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February 13th, 2023

RE: Centers for Medicare & Medicaid Services (CMS) Request for Public Comment on Form CMS-2728 (OMB control number: 0938-0046)

The Southeastern Kidney Transplant (SEKTx) Coalition of Georgia, North Carolina, and South Carolina appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) request for public comment on CMS' intention to collect information from the public. In 2010, the Southeastern United States, including Georgia, North Carolina, and South Carolina, was identified as having the lowest rates of kidney transplant in the nation. In response, the End-Stage Renal Disease Network 6 collaborated with stakeholders in the kidney disease community to form the SEKTx Coalition, with a shared mission to reduce barriers and disparities in access and improve transplant outcomes. Although concentrated in the Southeastern US, we have continued to work with national collaborators within the kidney disease community to improve access across the nation. For over ten years, the Coalition's grassroots efforts have focused collaborative, research, and quality improvement efforts on identifying and reducing barriers to kidney transplantation for ESKD patients in the Southeast U.S. and reducing disparities in access to transplant. The Coalition's goal to improve access to and equity in kidney transplantation is well-aligned with the CMS goal of creating system-wide improvements that will lead to enhanced quality of care for ESKD patients, including reducing disparities in access to transplant. Thus, we are making several recommendations and highlighting the need for national data collection on pre-waitlisting steps that will provide numerous opportunities for the coordination of care within health systems and improve equity in access to transplant.

One overarching recommendation to CMS is that there needs to be a requirement to collect data on pre-waitlisting steps (e.g., referral for transplantation and start and completion of the transplant evaluation process) nationally to improve transparency in access and equity in transplantation. While access to kidney transplant and placement on a waiting list for transplant have been well-studied, there are a limited number of research studies that have explored variation in access to transplant at earlier steps in the process before waitlisting. Evidence has shown that barriers and facilitators at each step in the kidney transplant process vary, and exploration of barriers to referral and evaluation for transplant is limited by the lack of national surveillance data collection at these steps¹. Our coalition has long advocated for the national data collection on the early steps in the transplant process, including transplant referral and evaluation start and completion. Established in 2012, the Early Steps to Transplant Access Registry (E-STAR) first collected pre-waitlisting data on these early transplant steps from transplant centers in Georgia. This data collection revealed substantial variation in dialysis-facility level referral for transplant (range: 0% to 75%).¹ In 2016, this data collection was expanded within our Southeastern region (GA, NC, SC), again finding substantial dialysis facility-level variation in both access to referral and evaluation start (range: 0% to 90%).² This extreme variation across centers suggests that there are center-level factors that are relevant to measure and identify to help patients make informed decisions about program selection. We have since expanded this data collection to collect referral and evaluation data from 30 transplant centers in New York, New England, and the Ohio River Valley. Prior research has highlighted that barriers and facilitators exist at each step in the kidney transplant process,³ and that exploration of barriers to referral and evaluation for transplant are limited by the lack of national surveillance data collection at these steps.⁴ Collection of pre-waitlisting data on a national scale would allow us to better understand factors that influence access to transplant nationwide, allow us to study how barriers to

accessing the early steps to transplant may differ geographically, and target interventions to steps in the transplant process that have been identified to have the largest impact on access and equity in transplantation.

Specifically, data collection on pre-waitlisting data should be collected by the Organ Procurement and Transplantation Network (OPTN), and data collection on these early steps in the transplant process should be included in the new OPTN contract. Increased recognition of the need for this pre-waitlisting data collection has been widespread. In 2021, the Centers for Medicare and Medicaid Services (CMS) chartered a Technical Expert Panel (TEP) to develop practitioner-level quality measures that allow measurement of patients' access to kidney transplantation.⁵ Notably, this TEP recognized the need for national data on referral as a more proximal step under the influence of clinicians caring for dialysis patients; other working groups are actively developing metrics to improve transplant access.⁶ On the transplant program side, the new Health Resources and Services Administration (HRSA) contract for the Scientific Registry of Transplant Recipients (SRTR) has several specific tasks relevant to addressing changing quality measures to support informed decision-making through a stakeholder-engaged process; this is the first time that HRSA has explicitly called attention to "pre-waitlisting" and "waitlisting" metrics specifically within the contract.^{7,8} More recently, stakeholders in the kidney disease community at a SRTR Consensus Conference and a new report released by the United Network for Organ Sharing (UNOS) called for the collection of pre-waitlisting data by the OPTN to adequately understand barriers in access and improve equity in access.⁹ Notably, the report notes that "true access to transplant...cannot be measured without understanding the national disease burden" and that a clear understanding of this burden and how to create a more equitable system cannot be achieved without this data on patients before placement on the national waiting list.⁹

The Coalition's collection of this data from 30 transplant centers during these early steps in the transplant processes has highlighted the feasibility of this data collection and results using this data have further demonstrated why this data is needed. **We strongly recommend that this be included within the purview of OPTN to require these data collection from transplant centers,** specifically Part 121 of the contract that states in section 121.8.c.3: "For each organ-specific allocation policy, the OPTN shall provide to the Secretary data to assist the Secretary in assessing organ procurement and allocation, access to transplantation, the effect of allocation policies on programs performing different volumes of transplants, and the performance of OPOs and the OPTN contractor...Such data shall be required on performance by organ and status category, [and] patients who were inappropriately kept off a waiting list or retained on a waiting list." Specific recommendations for the rationale and for how this data collection could occur are outlined in a recent publication.¹⁰ **Importantly, OPTN should require data collection from transplant centers to allow for the collection of data on all referrals, including self-referrals and preemptive referrals which make up a considerable portion of all referrals to transplant centers for evaluation.**

Given the numerous non-medical barriers that impact access to transplant for ESRD patients, there is a need to collect national data on these social determinants of health (SDOH) and increase transparency and standardization of transplant education. Social determinants of health have a significant impact on nearly all aspects of living and deceased donor transplantation including patient interest in and access to transplant, the number of organs available for transplant, and post-transplant outcomes. Further, many of these non-medical factors at the patient-, provider-, and system-level, including medical mistrust, patient knowledge, provider communication, and differing opinions on organ donation and transplantation are barriers to access to transplant for many patients.^{3,11-13} The lack of national data on these upstream social determinants of health hinders our understanding of the underlying causes of these disparities in access and the creation of effective interventions aimed at creating equitable access for patients. Further, patients, dialysis staff, and transplant staff education about the transplant process and transplant as a treatment option have continued to be identified as a barrier to access to transplant. Although education among patients about transplantation is required by CMS, data on the type or quality of this education is limited emphasizing the **need for this basic education to be standardized and the need to devise strategies to ensure that access to this education is equitable and communicated in a culturally sensitive manner to all patients.**

As a coalition, our stated mission is to improve access, and decrease disparity in access, to kidney transplantation. We firmly believe collection of these data is a necessary step to achieving this mission. **We also recognize that data collection can result in adverse outcomes that can unintentionally worsen transplant access.** Whenever a new data collection is undertaken the burden on transplant centers and dialysis units must be carefully weighed, as these organizations have limited resources that must be shared between patient care and administrative tasks. **Similarly, clinical care metrics, and accompanying quality initiatives which utilize new data sets, must be designed so they lead to actual improvements of patient care, and do not unduly burden dialysis units and transplant centers.**

Thank you for raising these critical issues for our country's organ donors, kidney disease patients, and transplant recipients. We greatly appreciate the opportunity to contribute to this CMS Request for Information and we thank you for your consideration of our Southeastern Kidney Transplant Coalition's response.

Sincerely,



Stephen Pastan, MD on behalf of the Southeastern Kidney Transplant Coalition

Chair, Southeastern Kidney Transplant Coalition
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