E-STAR
EARLY STEPS TO TRANSPLANT
ACCESS REGISTRY

July 31, 2025

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Submitted electronically

Re: ***Submission to OMB for Review and Approval; Public Comment Request; Process Data for Organ Procurement and Transplantation Network, OMB No. 0906–xxxx–New***

Dear Administrator Engels:

On behalf of the Early Steps to Transplant Access Registry (E-STAR) Executive Management Team, we appreciate the opportunity to respond to the Health Resources and Services Administration (HRSA) Department of Health and Human Services (HHS) request for public comment for the July 1, 2025 Submission to OMB for Review and Approval; Public Comment Request; Process Data for Organ Procurement and Transplantation Network, OMB No. 0906–xxxx–New.

The E-STAR team is a multidisciplinary team with extensive experience in collaborative research and quality improvement efforts to identify and reduce barriers to kidney transplantation for patients with end-stage kidney disease, as well as to reduce disparities in access to transplantation. Our team has collected pre-waitlisting data from kidney transplant centers annually since 2012, and our registry now includes data from more than 35 centers. E-STAR is presently the only multi-regional registry capturing information on measures of referral and evaluation start (pre-waitlisting care processes) in the nation, and its data have been used in numerous studies to advance understanding of the high variability observed in transplant access steps.[1-7] These data collected within E-STAR, in many ways, offer a preview of the data that HRSA proposes to collect nationwide. Thus, the E-STAR Executive Management Team strongly supports HRSA's efforts to improve access to kidney transplant nationwide through the systematic collection of pre-waitlisting data. During the January 2025 public comment period for this planned collection effort, we offered comments informed by our leading expertise and experience working with such data and our experience leveraging such data to advance the goal we share with HRSA of expanding transplant access through quality improvement initiatives and pragmatic trials. In the present public comment, we **reaffirm our support, reiterate our prior recommendations for a phased-in approach and concerning information technology (IT) improvements, and offer new recommendations, including to collect dialysis facility Centers for Medicare and Medicaid Services (CMS) certification number (CCN) and evaluation start data.**

Transplantation is the optimal treatment for patients with kidney failure, offering a survival advantage, better quality of life, lower hospitalization rates, and lower costs.[8,9] For these reasons, HRSA, Congress, the White House (e.g., through its Advancing American Kidney Health initiative), and other policymaking authorities share the goals of promoting access to transplantation among populations with organ failure and strengthening the performance of the transplant care system overall. Specific to HRSA and kidney disease, Congress has mandated that HRSA oversee the performance of the transplant system and ensure appropriate access to kidney transplant for all patients with kidney failure. However, the lack of data on pre-waitlisting care steps (referral, evaluation start, completing evaluation-related tests and screenings, evaluation completion, and full case review at the waitlist conference) constrains HRSA's ability to evaluate performance and provide guidance to transplant care providers on these critical opportunities to foster patients' access. These data gaps also hinder researchers seeking to uncover why certain patients do or do not make it on the waitlist and to generate evidence that can inform HRSA and providers working to reshape transplant care systems to promote access. For example, our team has used E-STAR data to develop and implement interventions at the dialysis facility, provider, and patient levels that have been successful in *increasing rates of referral and evaluation start.*[10,11] Importantly, the evidence generated using these data will also be valuable to patients and families navigating the complex patient journey towards a transplant. **HRSA's plans to collect pre-waitlisting data will be essential for filling this gap in national data on these care steps and ensuring the fulfillment of its Congressional mandate and, more importantly, for advancing meaningful quality improvement and research efforts that foster the identification of barriers in the process, assess the performance of referring providers and transplant care providers, inform policy and practice improvements, and promote transparency in the patient journey.**

While the proposed data collection efforts will be of great value, we see important opportunities to strengthen this plan. **The collection of critical components—such as dialysis facility CMS Certification Numbers (CCNs) and evaluation start dates—remains missing from HRSA's data collection plans, yet these elements contain information that is essential to drive improvement in transplant access and system performance.** Dialysis facilities play multiple critical roles in enabling patient access to transplant—in providing education about transplantation among other treatment options, in referring patients to one or more transplant centers for evaluation as prospective transplant candidates (we estimate dialysis facilities are the source of >75% of kidney transplant referrals nationwide), and in coordinating the patients' care leading up to and through the transplant evaluation. The collection of dialysis facility CCN is crucial for enhancing transplant access through measures of dialysis facility performance measurement and accountability, and improved transparency for patients and their family members when seeking high-quality dialysis and transplant care. These measures can also provide the needed information to support initiatives that promote referral at transplant centers; our studies have shown wide variability in referral rates across dialysis facilities, with the within-dialysis facility proportion of ESKD patients referred within 1 year ranging from 0% to 100%.[4] In other studies, we have shown that many patients drop off between referral and waitlisting, yet how dialysis facilities contribute or do not contribute to patients' progress through these steps remains understudied.[4] Including CCNs in national transplant data collection from transplant centers would enable linkage of transplant referral and evaluation data to dialysis facilities and the use of such information in dialysis facility-level quality metrics, including Dialysis Facility Compare, allowing for a more comprehensive assessment of access. Additionally, this linkage is crucial for research and quality improvement initiatives that quantify performance, identify facility-level barriers, and implement and evaluate targeted dialysis facility-level interventions. Further, this data element will allow referring health systems to understand and monitor transplant access-related quality measures, in alignment with ongoing CMS initiatives aiming to improve transplant access and outcomes.

We also observe that HRSA's data collection plan does not include the capture of data on transplant evaluation start. This information is essential for measuring time to complete key early steps of the transplant care process and for identifying delays in the process. Consequently, the absence of this information will greatly limit transplant centers', dialysis facilities', and researchers' ability to fully assess and improve early transplant access. Using data from E-STAR, our team has been a leading contributor to a growing body of research on variation and gaps in evaluation start rates across dialysis facilities, transplant centers, and regions.[4-6] In the Southeast (GA, NC, and SC), we have shown substantial variation in transplant evaluation start among those referred. In a study of >15,000 dialysis patients, only 16.1% of patients started the evaluation, and start rates varied from 0% to 100%.[4] In a later study including data from 36 transplant centers in the Southeast, New England, New York, and the Ohio River Valley, we showed that the 6-month evaluation start rate among those referred for kidney transplantation varied from 16% to 93%.[1,7] Further, a recent study by McPherson et al. identified substantial variation in evaluation start within six months of referral across transplant programs, and found that the referring dialysis facility's characteristics contributed meaningfully to this variation as well.[5] The substantial variation observed in these critical steps suggests that quality metrics using referral and evaluation start data are needed to assess center performance and adequately implement operational improvements. Without capturing this data element, we cannot accurately assess the impact of such interventions, changes in clinical care models, or new federal payment models, such as the Increasing Organ Transplant Access (IOTA) Model, on early transplant access.[12]

Lastly, appropriate technology adoption and well-thought-out collection procedures are essential to support high-quality data collection that is mindful of the resource constraints faced by transplant centers. Presently, there are limitations in the information technology (IT) infrastructure at transplant centers that will significantly impact the execution of the proposed data collection.

To mitigate challenges likely to arise due to the increased time burden on transplant centers associated with submitting these new data, particularly among transplant centers experiencing rises in low-quality referrals and/or staffing shortages (reported anecdotally by multiple transplant center leaders), we strongly recommend that this data collection proceed through quarterly batch submissions (rather than weekly or monthly) and incorporate a phased approach as transplant centers learn the submission requirements and refine submission processes. Further, mechanisms for data sharing via Application Programming Interfaces (APIs) and FHIR standards should be required and integrated into the procedures for this data collection to streamline data submission, reduce the time burden, and improve the quality of batch submissions, ideally moving to a more real-time data collection process after a phase-in period. HRSA should also consider working with leading health data standards teams (e.g., LOINC, SNOMED) to ensure data are standardized and will be pushed out to leading EHR vendors such as Epic and Cerner.

Instrumental to the success of the collection will be the allocation of time for piloting and refining this collection, which can be achieved through a phased approach. In alignment with the American Society of Nephrology, we recommend that this collection occur in three phases: 1) a pilot phase that allows for centers to opt-in to participate to gain experience and for HRSA, the OPTN, and transplant centers to implement necessary revisions to the collection and submission procedures, 2) a second phase involving mandatory collection period via batch submission or API, and 3) a final phase that would involve the fully automated submission across electronic medical record (EMR) vendors, supported by planned enhancements to IT.

As aforementioned, the current IT infrastructure at many transplant centers is not quite ready to support the proposed collection. Two levels of IT modernization are needed to ensure successful implementation. First, the OPTN IT system must be updated to enable patient identification prior to waitlisting. Second, the transplant center IT and EMR systems will require modifications to support batch submissions. Given the numerous competing priorities many centers face, the recommended phased implementation would allow adequate preparation of these systems and minimize disruption, while ensuring high-quality and sustainable data reporting.

The modernization efforts needed, as outlined in this comment, should be prioritized as part of the implementation of the *Securing the U.S. OPTN Act*, as they are urgent and essential to support planned batch submissions and ensure the success of the proposed collection initiative.

In summary, the Early Steps to Transplant Access Registry Executive Team reiterates its support for the collection of pre-waitlisting referral and evaluation-related data, as well as its potential positive impact on access to transplantation. However, we urge careful consideration of several key factors, as outlined in this public comment, before implementing this mandatory data collection. 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 Public Comment Request, and thank you for considering our response.

Sincerely,

Rachel E Patzer

Rachel Patzer, PhD, MPH, on behalf of the Early Steps to Transplant Access Registry Executive Team
President and CEO
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Supporting References

1. *Early Steps to Transplant Access Dashboard*. 2024. https://estardashboard.shinyapps.io/public/
2. Early Steps to Transplant Access Registry (E-STAR). Accessed 6/2/2025, 2025. https://estar-transplant.org/
3. Patzer RE, Plantinga LC, Paul S, et al. Variation in Dialysis Facility Referral for Kidney Transplantation Among Patients With End-Stage Renal Disease in Georgia. *314*. 2015;(6)doi:10.1001/jama.2015.8897
4. Patzer RE, McPherson L, Wang Z, et al. Dialysis facility referral and start of evaluation for kidney transplantation among patients treated with dialysis in the Southeastern United States. *Am J Transplant*. Jan 25 2020;doi:10.1111/ajt.15791
5. McPherson L, Plantinga LC, Howards PP, Kramer M, Patzer RE. Disentangling Dialysis Facility and Transplant Center Factors on Evaluation Start Following Referral for Kidney Transplantation: A Regional Study in the United States. *Kidney Medicine*. 2025/04/01/ 2025;7(4):100974. doi:https://doi.org/10.1016/j.xkme.2025.100974
6. Kelty CE, Buford J, Drewry KM, et al. Sociodemographic barriers to starting the kidney transplantation evaluation process and waitlisting in the Ohio River Valley. *American Journal of Nephrology*. 2025;doi:10.1159/000546108
7. Kelty CE, Buford J, Di M, et al. The Early Steps to Transplant Access Registry (E-STAR) dashboard: center-specific reporting on prewaitlisting data to improve access to kidney transplantation. *Current Opinion in Organ Transplantation*. 2025;30(2):130-138. doi:10.1097/mot.0000000000001202
8. Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *Am J Transplant*. Oct 2011;11(10):2093-109. doi:10.1111/j.1600-6143.2011.03686.x
9. Wolfe RA, Ashby VB, Milford EL, et al. Comparison of Mortality in All Patients on Dialysis, Patients on Dialysis Awaiting Transplantation, and Recipients of a First Cadaveric Transplant. *New England Journal of Medicine*. 1999;341(23):1725-1730. doi:10.1056/nejm199912023412303
10. Patzer RE, Buford J, Urbanski M, et al. Reducing Disparities in Access to Kidney Transplantation Regional Study: A Randomized Trial in the Southeastern United States. *Clinical Journal of the American Society of Nephrology*. 2025;20(2):256-266. doi:10.2215/cjn.0000000586
11. Patzer RE, Paul S, Plantinga L. A Randomized Trial to Reduce Disparities in Referral for Transplant Evaluation. *Journal of the American Society of Nephrology*. 2017 2017;28(3):935-942.
12. Increasing Organ Transplant Access (IOTA) Model. Centers for Medicare & Medicaid Services. https://www.cms.gov/priorities/innovation/innovation-models/iota