January 3, 2025

Health Resources and Services Administration (HRSA)
Department of Health and Human Services (HHS)
Room 14NWH04, 5600 Fishers Lane
Rockville, MD 20857

Subject: Public Comment on Proposed Data Collection for Organ Procurement and Transplantation Network (OPTN) [Docket No. 2024-25522]

Dear HRSA Information Collection Clearance Officer,

Thank you for the opportunity to provide feedback on HRSA's proposed data collection expansion. Epic is a developer of health information technology software used by many healthcare organizations in the United States, including for transplant services. Our feedback in this letter is informed by our experience developing software used by 65% of transplant centers, performing over 80% of the transplants in the United States, and by what the users of our software have shared with us.

We commend HRSA's efforts to enhance the organ procurement and transplantation process. We agree that having more comprehensive and standardized data on pre-waitlist transplant patients is crucial. Such data can significantly enhance our understanding of the barriers to transplantation, including financial, socioeconomic, and geographical challenges. By identifying and analyzing these barriers, we hope HRSA, along with other partners in the transplant community, can develop more effective strategies to address them, ultimately improving access to transplantation for all patients in need.

Our comments focus on several key areas: electronic submission methods, definitions of referral and evaluation, the referral and evaluation forms, and implementation timeline.

Electronic Submission Method

We strongly recommend the inclusion of an Application Programing Interface (API) for transplant centers to use to bulk submit electronic data. This API should use healthcare industry standards such as FHIR to leverage existing industry investments and streamline the data submission process.

The API should also use the industry standard data set of the United States Core Data for Interoperability (USCDI) or USCDI+, to maintain consistency and relevance. We understand that transplant-specific data points are not included in USCDI domains today, so we encourage working with ONC-ASTP to enhance existing USCDI and USCDI+ for transplant interoperability.

Defining Referral and Evaluation

Clear definitions of what constitutes a referral and when a patient transitions from referral to evaluation are crucial. Inconsistencies across transplant centers can lead to data discrepancies and hinder the evaluation process. We recommend establishing standardized definitions to ensure uniformity and reliability in data reporting.

For example, in the proposed referral form there are currently two definitions for Evaluation Started: *Patient began testing for evaluation* and *Patient completed the initial visit for evaluation*. Having two definitions for evaluation start will lead to reporting inconsistencies across transplant centers.

Referral and Evaluation Forms

We seek clarification on the specific circumstances under which the referral and evaluation forms are required. It is essential to define the submission timeline clearly and to consider the feasibility of bulk submissions to minimize the administrative burden on health systems. Here are several specific recommendations:

- Forms should only be required when there is a change in the patient's status to reduce reporting burdens.
- There should be clear definitions of when a patient is included in the submission period to ensure consistency and accuracy. For example, the selection committee decision fields are required. Should centers only report evaluation patients after they've been presented at committee?
- As mentioned above, the ability to bulk submit/upload these forms should be implemented to streamline the submissions process in conjunction with an electronic API. This would match existing functionality that transplant centers use with the UNOS TIEDI electronic submissions API.

To improve efficiency, we suggest consolidating multiple forms into a single dynamic form that captures all necessary data based on the organ being listed. This approach will reduce redundancies and streamline the data collection process. For example, when a patient moves into the evaluation process, do not require a separate referral closure form since it can be inferred that the patient's referral was accepted in this circumstance.

Additionally, it will be important to handle the complexities of multiple-organ transplants without adding administrative burden on transplant centers. For example, will an individual form be needed for each organ? How will centers document adding an organ for consideration in the middle of a patient's evaluation, such as referring and evaluating a patient for a pancreas while they are already being evaluated for a kidney?

Implementation Timeline

The implementation timeline for the new regulations should allow sufficient time for technical support and transplant center adoption. This will require changes in technical infrastructure, staffing, and clinical protocols. Allowing at least 12 months of preparation time after the relevant data points are included into USCDI standards and upon release of final technical specifications is critical. A phased approach with adequate training and resources will enable health systems to

adapt to the new requirements effectively. Additionally, aligning the timing with other regulatory changes for transplant centers will reduce the burden of change management.

Conclusion

We appreciate the opportunity to provide comments on the proposed data collection for the OPTN. We believe that our recommendations will help enhance the efficiency and effectiveness of the organ procurement and transplantation process while minimizing the administrative burden on health systems. We look forward to continued collaboration with HRSA to achieve these goals.

Thank you for considering our comments. We would be happy to answer any questions you might have on our feedback and discuss how we can work closely with HRSA and OPTN to advance this data collection expansion.

Sincerely,

Patrick Lammert

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