

We are writing in response to the recent HRSA directive mandating the expansion of data collection through the Organ Procurement and Transplantation Network (OPTN). While we recognize the importance of comprehensive data collection in improving transplant outcomes and advancing equity, we must express significant concerns regarding the feasibility and potential unintended consequences of this mandate.

While the expansion of data collection may seem like a positive step toward enhancing transplant practices, it is critical to address several substantial issues that may arise from this initiative. Below are our main concerns:

- ❖ **Data Submission Modality:** One of the most pressing concerns related to the expanded data collection mandate is the logistical challenge of submitting data through individual forms for each patient. This process is highly inefficient and time-consuming, particularly for larger transplant centers with high patient volumes. To streamline this process and reduce administrative burden, we strongly appeal that HRSA and OPTN allow for the submission of data via batch processing rather than requiring individual data entry for each patient. A batch submission system would significantly improve efficiency, reduce errors, and allow transplant centers to manage data reporting in a way that minimizes disruptions to patient care and administrative workflows. We believe this would also improve the overall accuracy and timeliness of data submissions, ensuring a more effective system for both transplant centers and regulatory bodies.
- ❖ **Excessive Administrative Burden:** The directive places an unrealistic burden on transplant centers, particularly smaller and community-based programs, which are already under-resourced. The need to collect, validate, and report additional data will require significant staff time and financial resources. Given the current staffing shortages in many transplant centers, this mandate could lead to burnout among clinical and administrative teams, and potentially detract from the quality of patient care. Unless adequate resources, including funding for additional personnel and technology upgrades, are provided, this new requirement risks overwhelming centers and affecting the quality of services provided to transplant recipients.
- ❖ **Unclear Resource Support:** HRSA's directive lacks clarity on the specific resources that will be provided to support the implementation of expanded data collection. Transplant centers need clear guidance on how they will be supported in managing these new responsibilities, including access to technical assistance, funding, and infrastructure. Without tangible support, transplant centers will face a significant financial strain, particularly those that are already operating with tight margins. The

absence of a robust support system suggests a top-down approach with little consideration for the realities on the ground.

- ❖ **Data Quality Concerns:** The expanded data requirements may dilute the quality of the data collected if there is insufficient standardization or guidance on how to accurately collect and report these new data points. While we understand the desire for comprehensive data to drive policy decisions, without proper training, implementation support, and oversight, there is a significant risk that centers may report inaccurate or inconsistent data, ultimately undermining the very goals of the initiative. It is critical that HRSA provides clear, practical guidelines and ongoing support to ensure that data integrity is maintained. Clear and consistent data definitions are also essential to ensuring the accuracy and reliability of the information collected. Without standardized definitions, there is a risk of misinterpretation or inconsistent reporting, which can undermine the validity of the data and the conclusions drawn from it, ultimately affecting decision-making and policy development.
- ❖ **Impact on Patient Care:** Given the additional administrative tasks associated with this new data mandate, there is a legitimate concern that clinical teams will be diverted from their primary mission of delivering high-quality care to transplant patients. With the added pressure of meeting reporting deadlines and ensuring compliance with expanded data requirements, it is possible that the time and attention needed for direct patient care could be compromised, particularly in centers already struggling with workforce shortages. This could have a detrimental effect on patient outcomes, particularly for those in urgent need of transplantation.
- ❖ **Equity and Inclusivity Issues:** While the intent to capture data on health disparities is commendable, we remain concerned that the expanded data collection will not adequately address systemic barriers to care. The focus must not only be on data reporting but also on ensuring that the data collected leads to actionable changes in policy and practice that address the root causes of inequities. We urge HRSA to ensure that this data collection initiative is accompanied by concrete steps to address disparities, including targeted interventions for underserved populations and transparency in how the data will be used to drive equitable outcomes in organ allocation and post-transplant care.

While we agree with the long-term goals of expanding data collection to improve outcomes and address disparities, we are deeply concerned about the immediate feasibility of this mandate, especially in the absence of adequate support and resources. We strongly urge HRSA to reconsider the timing and scope of this directive, to provide clearer guidance and

financial support, and allow for batch data submission to develop a more sustainable and realistic plan for implementation.

We look forward to further dialogue on this issue and remain committed to working together to improve transplant practices. However, we believe that HRSA must consider the operational realities faced by transplant centers to ensure that any new mandates do not inadvertently undermine the quality of care or the overall effectiveness of the transplant system.

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