

December 23, 2024

HRSA Information Collection Clearance Officer
Room 14NWH04
5600 Fishers Lane
Rockville, MD 20857

Department of Health and Human Services, Health Resources and Services Administration:

We appreciate the opportunity to comment on the proposal to expand data collection. While we acknowledge the potential value of collecting data to improve healthcare outcomes and address disparities in the Organ Procurement and Transplantation Network, we have several concerns and recommendations regarding the proposed information collection expansion, particularly the Referral Form.

Necessity and Utility of the Proposed Information Collection

The stated goals of the data collection — improving access to care, addressing disparities, and ensuring patient safety — align with our organization's mission. However, the necessity and utility of the specific data points to be collected, particularly regarding who is referred, who does the referring, and the referral outcome, are not entirely clear nor evidently uniform among heterogeneous health systems. While these data may be perceived to offer insight into system performance, the direct impact on improving patient outcomes or healthcare delivery is not fully articulated in the proposal, there is not sufficient information to effectively define referrals within disparate health systems, nor would there be enough context provided as to an outcome of a referral made.

A critical concern is that the expanded data collection on referrals may inadvertently lead to an unintended consequence: the potential for turning patients away from evaluation based on information at time of their referral rather than allowing the opportunity to be seen and assessed by a transplant team. Such an outcome would be contrary to our goal of providing patients with equitable access to care, especially for individuals from underserved or underrepresented communities. Pseudo-selection criteria would be applied to referrals to move forward with the initial consult for potential evaluation.

Additionally, the variable definitions of what constitutes a "referral for transplant" across providers, institutions, including a patient's understanding of a referral (if self-referring), create ambiguity and pose challenges for consistent data collection. A clear and standardized definition of a "transplant referral" would need to be defined and agreed upon by the community to allow consistent interpretation of these data from disparate health systems. Without this, the data collected may not accurately reflect the true referral landscape or provide the clarity needed for effective policymaking. However, it is not clear that a uniform definition is achievable. As some transplant programs are also responsible for substantial disease management activities in addition to transplant while others are more transplant specific, a 'referral' to the transplant program may represent a wide range of clinical intentions by referring clinicians and may have no relation to transplant processes.



Accuracy of the Estimated Burden

While we understand the goal of collecting additional data to improve healthcare outcomes, we are concerned that the burden estimate may not fully account for the time and resources required to implement and execute these new data collection processes. We believe that the current estimate underrepresents the resources needed to effectively implement the proposal, particularly in smaller healthcare settings where administrative capacity may be more limited.

Ways to Enhance the Quality, Utility, and Clarity of Information

To maximize the effectiveness and utility of the data collected, we offer the following recommendations:

- **Standardization of Definitions:** It is crucial that a clear and standardized definition of a "transplant referral" be established and communicated to all involved in the data collection process. This definition should consider the wide variability in referral practices across healthcare institutions to ensure consistency in reporting and meaningful data analysis.
- **Transparency of Purpose and Benefits:** We recommend clearly outlining the specific benefits of collecting each data point and how it will contribute to improved access, reduced disparities, and better patient outcomes. This clarity will help healthcare providers understand the value of the data collection process and ensure their continued engagement.

Use of Automated Collection Techniques and Information Technology

Given the complexity of the data collection process and the anticipated burden on healthcare providers, we strongly encourage the use of automated collection techniques to minimize administrative load. Integration of the new data fields into existing Electronic Health Records (EHR) systems or development of a centralized data submission platform would streamline the collection process. We would strongly encourage adequate time to allow participation from existing EHR systems that support current reporting requirements to have the opportunity to develop the infrastructure needed to ensure smooth implementation.

Inova Transplant appreciates the opportunity to provide feedback and hopes that the concerns outlined here will be considered to ensure that the data collection process is both effective and feasible for all stakeholders involved.

Sincerely,

A handwritten signature in blue ink, appearing to read "Shashank Desai", with a long horizontal flourish extending to the right.

Shashank Desai, MD, MBA
Executive Director of Thoracic Transplant