organs, and transplant centers for ensuring equitable access to the transplant waitlist. In 2019, 4,324 kidneys recovered for transplant were discarded. ⁹ Black/African American, Native American, Hispanic, and Asian American people are more likely to need a transplant than their White counterparts. Yet, transplant centers are less likely to list people of color for transplant.	Increase access to the transplant waitlist	Transplant centers must implement documentation policies that explain why a patient was denied access to the waitlist.



	Black/African American people remain severely disadvantaged as they are 25% less likely to become active on the waitlist in comparison to those who are White. ^{15 16}		
§ 482.104: Condition of participation: Additional requirements for transplant centers	NKF supports a kidney disease and transplant education model that takes advantage of education offered in the traditional health care setting, education offered in the community setting, and peer-to-peer education.	Improve transplant education	Kidney transplant programs should partner with third-party organizations and community organizations to create and implement engagement initiatives to educate the public on transplantation, including living donor transplantation, especially in low-income communities, communities of color, and rural communities where health literacy may be less prominent. Transplant centers should also partner with dialysis centers, nephrologists, primary care physicians, the

			local organ procurement organization, and other community stakeholders to dispel transplantation myths and educate prospective patients and donors on the transplant process.
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Figure 1



2. We are seeking ways to harmonize policies across the primary HHS agencies (CMS, the Health Resources and Services Administration (HRSA), and the Food and Drug Administration (FDA)) that are involved in regulating stakeholders in the transplant ecosystem so that our requirements are not duplicative, conflicting, or overly burdensome. Are there any current requirements for transplant programs, ESRD facilities, or OPOs that are unnecessarily duplicative of or in conflict with OPTN policies or policies that are covered by other government agencies?

CMS, UNOS, HRSA, SRTR and the Joint Commission share oversight of the donation and transplantation system. This fragmented oversight contributes to communication, process, and

alignment gaps. NKF reiterates our desire for one HHS-level office that would provide broad oversight of the transplant ecosystem to mitigate deficiencies that result from lack of cohesion and accountability. We also note that there are multiple metrics workstreams in process as CMS considers a replacement for the one-year patient and graft survival metric, the UNOS MPSC implements its new performance monitoring system, and SRTR's "Task Five" considers new measures of transplant center performance. It is of the utmost importance that these efforts are aligned, in both process and implementation. CMS performance measures have the greatest impact on behavior because they are tied to the certification of programs, but MPSC measures and metrics used for SRTR reporting also influence how transplant centers are managed and how patient's experience the process. Thus, multiple, misaligned measures create differing incentives serve only to muddle behavior rather than to direct it towards shared goals.

3. What are the impacts of these duplicative requirements on organ utilization and transplant program/ESRD facility/OPO quality and efficiency?

Duplicative regulatory requirements are a symptom of underlying problems with oversight of the transplant system rather than a cause. Multiple organizations and regulatory bodies overseeing parts of the transplant ecosystem with no single entity accountable for the whole exacerbates fragmentation. Stated simply, duplicative regulatory requirements reflect fragmentation, the implication of which is a population of patients trying to navigate amongst a broken system in hopes of receiving a life-saving organ transplant. **The ultimate impact of regulatory inefficiencies is that patients die on the waitlist or without ever knowing transplant is an option for them.**

The U.S. healthcare system is fragmented by design, so it is exceedingly important that policy incentivizes process efficiencies across each entity involved in donation and transplant. There are wide communication gaps between nephrologists, dialysis facilities, OPOs, donor hospitals through which patients easily fall. CMS should require that dialysis facilities and transplant centers use electronic health records (EHRs) that are interoperable in order to put a foundation in place for seamless communication about referrals and waitlist status. CMS oversight should continue to ensure that OPOs are collaborating with transplant centers on best practices that will reduce the number of organ discards. CMS should continue to pursue a physician-level measure of transplant referral in order to close the gap between nephrology and transplant. In addition, HRSA should immediately direct the OPTN to collect data on transplant referral so as to

understand where there are gaps between the dialysis facility's regulatory obligations for referral and the referrals accepted and acted upon by the transplant center.

Most importantly, CMS must align financial incentives. Dialysis is still highly lucrative for nephrologists and dialysis facilities. Dialysis facilities are mandated to provide transplant education and assess for suitability for transplant referral, but these activities are not accounted for in the ESRD bundle. Physicians similarly are not compensated for transplant-related activities. CMS reimburses for the transplant procedure, the surgical fees, and the costs of acquiring the organ, but by and large does not reimburse for the pre-transplant workup and waitlist management beyond what is allowable on the cost report. Transplant reimbursement also does not account for the use of high-cost products used to treat delayed graft function (DGF) and there is no additional payment for the use of innovative treatments and technologies that may improve patient outcomes. NKF has unique visibility into innovative technologies in the marketplace for which reimbursement is almost universally a barrier. Transplant centers have little financial incentive to continue managing transplant recipients after one year and community nephrologists generally lack the time and expertise to do so. If CMS wants to incentivize more, long-lasting transplantation, a more comprehensive reimbursement structure is needed.

4. 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?

In general, payment, quality, and regulatory levers are blunt tools with which to incentivize communication since the quality of communication is challenging to assess in site surveys, which can only evaluate whether the communication happened, not its quality. Nevertheless, timely communication between entities in the transplant system is an important component of quality improvement. Enhanced communication practices should be a target of the ESRD Treatment Choices (ETC) Learning Collaborative and other voluntary, cross-cutting quality improvement initiatives.

The interactions between OPOs and donor hospitals have not been the focus of policy efforts in transplantation, except indirectly through the OPO rule, despite the importance of these relationships in the efficiency and effectiveness of procurement. While OPOs have a strong

incentive to maximize organ procurement, no attending incentive exists for donor hospitals. NKF recommends the following:

- **Donor hospital EHR clinical trigger** – Timely communication between the donor hospital and the OPO is crucial to the organ donation process. CMS should ensure that hospitals are doing all they can to recognize every opportunity for donation and make a prompt referral to the OPO. CMS can incentivize the building of electronic clinical triggers in the EHR that prompts clinical staff to call the OPO when a provider documents specific patient criteria. For example, if a nurse charts that a patient is intubated and documents a loss of two cranial nerve reflexes, or documents that the patient has a Glasgow Coma Scale of 5 or less, a prompt should appear notifying the nurse to call the OPO. The responsibility to refer the patient to the OPO lies with the hospital staff.
- **Regulatory consequences for missed organ referrals** – Donor hospitals should face regulatory consequences for substandard missed referral rates. When a hospital fails to notify an OPO of a potential donor, critically ill patients continue to wait on the list for a life-saving organ transplant. Further, families lose the opportunity to continue the legacy of their loved one through the selfless gift of organ donation, and a person who has designated their wish to become an organ donor is unfairly forfeited.
- **Regulatory consequences for OPOs failing to make timely responses to donor hospitals to evaluate potential organ donors** – When donor hospitals make a referral for a patient who is not automatically clinically ruled out, OPOs should make every effort to elicit a timely onsite response for an evaluation.

4. Are there additional data, studies, and detailed information on why the current number of organ discards remains high, despite CMS' decision to eliminate the requirements for data submission, clinical experience, and outcome requirements for re-approval?

The one-year patient and graft survival measure contributed to but is not the only cause of the risk averse culture in transplant centers. Performance measures and reimbursement structures that are not only risk neutral but risk promoting (i.e., that actively encourage transplant centers to take on risk) are likely needed to influence practice patterns in transplant centers. Transplant center reimbursement must be modernized to account for the higher costs of higher risk, and thus higher cost, transplants. Commercial payers also still rely on the one-year patient and graft survival metric when implementing Center of Excellence (COE) contracts. A transplant center that

is not a COE will not receive referrals through a plan and will not receive the higher commercial reimbursement from the private payers. The one-year measure thus still exerts a significant influence over center behavior. As commercial payers often adopt CMS policies, it is extremely important that CMS expeditiously develop a new measure for the CoPs that will increase risk tolerance among centers.

CMS should also consider the extent to which regulation, quality and payment policies, and voluntary quality improvement initiatives can incentivize OPO and transplant center practices that, if adopted, could minimize discards such as:

- Beginning the organ allocation process earlier in the donor evaluation phase.
- Improving communication between OPO and transplant surgeons. The Kidney Allocation System relies on an electronic communication platform, DonorNet, that limits verbal communication between the OPO and transplant center. The exclusive use of DonorNet without collaborative conversations between the OPO and transplant center contributes to decreased organ utilization.¹⁰
- Accelerating virtual crossmatching and sending early prospective crossmatch samples.
- Requiring more frequent QAPI meetings with OPOs and transplant centers to review and analyze data and investigate root causes for low organ transplant rates.
- Securing “local backups” to mitigate the possibility of a kidney discard.

Increased patient-centricity around organ offers may also contribute to reduced kidney discards. Generally speaking, patients are less risk averse than their surgeons and centers. As they spend more time on the waitlist, they may be willing to accept an imperfect organ that still confers clinical value when compared to dialysis. Patients thus have an essential role in improving risk aversion and reducing discards by making their wishes clear to their care teams. **Incentives for transplant centers, nephrologists, and dialysis facilities to engage in shared decision-making are needed.** Shared decision-making is not a one-time activity. Patients’ tolerance for risk can vary throughout their time on the waitlist and must be continuously assessed. Increasing utilization is closely linked to reimbursement, transparency, and improved organ acceptance practices, however, begins with a patient-centered approach of understanding the waitlisted patient’s goals and preferences. Transplant programs should remain cognizant of promoting shared decision-making with inactive waitlist patients also.

In 2013, Congress allowed for the transplant of organs from human immunodeficiency virus (HIV)+ living and deceased donors to HIV+ recipients under clinical research protocols. Despite the authority provided by Congress, the growing numbers of people with HIV on dialysis, and the markedly poorer survival among people with HIV on dialysis, organs from HIV+ donors go unprocured and, even if procured, are discarded at alarming rates. It has not been possible to characterize full the scope of the problem because of lack of data transparency. Under clinical research protocols, HIV-to-HIV transplants are still theoretical more than an actual possibility for donors and recipients living with HIV. Following the lead of patient advocates who have called for the same, NKF recommends removing HIV+ to HIV+ transplants from research in order to provide the equity that the HOPE Act was designed to provide. NKF further calls on HRSA to provide a clear and easily accessible list of HOPE Act transplant programs at organdonor.gov.

5. 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.

Please see our answers to the preceding questions. We agree that an overarching approach to the performance of the transplant system is needed to overcome the natural silos that emerge when different organizations and regulatory bodies have responsibility for different aspects of the transplant ecosystem. The common thread to weave each of these entities together—which is currently missing—is a comprehensive alignment of incentives that would promote system-wide improvement.

6. In the context of organ shortage and expanded use of marginal, suboptimal quality organs, and transplantation into standard and high-risk recipients, we are seeking public comments from the recipient perspective and expectations on meaningful measures including but not limited to graft survival benefit, shorter waiting list time, frailty improvement and quality of life after transplant, and other transplant benefits.

NKF has a longstanding interest in metrics of transplant center performance. NKF welcomed the removal of the one-year patient and graft survival metric, and we are eager to work with CMS and UM-KECC to develop a patient-centered measure or measures to replace it in the CoPs. NKF is particularly interested in pre-transplant measures. Outcome measures will always be a necessary component of performance, and these should be paired or incorporated into a composite measure with other aspects of the transplant experience that matter to patients. Patients highly value the opportunity to enter into the process of receiving a transplant and the efficiency and effectiveness of the process itself. It is currently not possible to develop these patient-centered metrics because data on, for example, evaluation rate as a % of all referrals, evaluations sought prior to the current evaluation, time to listing from referral and proportion of referred patients that are listed within a predefined time interval e.g., 1 year, health-related quality of life (HRQoL) after transplant, and long-term graft survival are not collected and reported. Improved data collection is a key component of meaningful measurement. We reiterate the necessity of aligning CMS' metrics efforts with those of the MPSC and SRTR, though we do not wholesale support the MPSC metrics policy. NKF strongly opposes a measure of waitlist mortality and would oppose it if used by CMS for the CoPs.

7. How can CMS meaningfully measure transplant outcomes without dis-incentivizing transplantation of marginal organs or dis-incentivizing performing transplants on higher risk patients?

NKF agrees that regulatory bodies should measure transplant outcomes. While it has been established that focus on relatively short-term survival of the patient and graft created by the one-year metrics has contributed to a culture of risk-aversion at transplant centers, the measure is not the only cause of risk aversion. As we have outlined here and in the Report of National Kidney Foundation Consensus Conference to Decrease Kidney Discards, the causes of kidney discards are multifactorial and interdependent.

CMS is tasked with considering outcome measures that incentivize two seemingly contradictory ideas: that outcomes should not preclude the transplantation of imperfect organs or higher risk patients, but also that patients desire longer lasting transplants. No single policy can achieve both objectives, so the goal should be creation of an environment that allows for flexibility and patient-centered decision making, acknowledging that one patient may take an organ of any

quality if it means getting off dialysis while another may wish to wait for an organ that is likely to last for as long as possible.

A mix of regulatory and payment policies are likely needed to achieve the aim of a flexible environment with the dual objectives of measuring long-term outcomes and creating a culture where transplant centers are willing to take on more risk. Excluding particular high-risk groups (e.g., Expected Post Transplant Survival (EPTS) >85 or transplanted with KDPI >85 organs) from outcome measures is one approach. This would be consistent with the European “old to old” transplant program that encourages organ utilization. Continuing to iterate on the DRG payment for kidney transplant to account for the higher cost of care or creating an add-on or bonus payment for the use of moderate-to-high KDPI kidneys would be important incentives for driving better organ acceptance practices. We note that CMS would need to closely monitor such a policy to ensure that these imperfect organs are being used judiciously.

Specific Comments: Transplant Recipient Patient Rights

NKF applauds CMS for highlighting patient rights and seeking knowledge about patients’ transplant experience in hopes of advancing patient-centered care models. NKF shared questions from the RFI with a diverse cross-section of transplant recipients and aggregated their responses below.

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?

Address Patients’ Mental and Emotional Well-being – “Organ failure is scary. Dialysis creates added stress and anxiety. Dialysis patients face a variety of challenges—healthcare complications, lethargy (too tired to participate in common daily activities), lack of social support, and depression to name a few. There is a general fear that patients experience when faced with organ failure and the prospect of their mortality. Organ donation and transplant surgery is overwhelming to think about. Transplant centers could assuage these feelings by communicating with their patients in as close to real-time as possible about what to expect during the process (not just once, but reminders throughout would be helpful).”

Improve Communication – “CMS could work to ensure that transplant centers have adequate resources and staff to support its patients with consistent and effective communication. Patients deserve to know when they are listed for transplant, along with actions they can take to maintain optimal health on the waitlist. Centers must alert patients of their waitlist status when they become listed and when they are made inactive or delisted. Physicians, Advanced Practice Providers, Nurses, Transplant Coordinators, Social Workers, and other transplant center staff that interface with patients should adequately and compassionately share the reasons for an inactive status with patients and why they have been delisted.”

Include the Patient as Part of the Care Team – “Clear and timely communication between the transplant team and patients can promote shared decision-making which should be afforded to each patient. Transplant centers have been known to complain about patient compliance; if transplant centers want improved cooperation from patients, they should prioritize shared decision-making.

Promote Cultural Sensitivity – Clinical and non-clinical transplant center staff must practice cultural sensitivity and inclusivity to decrease the risk of patients falling through the cracks due to language barriers and cultural misunderstandings. Transplant centers need appropriate communication strategies and mechanisms to relay messages with non-English speaking patients to prevent patient isolation and poor patient outcomes.

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

Most feedback from our patient advocates (kidney recipients) stated that pre-transplant communication was inconsistent, with very little explanation of the process and transplant outcomes after the initial visit with the transplant team. It would have been helpful for the transplant center to inform pre-transplant patients throughout the process to better understand what to expect during the transplant process. The transplant team explained management of comorbidities (hypertension, diabetes) frequently. Post-transplant communication was generally perceived as better than the pre-transplant communication.

3. 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?

We received varied responses from our patient advocates (kidney recipients) regarding wait time communication. Some reported not learning or hearing about wait times, while others stated their transplant center shared the current wait times for a kidney. There was no communication about waiting time status shared by the transplant center.

4. 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?

None of the advocates we surveyed received communication regarding organ offers that were declined on their behalf. For this reason, transplant centers must periodically update all active and inactive waitlisted patients on their transplant status, including quarterly reports on organ offers that were declined on their behalf. Further, transplant centers should be responsible for updating and documenting patients' organ offer preferences annually, or whenever patients choose to initiate a change in the types of organs, they are willing to accept for transplant. Allowing patients to be active participants in their healthcare decision-making should be standard for all transplant programs.

5. What is/was the most helpful information about organ transplantation you received? From which source did you receive this information? Did you receive other helpful information from other sources? If so, what were those sources?

- "At the outset, most information was from my care team at the hospital, including my transplant and nephrology teams. As time has gone on and I've gotten further out, I get some information from my new transplant nephrologist, as well as from my participation in National Kidney Foundation activities and the friends I've made along the way. There is SO much I didn't know after my transplant that I've learned over time. Another great resource has been random fact sheets from transplant centers all over the country that talk about post-transplant, including what over the counter medications are safe. Reliable, comprehensive resources are VERY difficult to find, especially that include new

innovations or medical advances. In the 13 years since my transplant, there have been some new bits about reducing or adjusting immunosuppressants, for example, and I have no way of knowing about those things. Neither my transplant team at the time of my transplant nor my new team have ever discussed how we might be able to adjust my medication regime, for example, or clinical trial opportunities, or really anything related to advances in the space. More importantly, the resources that do exist are usually decades old, so even less up to date!”

- “The most helpful resource that I received about transplantation was a flyer that the ESRD National Patient and Family Learning and Action Network (NFPE) developed titled Tackling Transplant Infections. As a two-time kidney transplant recipient, I have never been sufficiently educated about the types of infections that may arise post-transplant.”
- “I only learned about them through experience. Throughout my kidney journey, I have referred to the ESRD NPFE resources and directed my mentees to its website. There is a host of patient-friendly information on their site that transplant programs and facilities can share with their patients. I have also received helpful information from NKF's website. One resource, in particular, is eGFR and how it is calculated for African Americans. Reviewing the information on NKF's website was the first time I had learned about this coefficient.”

6. Are you satisfied with the communication and support you have received from your transplant program? What information from your transplant program did you find helpful in making your decision?

We received mixed responses; some of our patient advocates (kidney recipients) felt well-supported and received thorough communication while other felt the opposite. Below is an example how communication can change during the transition of care from pediatric to adult transplant care:

- “I was followed very closely and was very supported. After that period, however, I gradually received less and less support, especially once I aged out of the children’s hospital. At that point, I was on my own. I was told on more than one occasion that I could be followed by a regular nephrologist instead of the transplant center if I wanted

to, but I didn't even know where to begin. I'd never seen a "regular nephrologist". I did not trust that a community nephrologist would be able to take care of someone like me. I always knew I was an outlier, an unusual case, and that made me wary of new doctors – it still does, 13 years later."

7. 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?

"As a professional, I have worked closely with current and former dialysis administrators and staff. Transplant is not their priority. As they say, "what gets measured gets managed" – and the large dialysis organizations (LDOs) measure quality and quantity of dialysis treatments. Progress to transplant is measured sparsely, if at all, relative to dialysis treatment, so it is not prioritized by center staff, who have to work very hard just to meet those measures that are prioritized. Every professional knows transplant is the best treatment option available, but without the incentives to pursue it, it just doesn't get priority relative to the day-to-day of getting dialysis treatment."

"I was on peritoneal dialysis and started it when I was 21 years old. I remember my first time meeting my dialysis nurse. She came to the hospital to dialyze me once I had my Tenckhoff catheter surgically placed. She was the most supportive person (outside of my family) throughout my dialysis journey. She took such good care of me until I received my transplant and she educated me about as much as she could along the way. I was given information on transplant—pamphlets from the transplant centers that were given to the dialysis center. My nephrologists were informative, too. I don't remember everything they shared, but I do remember having most if not all of my questions asked with compassion and felt an urgency from them to get me transplanted."

Specific Comments: Equity in Organ Transplantation and Donation

NKF is committed to closing gaps in access to transplantation among structurally disadvantaged populations. There is no shortage of studies that show that people facing systematic barriers are disadvantaged at every step of the donation and transplantation process, beginning with chronic kidney disease (CKD) underdiagnosis.¹⁷ OPO and transplant center data transparency is crucial to

identifying performance improvement opportunities, especially to determine where inequities exist along the kidney care continuum and how to resolve this issue.

NKF emphasizes the need for outreach and education to increase organ donation and transplant awareness in underserved communities. We support resource allocation to dialysis facilities, OPOs, and transplant centers that facilitates a two-pronged approach to education. First, dialysis centers, OPO, and transplant center staff should have cultural sensitivity training to mitigate biases and prejudices against the people they serve. Second, each of these entities should have staff dedicated to outreach and education to improve understanding about organ donation and transplant within the community.

Also of great importance, is the need to strategize how we can help patients overcome hurdles that hinder access to transplantation, such as lack of transportation, challenges in receiving dental care, and implicit and explicit bias. Neither socioeconomic status nor disability should create roadblocks to transplant.

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

Code of Federal Regulation (CFR) Citation	Recommendation
§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks	NKF recommends that hospital agreement should include protocols for both donation after brain death (DBD) and donation after cardiac death (DCD) cases. In addition, CMS should increase designated requestor training for hospital staff to at least quarterly.
§ 486.326 Condition: Human resources.	NKF recommends the following: OPOs should have staffing measures in place for when interacting with potential donors' next of kin for donation authorization. To the extent possible, preference should be for staff to reflect the demographics (in terms of race and language) of the community in the OPO's DSA. Additionally,

	<p>staff should undergo cultural sensitivity training for the demographics represented in their regions.</p> <p>Specifically for standards on qualifications, individuals involved in donor assessment, procurement, and organ placement should have documented clinical training.</p> <p>For standards on staffing, rule-out of medical suitability for organ donation must be done by individuals with a clinical background; and OPOs must have enough qualified staff to respond to 100% of potential donor referrals, including going onsite in all cases when possible.</p> <p>For standards on education, training, and performance evaluation, individuals involved in donor assessment, procurement, and placement must undergo annual continued education clinical training. Individuals directly involved in, or who supervise, clinical donor management must undergo or have documented training on deceased donor management protocols and best practices. Individuals involved in speaking with next of kin for donation authorization should undergo training on donor family communication best practices, implicit bias, racial-equity, and trauma-informed care.</p>
<p>§ 486.328 Condition: Reporting of data</p>	<p>NKF recommends that the following verifiable data are reported to CMS: timeliness of OPO staff follow-up on eligible donors and whether follow-up was onsite, data on demographics of donor families/next of kin who were approached for authorization (including at a minimum race/ethnicity, language, age, etc.), and data on staff demographics (gender, race, languages spoken) and background (clinical/non-clinical).</p>
<p>§ 486.330 Condition: Information management</p>	<p>This Condition should be revised to add a requirement that the OPO create a record for every referral using CMS</p>

	<p>provided data protocol: The record must include, at a minimum: date, time, and origin of referral; who at the OPO received the referral; how it was triaged (followed by phone, onsite evaluation, etc.); how long it took OPO staff to follow-up and whether it was onsite or not. CMS and OPOs should be analyzing this data as part of their QAPIs.</p>
<p>§ 486.342 Condition: Requesting consent</p>	<p>Regulations should clarify that OPOs must ask about and clearly document any family time constraints, as well as provide the following information to the donor family: costs associated with donation (there should be none), estimated time frames for the donation decision and donation process, including any potential delays to funeral arrangements; OPO staff should communicate time updates with donor families, the donor’s eligibility to donate and ability for the family to decide which organs to donate, the need for organs and the potential to help others, especially within that donor’s demographic community if applicable, and the treatment of the donor’s body during organ recovery.</p>

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?

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 (QoL) outcomes. Obtaining consent for donation is vital to increasing the number of organs available for transplantation. However, studies have demonstrated that Black/African American people are half as likely as White people to agree to donate a loved one’s organs. In addition, studies have shown a “lower donation rate among racial/ethnic minorities, specifically including Black/African American, Hispanic, and Asian people.” 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. CMS has an important role in incentivizing OPOs to build trust and awareness in historically underserved populations and communities (including racial and ethnic minorities). **NKF strongly opposes race-based adjustments to the OPO metrics, which would perpetuate these inequities rather than encourage OPOs to improve their service to underserved communities.**

Prejudice and implicit bias are common elements of OPO practice. Beliefs that people of Color will not donate perpetuates patterns where hospitals are less likely to refer prospective donors to the OPO. In studies, Black/African American families have declined donation because of insufficient time to process and discuss important issues and a lack of sensitivity and empathy during the approach process.¹⁸ Research has also found that OPOs are more likely to approach White families over Black/African American families.¹⁹ In addition to declining to implement race-based adjustments to the OPO metrics, CMS should consider how regulatory policies can encourage OPOs to adopt best practices to overcome the effect of bias and prejudice on the ability of families to donate their loved ones' organs, for example hiring staff that represent the communities they serve and implementing frequent training on cultural sensitivity, diversity, and inclusion to improve conversations with non-White populations about donation. Education and outreach are critical components of overcoming every challenge in kidney care, including racial and ethnic bias in donation. NKF recommends that CMS implement a multipronged kidney disease and transplantation education initiative. Such an initiative could support partnerships with community religious leaders or hospital clergy to provide family support and spiritual guidance to potential donor families with the goal of increasing authorization rates and health literacy initiatives that educate underserved, rural, and diverse communities on organ donation, living donation, and transplantation.

A lack of transparent data on how race, ethnicity, and disability impact the success of organ procurement prohibits donation and transplant stakeholders from improving health equity. Transparent, verifiable, and publicly available process data, including approach, consent/authorization, and conversion rates broken down into specific demographics (ethnicity, religion, age, location, etc.) are essential. OPOs that consistently underperform, especially due to lack of engagement with communities of Color, should be decertified. Donor families find organ donation to help with grief, knowing the legacy of their loved ones lives on through the selfless act of donation. Yet, this is often not afforded to Black families, because they are approached at lower rates than white families. Better data collection and reporting will reveal these inequities

and incentivize performance improvement by OPOs. In addition, transplant centers should be required to demonstrate that they have provided information to patients on how to report discrimination, including disability-related discrimination, to either the Medicare Beneficiary Ombudsman and/or the Medicaid Ombudsman.

Access to dental care has a disproportionate effect on the ability of people to be waitlisted for a transplant. Dental care is rarely covered by health insurance, but dental hygiene and often, dental work, are essential for access to a transplant. Without proper oral hygiene, transplants are delayed. In fact, candidates must maintain good oral hygiene to stay active on a transplant list. After transplants, medications used to prevent organ rejection weaken the immune system such that even a common periodontal infection may lead to much broader health complications when left untreated on 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.”

Currently, Medicare only covers the final oral exam before transplant surgery at a hospital. All other dental care for chronic kidney disease patients before their transplant surgery and before they are even accepted onto an organ waitlist, must be handled outside of Medicare. Most must turn to the private individual market for a stand-alone dental plan (SADP) to pair with their healthcare or Medicare coverage. 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 which inhibit CKD and transplant care. Black and Hispanic Americans are also less likely to have dental insurance coverage, which is vital to ensure continuing access to oral health treatment.

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 because they did not have adequate access to oral health treatment. **Therefore, to increase access to dental care, 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, trusted 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.

As we continue to address transplant disparities, NKF is focusing on legislation that prioritizes solutions to barriers patients face in their attempt to receive access to appropriate healthcare and kidney transplantation. Legislative solutions must address the critical need for patients to access safe and reliable transportation. This is crucial, as patients must be able to attend required dialysis and transplant appointments. A 2021 study revealed transportation as a primary barrier to transplantation by dialysis and transplant center staff.¹³ Further, resources for child care and elder care can also mitigate impediments to patients making it to their appointments. Recent final rulemaking by HRSa expanded the categories for reimbursement by the National Living Donor Assistance Center (NLDAC) to include childcare and elder care. No such support exists for transplant recipients.

Inadequate patient education is a significant reason patients do not pursue transplants; they do not sufficiently understand the process to make an informed decision.¹³ Studies have reported that patients are “unaware transplant was even a possibility, illustrating the existence of a communication gap between physicians and their patients.”¹³ Lack of patient education and inadequate health literacy are linked to the substandard access to transplantation for people of lower socioeconomic status, which leaves them reliant upon dialysis instead of receiving the optimal treatment for kidney failure, transplantation.²⁰

Paid leave for organ donation, transplantation, and recovery for both the organ donor and the recipient can help address racial disparities in transplantation. Black/African American people are more likely to have kidney failure but less likely to receive a deceased or living donor kidney transplant when compared with White patients, even after taking differences in comorbidities into account.²¹ Black/African American patients and living donors are also less likely to work in positions that provide paid time off for organ donation, transplantation, and recovery. Providing paid leave during the preparation, transplantation, and recovery process would support more successful donations and transplantations, especially among Black/African American, Hispanic, and Native American patients. NLDAC provides financial assistance to living donors, however, as noted, no similar support is available to assist transplant candidates.

Cultural and religious beliefs, trust in the healthcare system, and linguistic and translation barriers also have a significant role in why structurally disadvantaged communities not only suffer from kidney disease at a higher rate, but also have poorer outcomes, which include faster progression to kidney failure and reduced access to transplantation.

3. How can those in the transplant ecosystem better educate and connect with these communities about organ donation, so as to address the role that institutional mistrust plays in consenting to organ donation? This would include ways that CMS can hold OPOs accountable for their outreach and communication to those underrepresented communities while maintaining cultural competency, such as awareness of various religious beliefs surrounding organ donation. Comments should include considerations of how to address issues pertaining to medical mistrust, disadvantageous social and economic factors, and the effects of systemic racism and discrimination on underserved populations.

- **Transparent OPO Data Collection.** Require OPOs to collect referral data that includes demographic and geographic criteria to ensure racial and ethnic minorities within their DSA are not left out of the donation process.
- **Organ Donation and Transplant Education.** OPOs and transplant centers need dedicated staff to provide outreach and education to diverse communities. Outreach and education staff should be tasked with developing partnerships with community stakeholders and faith-based organizations to connect with and educate underrepresented communities on organ donation and transplantation.
- **Funding for Transplant Education** Direct federal funding to state and local health departments and organizations located within these communities to help them organize and educate the communities on the benefits of living donation and transplantation.

Section II. Kidney Health

One in seven U.S. adults is estimated to have CKD. The vast majority are unaware.¹ The risks of mortality and other adverse outcomes for patients with CKD are comparable to those for patients with nonmetastatic cancer.²² The majority of CKD cases will not result in kidney failure, which has been used to justify the lack of attention given to kidney disease. Such reasoning reflects an

incomplete understanding of CKD. Most diagnosed cases of CKD in the U.S. and in the Medicare population are Stage 3.^{23 17} Among Medicare beneficiaries with CKD stage 3 in 2014, 42.9% died before ever reaching ESRD in the ensuing 5 years.¹⁷ **CMS investment in CKD is equally about preventing kidney failure and protecting millions of socially vulnerable people living in the U.S. from premature death.**

In this section, we offer general and specific recommendations for actions CMS can take to improve prevention, detection, and management of CKD.

General Comments

1. Improve Access to Healthcare

CKD prevalence is nearly 25% higher in the uninsured population relative to the insured.¹⁷ While the Affordable Care Act (ACA) narrowed some disparities in health coverage, nonelderly Native American/Alaska Natives, Hispanic, Native Hawaiians and Other Pacific Islanders, and Black people were less likely to have health insurance than White people as of 2019.²⁴ Access to healthcare is a significant mediator of disparities in kidney disease. Poorer access to health care contributes to the excess risk of chronic kidney disease (CKD) seen in structurally disadvantaged population.^{25 26} Access to health care also has a direct impact on CKD progression and ESRD. States with more robust Medicaid coverage have a lower incidence of kidney failure.²⁷ Further, the lack of a regular health care provider among 25% of Hispanic people living in the U.S. contributes to their lower likelihood of pre-ESRD nephrology care.²⁸ In short, patients who are not in the health system in some capacity have extremely limited opportunities to have CKD diagnosed and appropriately managed. Though access to health care is not in and of itself a panacea for the CKD public health emergency, **continued expansion of Medicaid, rejection of Medicaid work requirements, and support for policies that encourage enrollment in ACA plans are of paramount importance in preventing and slowing the progression of CKD.** Ongoing investment in culturally competent Navigators that can support consumers in enrolling in and understanding their coverage options is especially important for people with or at risk for CKD.

2. Increase CKD Screening & Detection

Once in the healthcare system, CKD must be detected and classified to be appropriately managed. When CKD is detected, profound improvements in the quality of care are possible. The Indian Health Service (IHS) demonstrated a dramatic decline in ESRD, from 54%, from 57.3 in 1996 to 26.5 in 2013 using a CKD population health model in diabetes based on simple and well-characterized interventions, including screening tests, disease management and food security to slow or stop CKD progression.²⁹ **Unfortunately, replicating this success is limited by the fact that CKD is under-detected.**² The International Kidney Disease: Improving Global Outcomes (KDIGO) 2012 clinical practice guideline characterized a classification system based on cause-GFR-albuminuria (C-G-A) to advance risk stratification based on eGFR and urinary albumin-creatinine ratio (uACR). This recommendation was endorsed by the NKF Kidney Disease Outcomes Quality Initiative (KDOQI). Guideline concordant CKD detection thus requires two simple, low-cost laboratory tests, serum creatinine to estimate glomerular filtration rate (GFR) and a test to measure the amount of the protein albumin in the urine. CKD is then diagnosed or not based on the results of these laboratory tests. Performance of these tests are remarkably low. A recent study of 28 million at-risk patients found that 80.3% did not receive the guideline concordant testing.³⁰ In Medicare beneficiaries with two risk conditions but without a diagnosis, albuminuria testing does not exceed 50% in either the Fee-for-Service (FFS) or Medicare Advantage (MA) populations.¹⁷ Like most health systems, the Medicare population has an extensive population of at-risk patients with undetected CKD. Low rates of albuminuria testing are especially concerning because increasing albuminuria is a major risk predictor for cardiovascular disease, and is strongly associated with CKD progression, and all-cause mortality.^{31 32 33} Albuminuria also guides interventions such as kidney and cardioprotective medications and interdisciplinary care.

NKF is the founding member of the Coalition for Kidney Health, a group of non-profit health organizations, patient advocates, pharmaceutical companies, and payers with a shared goal of increasing early detection and management of CKD. In 2021, The Coalition is advocating with the United States Preventive Services Task Force (USPSTF) for CKD screening in the at-risk population based on the results of guideline-concordant eGFR and uACR tests. **NKF requests that CMS support a USPSTF screening recommendation for CKD. We further recommend that CMS works with NKF to undertake an effort to locate at-risk patients in the Medicare**

² In this document, the term detection means a finding of reduced glomerular filtration rate (GFR) or proteinuria, diagnosis means confirmation of the findings after 90 days, confirming the cause, and entering the diagnosis in the electronic health record (EHR), and assessment means ordering of the tests to determine cause and stage

population and assure these Medicare beneficiaries are receiving guideline concordant eGFR and uACR assessment. This is consistent with CDC’s Healthy People 2030 goal to “increase the proportion of people with chronic kidney disease who know they have it” (CKD-02).³⁴

CKD progression is more modifiable than ever before. In addition to lifestyle modifications and existing pharmacologic interventions, innovative and highly efficacious therapies have the unprecedented ability to improve CKD outcomes. The drug class of sodium-glucose co-transporter-2 (SGLT-2) inhibitors show efficacy in slowing CKD progression and reducing risk of cardiovascular disease (CVD) and heart failure in patients with Type-2 Diabetes Mellitus (T2DM) and CKD, as well as in patients with CKD without diabetes. Finerenone is a first-in-class CKD treatment that reduces the risk of kidney function decline, kidney failure, cardiovascular death, non-fatal heart attacks, and hospitalization for heart failure in patients with T2DM and CKD. In addition, there are several interventions that have no effect on CKD progression, but reduce risk of CVD, including statin-based therapies and the glucagon-like peptide receptor agonists (GLP-1 RA) drug class for T2DM. Patients face access and affordability challenges in accessing these powerful therapies. If addressed, there is extraordinary potential to reduce the nation’s burden of kidney disease

Access to health care and CKD detection are the foundation upon which all solutions to preserve kidney health and advance health equity in kidney disease rest. People at risk for CKD must have access to a health care system that prioritizes kidney health in order to achieve the ideal course of care.

3. Take Accountability for the Full Spectrum of Kidney Disease in the Medicare Population

CMS has a unique ability to manage kidney disease across the spectrum of care, beginning with CKD. Prevalence of CKD in the 65+ Medicare eligible population nears 40%.¹⁷ With age as a risk factor for CKD progression, 33% of come to their initial treatment with Medicare as their primary payer either due to disability or age.¹⁷ **CMS is accountable for a significant at-risk population of kidney patients from risk conditions for CKD through CKD-related mortality and progression to ESRD.**

Regardless of payer, CMS is accountable for CKD's most expensive consequence. Despite 21st Century Cures Act provisions that allowed for end-stage renal disease (ESRD) enrollment in Medicare Advantage (MA) and the growing trend towards MA enrollment overall, traditional Medicare is still responsible for the majority of ESRD, covering 61.4% of the prevalent ESRD population in 2019.¹⁷ It is well characterized that total Medicare spending on ESRD exceeds 7% of fee-for-service (FFS) expenditures, raising the specter for CMS to invest in CKD detection and management in its own FFS population, as well as across health plans.

Unlike many other payers, CMS can improve management of kidney disease across the care continuum. The Center for Medicare and Medicaid Innovation (CMMI) designed the Kidney Care Choices (KCC) model to encompass the transition between late-stage CKD and ESRD. NKF strongly supports the model, as the inclusion of CKD 4 and 5 in KCC ensures accountability for delayed progression and optimal starts. Nevertheless, for the purposes of CKD, a more expansive effort is required to capture at-risk and early-stage CKD patients. NKF, in partnership with the National Committee for Quality Assurance (NCQA), developed the Kidney Health Evaluation measure to increase guideline-concordant assessment of eGFR and uACR in adults with diabetes. The plan-level version of the measure is being reported in the Healthcare Effectiveness Data and Information Set (HEDIS). The clinician-level measure, intended for the Merit-Based Incentive Payment System (MIPS), is in the pre-rulemaking process. Once Kidney Health Evaluation is fully endorsed for use in federal programs, **we ask that the measure is expeditiously adopted into CMMI's primary care models and the Medicare Shared Savings Program (MSSP).**

The Kidney Health Evaluation quality measure is one component of NKF's *CKDintercept* program, a comprehensive blueprint for improving CKD care in primary care. Another component of *CKDintercept* is the NKF CKD Learning Collaborative. This quality improvement initiative for primary care practices focuses on the implementation of population health strategies to reduce cardiovascular and kidney disease risk. The Learning Collaborative leverages a practice or health system's electronic medical record (EMR) to assess the impact of CKD on the practice or institution and then supports the shaping and application of population health strategies and quality improvement plans. NKF would be pleased to partner with CMS on the implementation of CKD Learning Collaborative in its primary care models and across the FFS environment. Taken together with the Kidney Health Evaluation measure in MIPS, this facilitated approach to changing primary care workflows can provide a more comprehensive and targeted understanding of the Medicare CKD population allowing CMS to develop and implement meaningful population health strategies to improve outcomes and reduce spending.

4. Invest in Primary Care

CKD policy is fundamentally, primary care policy. Ideally, CKD is detected and managed in the primary care setting. KDOQI's seminal guideline on CKD evaluation, classification, and stratification suggests that patients with an eGFR of less than 30 mL/min/ 1.73 m² (CKD Stages 4–5) should be referred to a nephrologist.³⁵ CKDIntercept cross references CKD classification by monitoring in the primary care setting and referral to nephrology (Figure 2). Superimposed with CKD classification by number of people, based on the 2021 United States Renal Data System (USRDS) Annual Data Report, almost 28 million people with CKD require monitoring in the primary care setting (Figure 3).

Figure 2

Classification of CKD Based on GFR and Albuminuria Categories: "Heat Map"

CKD is classified based on:

- Cause (C)
- GFR (G)
- Albuminuria (A)

				Albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased	Moderately increased	Severely increased
				<30 mg/g <3 mg/mmol	30-299 mg/g 3-29 mg/mmol	≥300 mg/g ≥30 mg/mmol
GFR categories (mL/min/1.73 ²) Description and range	G1	Normal or high	≥90	1 if CKD	Monitor 1	Refer* 2
	G2	Mildly decreased	60-89	1 if CKD	Monitor 1	Refer* 2
	G3a	Mildly to moderately decreased	45-59	Monitor 1	Monitor 2	Refer 3
	G3b	Moderately to severely decreased	30-44	Monitor 2	Monitor 3	Refer 3
	G3	Severely decreased	15-29	Refer* 3	Refer* 3	Refer 4+
	G5	Kidney failure	<15	Refer 4+	Refer 4+	Refer 4+

Colors: Represents the risk for progression, morbidity and mortality by color from best to worst. Green: low risk (if no other markers of kidney disease, no CKD); Yellow: moderately increased risk; Orange: high risk; Red, very high risk.

CKD patients require intensive management by primary care physicians. CKD patients are often older, face SDoH such as reduced access to healthcare, lower incomes, lower access to quality education, reduced health literacy, reduced access to healthy foods, stable housing and transportation, have unhealthy behaviors, and are more likely to face discrimination and have multiple comorbidities such as diabetes, hypertension, and hyperlipidemia.

Figure 3

(a) Number of persons by estimated glomerular filtration rate and albumin to creatinine ratio

eGFR Categories	A1: Normal to mildly increased (ACR <30 mg/g)	A2: Moderately increased (ACR 30-299 mg/g)	A3: Severely increased (ACR ≥300 mg/g)	Total
G1: Normal or high (eGFR ≥90ml/min/1.73m ²)	127,706,334	9,626,498	1,424,334	138,757,167
G2: Mildly decreased (eGFR 60-89 ml/min/1.73m ²)	61,824,016	6,087,738	841,639	68,753,394
G3a: Mildly to moderately decreased (eGFR 45-59 ml/min/1.73m ²)	7,476,906	1,625,313	561,625	9,663,844
G3b: Moderately to severely decreased (eGFR 30-44 ml/min/1.73m ²)	1,971,690	876,156	334,234	3,182,081
G4: Severely decreased (eGFR 15-29 ml/min/1.73m ²)	228,891	205,735	423,003	857,629
G5: Kidney failure (eGFR <15 ml/min/1.73m ²)	23,113	42,892	201,777	267,782
Total	199,230,951	18,464,334	3,786,611	221,481,896

In addition to assessing individuals for CKD, primary care is responsible for monitoring progression, treating CKD with drug therapies, education, patient activation, referral to Medical Nutrition Therapy (MNT), and co-management of more complex patients. Highly efficacious drug therapies to reduce the risk of CKD, deployed in the primary care setting, can require multiple visits to dose correctly and monitor side effects. Traditional FFS reimbursement does not capture this effort, though NKF does support and commend CMS for shifting Medicare dollars towards non-procedural services, which may incentivize more clinicians to enter primary care. NKF strongly supports the work of CMS and the Center for Medicare and Medicaid Innovation (CMMI) to execute the Medicare Shared Savings Program (MSSP) and other primary care models that increase focus on achieving value. Multidisciplinary care has value in CKD, particularly with regards to the novel therapies on the market used for delaying CKD progression and reducing cardiovascular risk. Uptake of these medications is urgently needed, but primary care physicians are overburdened, and CKD patients have additional medication-related complexities that require specialized medication management. Pharmacists in a multidisciplinary care model could assist with patient activation, assistance with medication regimens, and education on safe and effective medication use if there was a mechanism for pharmacists to bill Part B. Medication management has demonstrated its value to clinical and economic outcomes in hypertension, diabetes, and related micro- and macrovascular disease.^{36 37} In addition, evidence suggests that integration of comprehensive medication management delivered by pharmacists improves both the patient experience and provider satisfaction.³⁶

Value-based care shows strong potential to improve kidney disease outcomes, particularly in the primary care setting. NKF asks that CKD detection and management be a more explicit focus of CMS and CMMI's primary care models.

Specific Comments

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

Section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) authorizes the Medicare program to cover Medical Nutrition Therapy (MNT) for patients with "renal disease" that "is not receiving maintenance dialysis."³⁸ Final regulations published November 1, 2001 defined "chronic renal insufficiency" as "the stage of renal disease associated with a reduction in renal function not severe enough to require dialysis or transplantation (glomerular filtration rate (GFR) 13–50 ml/min/1.73m²)."³⁹ The CY2022 Physician Fee Schedule updated the MNT regulations to align with accepted standards for CKD G stages 3 and 4, specifically glomerular filtration rate (GFR) 59 – 15 mL/min/1.73m² and to remove the treating physician requirement to increase the number of physicians who can refer beneficiaries to MNT.

CMS has not realized the full extent of its authority with regards to making MNT available for Medicare beneficiaries. Covering MNT for earlier stages of CKD is a low-cost intervention proven to slow or prevent CKD progression.^{40 41} Combined with efforts to detect CKD earlier in its progression, making MNT available to CKD patients as early in their disease progression as possible would result in significant savings to the Medicare program. **CMS should expand the definition of renal disease at § 410.130 to include CKD Stage G1 Kidney Damage with normal kidney function (GFR 90 ml/min/1.73m² or higher) G Stage 2 Mild CKD (GFR 60-89 ml/min/1.73m²) and non-dialysis dependent G Stage 5 (GFR <15 mL/min/1.73m²) to include the full spectrum of non-dialysis dependent chronic kidney disease.**

2. 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?

The Kidney Disease Education (KDE) benefit is the only educational benefit in the Medicare program focused on kidney disease. KDE is not an early-stage CKD benefit; rather the benefit is intended to provide reimbursement for education on modality choice, in addition to management of comorbidities, prevention of uremic complications, and active participation in all aspects of care. Diabetes Self-Management Training (DSMT) and MNT fill some gaps in kidney disease education but taken together still do not represent a comprehensive strategy. **NKF recommends that CMS develop a broad kidney disease education initiative that builds on the existing KDE, MNT, and DMST benefits while providing opportunities for patients to be educated on topics specific to the stage of their CKD diagnosis.**

An essential component of successful kidney disease education is that it is provided early and consistently. Successful early education provides basic information about the kidneys and what they do, is relevant to the patient's CKD diagnosis (i.e., a patient with moderately decreased eGFR and normal to mildly increased albuminuria necessarily needs different education than a patient with moderately decreased eGFR and severely increased albuminuria), and is meaningful (i.e., internalized by the patient such that the information is actionable). Overall, improved CKD education is predicated on detection and classification of CKD and a primary care model that rewards clinician time spent educating and coaching patients. Specifically, a CKD-focused education initiative should include:

- Community-based education. NKF recommends leveraging best practices from DSMT or the Chronic Disease Self-Management Program (CDSMP)
 - Ongoing peer-to-peer education
 - Reimbursement structures that incentivize chronic care education and management in the primary care setting. Primary care physicians and nephrologists caring for patients with diagnosed CKD or at risk for it should be able to bill the Chronic Care Management (CCM) codes for patients with CKD.
 - Consistently high-quality education targeted to CKD stage and the patient's risk of progression.
3. 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?

Patients at risk for CKD must be periodically screened in order for CKD to be detected and its progression slowed. A USPSTF CKD recommendation and the implementation of NKF's physician-level measure of annual eGFR and uACR testing will result in considerable progress in CKD awareness and detection. The Kidney Health Evaluation measure is specified for adults with diabetes, as diabetes is the underlying cause of the majority of CKD cases. **We ask CMS to support iteration on the Kidney Health Evaluation measure to incentivize CKD screening in other high-risk populations.**

The gold standard CKD quality measure is a measure of delayed CKD progression. The nephrology community lacks consensus on clinical research and epidemiology that would underpin such a measure. There is still much to be gained through process measures of guideline concordant care for patients at risk for CKD or with a CKD diagnosis. Nevertheless, **it is important that CMS continue to pursue a measure of delayed progression** that would encourage the use of the range of lifestyle modifications, clinical interventions, and drug therapies available to slow or stop CKD progression while reducing the burden on physicians to report on multiple process measures.

NKF recommends that referral to nephrology follow the CKDIntercept recommendations based on the KDIGO heat map (Figure 1). The heat map can be implemented in CMS and CMMI's primary care models. NKF would be pleased to assist CMS with this work. As many as 30% of incident ESRD patients "crash" into dialysis.¹⁷ Ensuring that as many people living in the United States as possible can access health care and have the opportunity to be screened for CKD will increase timely referrals to nephrology, co-management of patients, and reduce crash starts. Notably, significant disparities are evident in pre-ESRD nephrology care, namely that Black, Native Hawaiian/Pacific Islander and Hispanic people are less likely to receive it.¹⁷ NKF believes disparities can be reduced through early detection of CKD, reinforcing the primary care infrastructure, and following best practices for timely referral to nephrology based on the detection and classification of CKD according to risk.

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

Education about treatment options is a key component of the kidney disease education initiative described in the response to question 2. With regards to the existing KDE benefit, kidney community advocacy has focused on statutory fixes to the benefit that would expand

the patient population that can receive KDE and the providers who can offer it. Less attention has been paid to potential policy solutions that would improve the consistency, quality, and value of the education.

Due to a poor understanding of kidney disease and kidney failure among the public at-large, patients facing irreversible kidney failure experience a great deal of fear. These patients cannot internalize information about treatment options until their fears have been assuaged. In addition to expanding the KDE benefit so more patients can benefit from treatment options education in the nephrology setting, NKF supports a comprehensive kidney disease education strategy that also encompasses community-based and peer-to-peer education programs. It is common for patients to approach ESRD with the belief that kidney failure is synonymous with the end of their lives, both literally and metaphorically. **Particularly as the Administration is putting resources towards growing home dialysis, it is essential that CMS implement mechanisms that enable late-stage CKD patients to see and learn from other people who continue to live meaningful, healthy lives using home dialysis options.** It is not uncommon for patients on the cusp of kidney failure to require multiple visits with the nephrologist to internalize the reality of their situation, or to simply stop coming in for appointments. Ongoing education that begins early in CKD progression ensures that patients understand the treatment options available to them if they reach kidney failure before the situation is dire and overwhelming. A patient should not be receiving kidney disease education for the first time at Stage 4.

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

Reimbursement has had wide-ranging effects on nephrology, helping to create and enforce a paradigm where in-center dialysis is the first and only treatment for the majority of ESRD patients. Reimbursement policies are only beginning to incentivize kidney transplant, and still largely fail to incentivize preemptive transplant, despite that a kidney from a well-matched living donor transplanted prior to dialysis initiation provides the best outcomes and generates the greatest cost savings.^{8 42} **CMS must modernize reimbursement so that nephrologists are compensated for referring patients to a transplant center *before the patient's eGFR is 20 and the patient can be evaluated for transplant and begin accruing wait time, supporting the patient in the search for a living donor, and participating in highly complex care coordination with the transplant center.***

There are currently no MIPS measures for nephrologists that pertain to transplantation. In 2021, CMS initiated a Technical Expert Panel (TEP) on physician-level measures of access to transplant.³ **NKF strongly supports such measures and encourages CMS and UM-KECC to develop, seek endorsement of, and implement measures that increase the accountability of the nephrologist for steps in the transplant process.** While the measure concepts proposed for consideration by the TEP were not specific to preemptive transplant, we believe that an increased focus on transplantation in the nephrology setting combined with earlier CKD detection, management and timely referral to the nephrologist will give clinicians more time and incentive to consider preemptive transplantation as an option for patients.

6. For people beginning dialysis, how can CMS support a safe transition/ 7. How can these care transitions be equitably provided?

NKF supports the CMMI Kidney Care Choices (KCC) model as a vehicle to improve the safety and quality of transitions of care. An unintended consequence of the Medicare ESRD benefit has been the divestment of group health plans (GHPs) from ESRD. Anticipating that payers would simply shift the expensive consequences of kidney disease onto the Medicare program, Congress instituted a Medicare Secondary Payer policy under which the GHP is the primary payer during the 30-month coordination of benefits period. The impact of the coordination of benefits period has not been defined, however what is clear is that pre-ESRD coverage is important for facilitating safe and high-quality transitions. Incident patients with Medicare as primary or secondary payer are significantly more likely to receive pre-ESRD nephrology care, less likely to transition to ESRD with a catheter, and more likely to transition to ESRD with a fistula.¹⁷ Black, Native Hawaiian/Pacific Islander, and Hispanic people are much less likely to receive this important pre-ESRD nephrology care than their White, Asian, and Native American counterparts.¹⁷ These data reinforce the general need for access to health care, early detection and classification of CKD, and timely referral to nephrology, and, specifically for models like KCC that impose risk on a single entity across the transition from CKD to ESRD. In particular, closing gaps in access to care and CKD detection and classification will have a distinct impact on well documented disparities in pre-nephrology care and optimal starts.

³ Practitioner Level Measurement of Effective Access to Kidney Transplantation

NKF also asks CMS to expand the ESRD C-SNP to include patients with CKD 4 and 5. An expansion of the ESRD C-SNP would allow CKD patients in MA plans to benefit from similar incentives to those in the KCC model to delay CKD progression and, where that is not possible, provide patients with a higher quality transition to ESRD. CMS defines a “special needs individual” as one who has one or more comorbid and medically complex chronic conditions that are substantially disabling or life-threatening, has a high risk of hospitalization or other significant adverse health outcomes, and requires specialized delivery systems across domains of care. MA eligible CKD 4 and 5 patients meet each of these criteria.

The transition from CKD to ESRD is rife with medication errors. Pharmacists that are working in transplant centers can assist patients that are getting a pre-emptive transplant. However, that is not true for patients that transition to dialysis. Pharmacists are not currently recognized as a key member of the interdisciplinary team (IDT) in the Conditions for Coverage (CfC) for facilities. Several academic centers have recognized the value of pharmacist medication management services for patients receiving dialysis, but they have absorbed the cost within their health system. Most patients receiving dialysis do not receive the benefit of medication management services by pharmacists, even though evidence suggests that pharmacist-provided medication management services can reduce hospitalizations, which drive costs in this population.^{43 44}

NKF hopes to see improved outcomes across the transition, including improved health-related quality of life (HRQoL). Another means to achieve improvement on comprehensive and patient-centered outcomes is the referral of CKD patients for physical and occupational therapy and vocational rehabilitation as services that can be coordinated with dialysis initiation if the patient is pursuing a dialysis modality.

Section III. Home Dialysis & Alternative Dialysis Modalities

A. Home Dialysis

As a preliminary matter, home dialysis is often framed as a single modality rather than many different modalities. **NKF ardently supports policy efforts to grow home modalities because**

home modalities offer diverse, flexible options for people to live their lives on their own terms while still receiving life-saving dialysis treatments.

Home modalities are growing. At the end of 2019, 11.2% of the prevalent ESRD population was using peritoneal dialysis (PD) and 1.9% home hemodialysis (HHD).¹⁷ In the last quarter of 2021, the two largest dialysis organizations in the United States, DaVita and Fresenius Medical Care, were projected to achieve 15% of prevalent patients on home modalities and 15% of total treatments using home modalities, respectively, by the end of the year.⁴⁵ Numerous factors are responsible for this growth including the Advancing American Kidney Health initiative that set aggressive goals for moving dialysis patients home, new market entrants in the dialysis space, changing consumer demands, and the growth of home dialysis in Skilled Nursing Facilities (SNFs). **It is of the utmost importance that CMS develop a broad strategy to align payment and quality policies with increasing uptake of home modalities, both to encourage continued growth of home dialysis and to ensure this growth is aligned with the patient's interests.**

Foundational issues in growing home dialysis are increasing patient and nephrologist comfort with home modalities. For many patients, the nephrologist is the major source of education about dialysis. Results from a recent survey of 450 current and past ESRD patients confirmed that a majority of patients surveyed (56%) rely on the nephrologist to provide educational information about treatment options. A nephrologist who has received training on and provided care to patients on home modalities, is comfortable prescribing them, and is prepared to support patients in the choice of home dialysis is in a much better position to help a patient go home than a nephrologist who has not received such training or experience and is not comfortable with home dialysis. A 2020 study of graduating nephrology trainees found only moderate levels of confidence with PD and low levels of confidence with HHD.⁴⁶ **Nephrology training programs must improve training and experience with patients on home dialysis and actively promote home modalities in order to sustain growth in and retention of patients on home dialysis.**

1. After the nephrologist, the NKF survey found that surveyed patients relied on the renal dietitian (50%) and social worker (43%) for education about modality options. This highlights a second, crucial problem. Dialysis patients are mostly likely to come into contact with renal dietitian and social workers as members of the IDT in the dialysis facility. An in-center dialysis patient may see the nephrologist four or more times per

month, more frequently than a pre-dialysis patient is being seen in the outpatient setting. One conclusion is that many patients are receiving modality education *after* dialysis has been initiated. This paradigm is problematic and misaligned with public policy goals of growing home dialysis. Home dialysis education must start early, before patients have adjusted to the default of in-center dialysis and are reluctant to switch modalities. The KDE benefit was designed to be a modality education benefit for late-stage CKD patients, but CKD stage G4, at which point patients become eligible for the benefit, may be too late for patients to learn about home modalities for the first time, or to have misperceptions, myths, or biases about home modalities corrected.

In general, awareness about options for how to live well with kidney failure follow low awareness of kidney disease. Home modalities must become part of the public's understanding of kidney disease and its treatments, as Weiner et al. describe it, "supplanting the default hemodialysis facility image."⁴⁷ As part of the Advancing American Kidney Health initiative, NKF and the American Society of Nephrology (ASN) signed a Memorandum of Understanding with the Department of Health and Human Services (HHS) to launch a national kidney disease awareness campaign targeted to people at risk for CKD and the clinician community. **Further awareness efforts are vital to improving understanding of kidney disease and the numerous options available to treat it.**

Specific Comments

1. 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?

Informed decision-making is the foundation of modality choice and individualized care. Informed decision-making begins with what a patient values about her and his life and what she or he wants from treatment. It is not effective to present treatment modalities in a vacuum; rather modalities should be presented as aligning or not with the patient's preferences. No option for treating kidney failure is without risk. Treatment options have meaningful benefits for different patients. When presented in the context of the patient's values and goals, she or he can then assess those benefits and risks in the context of what the patient most wants from her or his life. NKF ardently supports the free and widespread use of [My Life, My Dialysis Choice](#) decision aid, developed by the non-profit Medical Education Institute (MEI). **All modality education should leverage a values-first approach.**

On a macro level, in-center dialysis remains the default treatment option for most dialysis patients.¹⁷ Systemic factors such as poor understanding of home dialysis among patients and clinicians, inadequate opportunities for high-quality home dialysis education, misaligned regulatory and payment incentives, lack of infrastructure, the outsized role of SDoH, and race and class bias contribute to a culture of in-center dialysis in which patient choice is naturally limited. Home dialysis and palliative care are both underutilized, though home dialysis often receives more attention. Over half of the incident dialysis population is over 65 with a one-year mortality rate of 30% in the Medicare eligible population.⁴⁸ Palliative care and hospice care are patient-centered options, but few dialysis patients have advance directives or are given the opportunity to understand the implications of dialysis, including intensive hospital care, readmissions, and a high symptom burden.⁴⁹

The most straightforward lever available to CMS to improve modality choice is to optimize Medicare's existing KDE benefit. KDE is underutilized but can be extremely meaningful in driving home dialysis access. Recent work by Huanguang et al. found that recipients of KDE were twice as likely to initiate dialysis with a home modality and more likely to use a home modality over the dialysis course.⁵⁰ The stakeholder community has a role in maximizing CMS' statutory authority to offer the benefit, however, **CMS can and should expand on the co-pay waiver in the ESRD Treatment Choices (ETC) model and waive the 20% coinsurance on KDE to reduce the financial burden on patients of pursuing modality education.** It is especially important to make kidney disease education financially feasible when Medicare premiums have significantly increased.

NKF proposes a comprehensive kidney disease education that includes but is broader than the KDE benefit. Education, even on home modalities, must start early. This, like many improvements to kidney care, rests on early CKD detection and classification and timely nephrology referral. We reiterate the need for endorsement by USPSTF of guideline-concordant CKD screening in people with risk factors. Increased albuminuria testing would allow for people at high risk of progression to receive more targeted and meaningful education that normalizes home modalities early on. Better detection and classification in the primary care setting can improve referrals to nephrology, reduce crash starts and the concomitant disparities associated with pre-nephrology care, and provide more time in the health system for patients to work with their clinicians to adjust to the idea of kidney disease and prepare early to initiate dialysis with a home modality.

CMS can also align regulatory and payment incentives to support a favorable environment for home dialysis and improve patient choice. The dialysis facility Conditions for Coverage (CfCs), last revised in 2008, were finalized at a time when there was less overt interest in and fewer incentives for growing home dialysis and dialysis in alternative settings. The CfCs enforce one set of regulations for all clinic types, which limits innovative modes of dialysis delivery. **NKF requests that CMS open the CfCs for public comment and modernize the regulations to support growth of home modalities.** As for payment, the notable example of misaligned incentives is the physician reimbursement for in-center and home dialysis. CMS reimburses more highly for 4 or more visits in the month (90960/\$361.29) than it does home dialysis when the physician has responsibility for overall management for the same period of time (90966/\$299.69). This incentivizes practice patterns of frequent rounding on in-center dialysis patients. **CMS should correct this discordance by creating parity between in-center and home dialysis reimbursement.**

Disparities in access to home dialysis impact patients' free choice of modality. Among prevalent ESRD patients, White and Asian dialysis patients have the highest rates of PD utilization (9 and 10%, respectively), while only 6.1% of Black/African American patients use PD. White patients also have the highest rate of HHD utilization at 1.8% of prevalent ESRD patients, followed closely by Black/African American patients at 1.7%.¹⁷ Inadequate care partner support, limited storage space, and SDoH including housing instability, poverty, limited education and low health literacy, are more common among people with lower socioeconomic status (SES), and are identified barriers to home dialysis.⁵¹ Zip-code level SDoH including poverty and lower high school graduation rates contribute to but do not fully explain the lower rates of home modalities among Black and Hispanic patients.⁵² Implicit bias on the part of providers likely also has a role. In NKF's survey of 450 current and past ESRD patients, Black/African American respondents were much more likely than White respondents to say their care team did not provide educational information on dialysis treatment options. Black/African American respondents also felt more encouraged by their care team to try in-center dialysis. The role of implicit bias aside, CMS has struggled with how to account for the role of SDoH, particularly low SES, in home dialysis access. In the ETC model, CMMI created separate benchmarks for facilities and nephrologists serving a higher proportion of dual eligible or low-income subsidy (LIS) eligible beneficiaries. **NKF's position continues to be that there are very few absolute clinical contraindications to**

home dialysis and that with the right empowerment and support, the vast majority of people can successfully use home modalities.

Empowerment and support are functions of education. The need for comprehensive, early education that familiarizes kidney patients with home modalities in multiple different settings cannot be overstated. As part of a broad kidney disease education initiative, peer-to-peer education, team-based education, and mentoring, particularly by mentors of Color, have an especially important role in empowering patients to select and remain on home dialysis. The first year of home dialysis can be very challenging as patients adjust to performing their treatments at home. This is a challenge that patient-centric education and support can overcome, not one that should preclude efforts to grow home dialysis. As patients interact with other home patients who have found freedom and wellbeing in home dialysis, they may be encouraged to pursue and overcome barriers to dialysis at home. Though ideally, patients are educated on home modalities before the need for dialysis is imminent, education in facilities and in hospitals clearly have roles in transitioning patients to home dialysis. Small operational changes can make a significant difference in the efficacy of facility-based education. Setting up a home machine in the facility so patients can better understand the machine, encouraging in-center self-care dialysis as a bridge to home, and providing education in the facility when the patient is not overwhelmed and feeling unwell can help make sure home education is more than a “box checking” exercise. With regards to education and in general, NKF is concerned that the survey process has fallen out of alignment with patient-centricity and patient priorities. We would be pleased to discuss how the survey process can better capture patients’ experiences of care, including how they are educated about the treatment options available to them.

The availability of staff to support home dialysis training and the consistency of the quality of home training are of critical importance to growing high-quality home dialysis. Like nursing as a whole, there is a growing shortage of nephrology nurses. Nephrology nurses with home training experience are in even shorter supply. The COVID-19 pandemic is exacerbating this already troubling trend.⁵³ As part of a broader regulatory effort to open the dialysis facility CfCs, **CMS should explicitly allow for greater involvement of the IDT in home training under the supervision of an RN.** NKF also supports the allowance of the home nurse to gain concurrent experience as an RN and with home modalities over the course of 12 months and for licensed vocational nurses (LVN), licensed professional nurses (LPN), and personal care technicians (PCTs) to support home training under the supervision of an RN. There is some disagreement in the

community about allowing for these flexibilities. We note that important components of home training can be communicating basic information such as how dialysis works. An RN is not necessarily needed to provide this basic, but very important information. In addition, we emphasize that the quality of the home education is more important than the nurse's credentials.

CMS should certify core competencies to assure the quality and consistency of home training. NKF is also interested in incorporating education from the manufacturer into home training, following the model of pacemaker and insulin pump manufacturers. With more home dialysis machines entering the market, it is important that patients have the most current expertise on how to use the machine. **NKF believes there is a role for the manufacturer in home training.**

Tangible support for patients is also needed to grow home modalities. Staff assisted home dialysis has a critical role in helping more people succeed with home dialysis and may help to close gaps in access for lower income dialysis patients facing SDoH that impede their access to home modalities. We thank CMS for clarifying that staff assistance is included in the ESRD bundle and thus does not pose a threat to facilities under the Beneficiary Inducements CMP. We emphasize, however, that facilities will not offer this benefit without additional payment. **NKF asks CMS to provide an add-on to the ESRD bundle to support staff assistance.** In the interim, NKF is pursuing a legislative solution that would specifically direct the Secretary to implement payment for staff to assist patients with dialysis in their homes. NKF also supports more frequent delivery of home dialysis supplies. This would be a simple solution to support patients who wish to dialyze at home, but do not have enough space to store the supplies. NKF is further interested in the role of the occupational therapist in supporting home patients in continuing to engage in meaningful work, perform activities of daily living, and increasing safety in the home including fall prevention.

Finally, **NKF strongly supports significantly increased transparency into the financial arrangements between dialysis facilities and other entities**, including entities with a financial interest in the facility, a facility subsidiary, joint venture partnerships, and joint venture partnerships that its subsidiaries are party to. At present, it is impossible to assess the extent to which financial arrangements are contributing to practice patterns.³⁴ Full transparency into these data will allow independent researchers to assess whether financial arrangements between dialysis facilities and other entities are helpful, harmful, or neutral with regards to clinical care and patient choice.

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

White and Asian individuals are most likely to initiate dialysis with PD, while Black individuals are least likely to. Among prevalent ESRD patients, White individuals are the least likely to be on in-center dialysis whereas Black, Native American, and Native Hawaiian/Pacific Islander people are most likely to be using in-center dialysis. Black patients have the lowest rates of PD utilization in the prevalent ESRD population.¹⁷ There are a paucity of data on retention by race and ethnicity, but it could be hypothesized that people of lower SES face different and more challenging barriers to retention on home modalities. Points raised elsewhere in this document apply to closing gaps in home dialysis access. Improving overall access to health care, reducing disparities in pre-ESRD nephrology care, and eliminating crash starts may all be meaningful mechanisms to improve initiation of dialysis with a home modality. Multi-pronged patient-centered education i.e., that is culturally competent, appropriate for different levels of health literacy, and leverages trusted community organizations and peer mentorship also has a significant role in improving equity in home dialysis access. NKF additionally supports staff-assisted home dialysis as a means to help patients who are interested in home dialysis, but who face structural barriers, to do so.

We strenuously endorse an add-on payment to the ESRD bundle to support staff assistance for home dialysis patients.

Modernizing the CfCs present another opportunity to increase home dialysis in lower SES communities. Dialysis facility regulations that are designed fundamentally for in-center facilities create a barrier to innovative models of dialysis delivery that literally meet patients where they are. **NKF asks to revise the CfCs to specifically define large in-center dialysis facility and home dialysis training and support facilities.** Such definitions will streamline the survey and certification process and make it significantly less burdensome to stand up home dialysis training and support facilities in communities otherwise divested of these resources. The CfCs are also a policy vehicle to bring mobile dialysis and a hoteling model, in which patients come to a permanent, central location to perform their own home dialysis or self-care dialysis treatments, to fruition. Both models would have special relevance to lower SES communities, though not to home dialysis specifically.

We also call CMS' attention to entrenched bias. Patients report interpersonal racism and classism that impact their ability to learn about and access their treatment of choice. People from structurally disadvantaged groups see that dialysis facilities are nicer and better staffed in predominantly White areas. They know that dialysis facilities located in lower income, majority non-White neighborhoods are less likely to offer the guidance people need to get on a successful path to home dialysis or transplant, engage patients in discussions about their Plan of Care, and support patients with their mental health. Interpersonal bias is a core impediment to modality choice. While payment, quality, and regulatory levers are not well suited to overcome interpersonal racism and classism, we encourage CMS to put policies in place that will encourage continued evolution of dialysis delivery and dialysis technologies that can meet consumer demand for health equity and justice.

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

When thinking about home dialysis safety, we encourage CMS to acknowledge that there is risk inherent in dialysis, regardless of setting. Discussions of home dialysis are often marked by concerns that patients will be unsafe at home. Home dialysis training includes infection prevention and identification, and current CMS regulations require clinics to provide emergency preparedness training to patients. Nevertheless, comprehensively educated patients should understand that they are bringing some risk to the home setting but that the alternative, dialysis in the facility, is also not without risk.

In NKF's comments on the proposed calendar year (CY) 2022 ESRD proposed rule, we noted that the existing dialysis quality program, the Quality Incentive Program (QIP), is best suited for in-center dialysis and provided recommendations for how CMS can define and measure home dialysis quality, of which safety is a fundamental component. **Specifically for home dialysis safety, we ask CMS to collect and report peritonitis data and more granular data on bloodstream infections (BSIs) particularly through the transition between hospital and home or dialysis facility.** These data are already collected and reported by the United States Renal Data System (USRDS). We reiterate our general recommendations on home dialysis quality here as follows:

Quality domains relevant to home dialysis are:

1. Home dialysis access
2. Clinical care
- 3. Safety**
4. Retention
5. Health Related Quality of Life (HRQoL)

Home Dialysis Access – A home dialysis access measure for practical purposes, can be modified for use in the QIP from the ETC model. The home dialysis access domain should also include patient-reported assessments of whether the individual was given a choice of modality, meaningful education on those choices and whether they are being treated with the modality they prefer. A home dialysis access domain could also include an assessment of the percentage of eligible patients who declare a preference for home dialysis who are successfully trained in a timely manner. Backlogs in home training are themselves a barrier to access.

Clinical Care – Measures in the clinical care domain could account for native kidney function, incentivizing nephrologists and providers to incorporate residual function into the dialysis prescription and dosing. Current practice is better in PD than in HHD, where overtreatment and loss of residual function are common. We appreciate CMS' adjustments to Kt/V for home patients and ask CMS to continue to decrease reliance on this measure for home patients in favor of a complete spectrum of lab values, routine native kidney function measurement, and assessment of how the patient feels and functions. Even with adjustment, Kt/V can still be punitive for home patients whose facilities will not exercise the flexibility they are allowed under the QIP.

Other concepts that should be captured in the clinical domain are:

- Intensive hemodialysis
- Volume status
- Blood pressure control

Safety – The current safety domain need only include a measure of peritonitis to evaluate safety across dialysis settings. We also encourage CMS to require BSI reporting by hospitals in order to better track how dialysis patients get infections.

Retention – Measures in the retention domain will by definition get at the quality of home training, one of the most important factors in a person’s ability to be successful on home dialysis. Retention measures will also elucidate the steps the facility is taking to anticipate and manage patient and care partner burnout. A measure of short-term retention on home dialysis is not useful and may be actively harmful. The goal should be to support patients through their first year on home dialysis, which can be very challenging, but after which many patients will experience substantial improvements in their quality of life.

Health Related Quality of Life (HRQoL) – The patient-centered outcome that matters to home dialysis patients, in fact, all dialysis patients, is health related quality of life (HRQoL). Nephrologists and dialysis facilities can and should be responsible for some elements of a patient’s HRQoL. We acknowledge that quality of life is unique to each individual, is affected by processes outside of dialysis, and does not necessarily correlate with quality of care and therefore that developing accountabilities associated with HRQoL may be challenging. As a preliminary step, facilities could report and monitor an individual’s Activities of Daily Living (ADLs) in conjunction with incentives for referral for occupational therapy (OT) evaluation. Dialysis facilities are already able to refer to OT evaluation, which is covered by Part B.

Existing mechanisms could be deployed to encourage nephrologists and providers to focus on HRQoL, for example better leveraging the Kidney Disease Quality of Life (KDQOL) tool that dialysis facilities must already administer to dialysis patients under the existing CfCs, the development of the Plan of Care and the ESRD Life Plan.

B. Alternative Dialysis Modalities

NKF’s dialysis policy is rooted in patient choice. As such, we are interested in improving the availability and quality of a range of treatment options for kidney failure. NKF appreciates CMS’ inquiries on dialysis in Skilled Nursing Facilities (SNFs) and mobile dialysis. We are very supportive of these modalities, both of which are important for meeting patient’s needs. We will eagerly provide the patient and professional perspective on how patients are experiencing dialysis in these settings as they become increasingly available. At this time, we have few specific comments to offer on the appropriate regulatory framework for either modality beyond our

desire to see dialysis in SNFs and mobile dialysis grow. Rulemaking on the dialysis CfCs would present an opportunity to enable mobile dialysis, which is precluded by current regulations.

NKF also has an enduring interest in improving the quality of in-center dialysis. Dialysis patients have access to a wide range of professional expertise in the form of the interdisciplinary team (IDT). Unfortunately, staffing challenges and extremely high caseloads make it difficult for patients to benefit from the knowledge and skills of the IDT. **NKF asks CMS to institute caseload limits for the IDT, particularly for social workers.** In 1998, the Council of Nephrology Social Workers (CNSW) recommended a 1:75 social worker to patient staffing ratio. NKF endorses this ratio. Social workers are uniquely positioned to support patients in overcoming SDoH, address patient mental health, and guide patients toward transplantation and home modalities. These tasks exceed what dialysis facility social workers can do with caseloads of up to 200 patients, when helping a patient obtain immediate insurance, and dialysis-related transportation take precedence. Social workers can play a pivotal role in improving equity, however not with the unmanageably high caseloads that are ubiquitous currently. As CMS considers revisions to the CfCs, we reiterate our support for adding pharmacists to the IDT to strengthen medication reconciliation and adherence.

The National Kidney Foundation (NKF) wishes to thank CMS once again for its solicitation of stakeholder input to enhance its understanding of kidney disease and the policy solutions that can enhance its detection and management, increase access to kidney transplantation, improve quality of care and generate a more equitable health care system. We are at CMS' disposal with regards to the recommendations contained herein. Please contact Morgan Reid, Director of Transplant Policy and Strategy (morgan.reid@kidney.org) or Miriam Godwin, Health Policy Director (miriam.godwin@kidney.org).





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