



February 13, 2023

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: [CMS-2728] Agency Information Collection Activities: Proposed Collection; Comment Request

The National Kidney Foundation (NKF) applauds the Centers for Medicare and Medicaid Services (CMS) for recognizing the need to improve the End-Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration, referred to as the CMS-2728 form. Considering that the Federal Government, ESRD Networks, treatment facilities, researchers, and other entities use data collected from the CMS-2728 to monitor and assess the quality and type of care provided to ESRD beneficiaries, it is imperative that any modifications to the form advance equitable access to high-quality treatment for kidney failure patients, like home dialysis and kidney transplantation.

NKF believes this initiative aligns seamlessly with the current *CMS Framework for Health Equity*; the correct amendments to the CMS-2728 could facilitate strategies to reduce health disparities among racial and ethnic minorities and underserved populations. It is well-documented that transplant and home dialysis access varies widely across racial, socioeconomic, and geographic strata. It is crucial for each stakeholder that relies on the CMS-2728 for evaluating kidney failure patients to have data on social determinants of health (SDOH) to rigorously analyze inequities in kidney disease and identify possible solutions to improve access to care. Therefore, we recommend the following revisions and considerations for the CMS-2728 to ensure every kidney failure patient has fair access to home dialysis and kidney transplantation; it is what every kidney patient living in the US deserves.

Improving Access to Kidney Transplantation

- **Question 20(g):** NKF fully supports the proposed change to this question, asking what types of transplant education a patient received and their understanding before initiating dialysis. Simply asking if a patient received transplant education is insufficient, considering a patient's physical, emotional, and psychological state at the time this form is completed.

We also recommend an additional follow-up question explicitly asking if the patient has been informed and educated about living kidney donation as a transplant option.

- **Question 28:** We appreciate the addition of this question to ascertain if a patient understands that a kidney transplant is an option. NKF is a strong proponent of patient engagement and shared decision-making. However, to differentiate this inquiry from question 20(g), we suggest changing the language to ***“Does the patient understand their options right now”*** creating an expectation to help patients comprehend that transplantation is a treatment option.

CMS should encourage clinical providers to use validated shared decision-making tools, and educational platforms, such as NKF’s Kidney Learning Center, to continue informative discussions with patients about transplantation. The informed consent process for ESRD patients beginning dialysis should include discussions about kidney transplantation, as it is advantageous for patients to understand treatment options, risks, and benefits.¹

- **Question 29:** NKF appreciates the addition of this question to determine why a patient has not chosen transplantation as a treatment option. However, we recommend the following revisions:
 1. Replace “patient has not been assessed” with “patient has not **yet** been assessed.”
 2. Replace “patient is not medically eligible” with “patient has **an absolute contraindication.**”

Dialysis centers and nephrologists must prioritize transplant awareness and education as part of their care plan for kidney patients. NKF urges CMS to leverage the dialysis center Conditions for Coverage as a vehicle to ensure the delivery of individualized, comprehensive transplant education.

- **Question 30:** We support the addition of this question but suggest CMS follow this question with two subsequent inquiries:
 1. Which transplant center was the patient referred to, along with the date of referral?
 2. If yes, was the patient placed on the kidney transplant waitlist before beginning dialysis?

To further reinforce the importance of kidney transplant awareness, it is insufficient only to ask if a patient was referred to a transplant center. Capturing this data illuminates equity in the transplant referral process and the ability to discern transplant referral patterns among different sociodemographic populations.

There is an urgent need to define “referral” and standardize referral processes for data collection from all dialysis centers and nephrology practices to be consistent; for the data to be

¹ Salter, Megan L et al. “Patient- and provider-reported information about transplantation and subsequent waitlisting.” *Journal of the American Society of Nephrology : JASN* vol. 25,12 (2014): 2871-7. doi:10.1681/ASN.2013121298

meaningful for research, analysis, and performance improvement; and to reduce inefficiencies and inequities in the referral process. Significantly, collecting this data on the 2728 form should *supplement and not supplant* referral data collection from transplant centers. Receiving information about this crucial step in the care process from multiple stakeholders is essential to enabling the research community to cross-reference the data and make inferences about improvement opportunities.

- **Question 38:** Instead of asking “type of donor,” we recommend asking “type of transplant” and including multi-organ transplant and kidney paired exchange as options. Framing the question in this way helps with more options and will improve data collection and research.

Improving Access to Home Dialysis

The same inequities in kidney transplantation exist for access to home dialysis. We appreciate CMS focusing on patient awareness, education, and understanding of home dialysis as an option for kidney failure. We have the following suggestions:

- Question 20(f): NKF fully supports the proposed change to this question, asking what types of home dialysis education a patient received and their understanding. Patients should unequivocally know that dialyzing at home is an option that may better suit their lifestyle and personal healthcare values.
- We recommend adding a question similar to Question 29, asking why a patient declined home dialysis modalities with the same follow-up questions:
 1. Replace “patient has not been assessed” with “patient has not **yet** been assessed.”
 2. Replace “patient is not medically eligible” with “patient has **an absolute contraindication.**”

Collecting Social Determinants of Health Data

Many non-medical obstacles affect access to home dialysis and kidney transplantation for ESRD patients; there is a need to collect national data on these social determinants of health (SDOH). Environmental and sociodemographic factors hinder access to home dialysis, and this data is critical to understand how barriers remain persistent among underserved populations to improve home dialysis access effectively. Further, SDOH also contributes to patient adherence to in-center dialysis and the success of in-center dialysis therapy, which furthers the importance of this data collection.

Regarding transplant, non-medical factors, such as cultural and religious beliefs, mistrust in the healthcare system, linguistic and translation barriers, provider communication, and misconceptions about organ donation and transplantation 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. The lack of national data on these upstream social determinants of health inhibits our understanding of the underlying causes of disparities in access and the creation of effective interventions to create equitable access for patients.

We propose that the CMS-2728 be amended to capture the following SDOH factors that data collection could help attenuate:

- **Housing insecurity:** Include “are you currently concerned about where you will live over the next 90 days”.
- **Caregiver/Social Support:** Include “do you have caregiver support to assist with home dialysis/kidney transplant” and the follow-up question “does the caregiver live with you.”
- **Immigration status:** We propose using the United States Citizen and Immigration Services classification of immigration status in the US that includes US citizens, asylees, asylum seekers, refugees, legal permanent residents, conditional permanent residents, non-immigrants, temporary protected status, and undocumented immigrants. Some of these non-citizen categories have access to kidney failure services based on federal or state laws and are not currently captured. Further, consider providing guidance on correctly completing the CMS-2728 when a patient does not have a social security number or a Medicare Beneficiary Identifier.
- **Transportation:** Include “do you have access to reliable transportation.”
- **Language:** Include “do you understand health literature in English” and “would you like to receive translation services.”
- **Race and Gender:** We ask that CMS omit the “decline to answer” options for race and gender, as it limits data collection and compromises strategy implementation to improve access to home dialysis and kidney transplantation.

Patient Engagement with the CMS-2728

At NKF, we understand that patient engagement may be limited due to the patient’s health when completing the CMS-2728. CMS should encourage dialysis centers and nephrologists to include patients and their caregivers as much as feasibly possible in filling out this form. Personal questions



related to race, housing, and transportation and inquiries associated with understanding transplantation as a treatment option should be self-reported by patients or their caregivers. We are strong advocates for shared decision-making between patients and their care teams. Also, incomplete forms may cause delays, and we encourage CMS to determine how to support providers and clinicians to avoid this potential barrier to care for ESRD patients.

Again, NKF commends CMS for its attention to revising the CMS-2728 to improve data collection and access to quality kidney care. Amendments could reduce disparate access to home dialysis and kidney transplantation. NKF is prepared to lend our expertise and guidance to support and further this initiative. Please contact Morgan Reid, Director of Transplant Policy and Strategy, at Morgan.Reid@kidney.org with any questions.

Sincerely,

A handwritten signature in black ink, appearing to be "K Longino".

Kevin Longino
CEO and Transplant Patient

A handwritten signature in black ink, appearing to be "S Rosas".

Sylvia E. Rosas MD, MSCE
President