Ohio River Valley Transplant Coalition
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January 3, 2025

Carole Johnson
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Submitted electronically

RE: Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx—New

Dear Administrator Johnson,

On behalf of the Ohio River Valley Transplant Coalition 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 on the necessity and recommendations on HRSA's intention to collect information on pre-waitlisting transplant care events.[1,2] For over seven years, the Ohio River Valley Transplant Coalition, serving patients and providers across Indiana, Kentucky, and Ohio, has been a collaborative network of kidney transplant providers, patients, and advocates dedicated to advancing transplantation care and outcomes. Thus, we recognize the tremendous step this proposed national data collection effort represents in addressing disparities and enhancing equitable access to transplantation opportunities across diverse patient populations. Our public comment serves to emphasize the necessity and utility of this data collection and makes several recommendations to improve these efforts to strengthen equity, access, and transparency in the transplantation process.

Briefly, our organization is supportive of the collection of pre-waitlisting data, and we have several points in this letter and suggestions for improvement.

1. HRSA should consider the inclusion of standardized social risk factors or social drivers of health (SDOH) data collection at the time of referral and evaluation start and we suggest HRSA consider working with the national Gravity Project to ensure data standardization and alignment.
2. The collection of Social Security Numbers, and not just Medical Record Numbers, will be critical to linking these data across other data sources to identify patients with organ failure.
3. Transplant centers have substantial shortages in the nephrology workforce, and pre-transplant processes can be time-and labor- intensive and may require hiring additional staff. These challenges must be addressed by ensuring transplant centers can cover these costs.

4. Preliminary data from >35 transplant centers across the country have demonstrated that at least some of these data elements are feasible to collect, but there may need to be a phase-in or period of voluntary data collection (e.g., first year) to ensure programs have enough time to conduct appropriate data quality work to ensure the data are valid and feasible to obtain.

5. Establishing concise and clear definitions for each of the early steps in the transplant process to ensure consistency across transplant practices. Currently, practices vary significantly, particularly regarding when the evaluation process begins (e.g., initial visit, chart review, etc.). Standardized definitions will promote uniformity and improve the accuracy and comparability of data collection.

6. We recommend using more advanced IT processes to automate the submission of these data, such as the use of software for automated referrals, and/or use of Application Programming Interfaces to collect these data, and/or submission of these data elements as a "batch submission" and ultimately real-time data collection, rather than adding new forms at different time points to collect for each patient at the time of the transplant phase to reduce data burden.

Calls for national data collection have persisted for decades, and the proposed initiative represents an important opportunity to enhance transparency and advance equity in access to transplantation. The disease burden of end-stage kidney disease is substantial in the United States.[3] Although transplantation is the optimal treatment for most patients, access is limited and variable.[3-6] The cost-effectiveness of transplant[4-6] underscores the need for increased efforts to improve access and this cannot be done without understanding upstream (pre-waitlisting) steps and barriers in this complex process. Access to kidney transplant and placement on the waitlist for transplant have been well-studied; however, the ability to critically understand why only *some* patients are referred, evaluated, or selected for listing, while others are not, is hindered by the lack of these data. Studies using the only multi-regional database capturing referral and evaluation data, the Early Steps to Transplant Access Registry (E-STAR), show substantial variability in dialysis facility-level referral and evaluation start rates in GA (range: 0% to 75%)[7], the Southeast (GA, NC, SC)[8], and in other regions (range: 0% to 90%)[9] participating in this voluntary data registry of pre-waitlisting steps managed by the Regenstrief Institute, Indiana University, and Emory University teams. Further, research has highlighted that barriers and facilitators at each step in the kidney transplant process vary.[8,10] This further emphasizes the need for national data collection to understand and intervene on factors causing differential access, as well as provide necessary information to help patients make informed decisions about program selection. Indeed, E-STAR demonstrates the feasibility of collecting comprehensive data on pre-waitlisting care processes across multiple transplant centers and regions, highlighting its value as a resource that can be leveraged to inform HRSA's initiatives. **We echo decades of calls and emphasize the overarching need for the collection of 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.** Such transparency also enables and strengthens research and quality improvement efforts that advance and ensure the performance of the HRSA

in alignment with its mission to "improve health outcomes and achieve health equity through access to quality services, a skilled health workforce, and innovative, high-value programs."[11]

HRSA's announcement of national data collection (2024) is only the most recent signal of rising national recognition of the importance of this issue. Increased recognition of the need for this pre-waitlisting data collection has been widespread following decades of support from researchers, clinicians, patients, and a recent National Academies of Sciences, Engineering, and Medicine report. Notably, in 2021, the Centers for Medicare and Medicaid Services (CMS) Technical Expert Panel (TEP) to develop practitioner-level quality measures for dialysis facilities that allow measurement of patients' access to kidney transplantation[12] highlighted the need for national data on referral as a more proximal step under the influence of clinicians caring for dialysis patients.[13] On the transplant program side, the members of the kidney disease community at an SRTR Consensus Conference (2022) and a 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.[14] **The 2022 National Academies of Science, Engineering, and Medicine (NASEM) report has called for prioritizing efforts to improve access to kidney transplantation through the creation of a more equitable, cost-effective, transparent, and efficient system for the procurement, allocation, and distribution of deceased donor organs**. Further, the report emphasized the "need to create new performance metrics for transplant centers…to include a focus on equity in access to transplant referral and evaluation, as well as equity in access to transplant."[15] This widespread recognition of the value and necessity for national pre-waitlisting data was culminated by the OPTN Modernization Initiative (2023), the organization of the Organ Transplantation Affinity Group with a goal to reduce variation in pre-transplant and referral practices, and the inclusion of referral information within the CMS-2728 form (announced in 2023, added in June 2024). However, we would note that the new CMS 2728 form field capturing information on referral for transplant, while significantly valuable, is not enough to advance the goal of improving transplant access for all individuals with kidney disease because the 2728 form is only collected for individuals with diagnosed end-stage kidney disease. Transplant access for individuals pre-emptively referred for transplant evaluation – that is, referred before initiating dialysis treatment (conventional non-transplant therapy for patients with end-stage kidney disease) – are not captured in this database. Understanding the care experiences of these patients is valuable because, on average, their transplant care and health outcomes are superior to patients receiving a transplant after starting dialysis.[16]

Further, these data will support the expansion of research and quality improvement activities to build understanding and describe inequities as well as to develop and effectively implement interventions to improve patient care and care systems. The Ohio River Valley Transplant Coalition believes that national pre-waitlisting data would allow for improved quality metrics better aligned to create a more equitable system. Kidney transplant program performance in the U.S. is commonly measured by transplant rates and short-term post-transplant outcomes, with few quality metrics used to evaluate patient access to

kidney transplant. The proposed data can be utilized to inform the creation of new metrics that provide a more comprehensive assessment of transplant program performance and provide necessary information for patient decision-making. Further, this data can also inform the creation of effective interventions and tools aimed at creating equitable access for patients. There are strong synergies to be leveraged given the active efforts to collect and use data on patients' social determinants of health (SDOH) as demonstrated by the OPTN's recent report on the relationship between SDOH and waitlisting outcomes.[17] There is strong evidence that social factors are often among the most significant drivers of early transplant access. Taken together with newly gathered information on pre-waitlisting care events, there are tremendous opportunities to significantly improve transplant access, particularly for patients in socially disadvantaged communities. HRSA and OPTN should consider the inclusion of the collection of social risk factor data within this data collection initiative given some of the unique social needs of patients pursuing a transplant. Importantly, the Gravity Project, launched in 2019, has been working to build and establish "consensus driver social determinants of health data standards for health and social care interoperability and use among multiple partners."[18] Given their extensive experience, HRSA should consider working with the Gravity Project to ensure alignment of the documentation of social determinants of health-related data. In addition to the necessity for the inclusion of data on social risk factors, a key component of understanding and addressing barriers and disparities in access to referral lies in the ability to link this proposed pre-waitlisting data with existing datasets on individuals with organ failure (e.g., End Stage Renal Disease Quality Reporting System and United States Renal Data System data). However, critical to this linkage is the collection of Social Security Numbers (SSNs) by HRSA and OPTN, and not just Medical Record Numbers, as SSNs remain the identifier most used by these other data systems and will be necessary for accurate data integration.

Lastly, it is essential to accurately estimate the burden and hesitations experienced by transplant centers due to concerns of resource limitations and lack of transparency regarding the specific requirements for data collection. Efforts to explore efficient data collection techniques should be prioritized. While we strongly support the proposed initiative, we must express concern about the increased time burden on transplant centers, particularly given the rise in low-quality referrals and ongoing staffing limitations. To mitigate these challenges, the CMS cost report should be updated to accommodate changes in the workforce within centers necessary to support the collection of this data. Also, we strongly recommend that this data collection proceed through quarterly batch submissions to reduce the time burden on centers and incorporate a phased approach. Further, the OPTN should include time for pilot testing, necessary revisions, and a period of voluntary submission to allow transplant centers to prepare for the substantial effort required for these submissions. As aforementioned, the feasibility of this data collection is demonstrated by the Early Steps to Transplant Access Registry (E-STAR). Thus, HRSA and OPTN should consider developing an advisory panel of experts who have worked in this space and engaging voluntary E-STAR participants to pilot test this initiative, which will help refine best practices, address potential challenges, ensure high data quality, and optimize processes for broader implementation of the

data collection framework. Additionally, mechanisms for data sharing via Application Programming Interfaces (APIs) should be explored and integrated into the procedures for this data collection to streamline data submission, reduce the time burden, and improve the quality of batch submissions, with funding for these efforts included as part of the OPTN modernization initiative. Ultimately, these data could be collected in real-time via APIs or FHIR connections between the transplant center and an OPTN vendor.

In summary, the Ohio River Valley Transplant Coalition supports the collection of pre-waitlisting referral and evaluation-related data and its potential positive impact on access to transplantation for the over 500,000 patients on dialysis in the United States. 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 Request for Information and we thank you for your consideration of our response.

Sincerely,

Anne Huml
Anne Huml (Jan 3, 2025 07:46 MST)

Anne Huml, MD on behalf of the Ohio River Valley Transplant Coalition

Chair, Ohio River Valley Transplant Coalition

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