From: Maxmeister, Christine
To: HRSA Paperwork
Cc: Monroe, Heidi K; Pickar, Bennett; Reilly, Joseph
Subject: [EXTERNAL] Comments regarding Information Request Title: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx-New.
Date: Friday, January 3, 2025 9:55:36 AM
Attachments: UCHealth Pre-WL Response_010225.docx

To Whom It May Concern:

Thank you for the opportunity to comment on the Information Collection Request Process Data for Organ Procurement and Transplantation Network, OMB No. 0906-xxxx—New. On behalf of the UCHealth University of Colorado, COUC, Transplant Center Informatics and Quality Teams, (supporting a large center transplanting over 550 patients annually - adult kidney, pancreas, liver, lung, and heart) we are sharing feedback regarding the Pre-waitlist Data Collection portion of the proposal.

We agree with HRSA that collecting data throughout a patient's transplant journey is important and may highlight areas where opportunities for improvement exist, including access inequities and bias. Equally important, though, is to develop a manner of data collection that does not increase the burden of work of the transplant center or require additional FTE. The collection should focus on clinically relevant elements and result from capitalizing on technical capabilities between the EHR vendors and transplant centers, the use of APIs, and the standardization of data definitions.

Data Flow and Cadence
Although the proposal does not specifically address how these data are to be gathered from transplant centers, it does mention the term "forms" throughout. We encourage HRSA to consider that since this data is not needed in real-time, it could be collected retrospectively via an API between UNOS (or any other OPTN contractor) and each EHR vendor. If mapped correctly in the EHR, the data could be pushed on a quarterly basis through the API. Transplant centers would need to ensure their documentation workflows were standardized with high compliance rates to support this process. Fortunately, many centers have this type of support in place already and would, likely, require a one-time heavy lift for initial mapping, with periodic increased support when upgrades are implemented.

This strategy could greatly reduce the need for adding additional FTEs to manually complete additional forms, and more importantly, duplication of already existing data. That said, it is critical that HRSA engage with EHR vendors now to ensure that they have time to develop the needed changes prior to the implementation of these updates.
Additionally, we recommend appropriate data be carried forward, i.e. demographic information, and verified by transplant center personnel, to reduce workload burden.

Data Definitions – Why & What
Providing clear, unquestionable definitions and rationale for these data elements is critical so all know exactly what data is being collected, correct data can be mapped, and the same data is standardized across all centers. In an effort to improve consistent and accurate data capture, please find specific recommendations below.

Pre-waitlist Referral Form – Field and Instructions Feedback
We recommend including a definition and start and end points for what constitutes a referral. **Proposed Referral definition**: The organ transplant referral phase begins with the date of notification to the transplant team of the following: Minimum of three patient identifiers (name, birth date, birth sex) and patient contact information. The organ transplant referral phase ends with the notification to the transplant team of any of the following: initial visit with the patient begins (in-person or virtual encounter) or the patient completes testing ordered by the transplant team. At this time, the referral closure and reasons are documented.

Please note that not all required fields can be completed by the transplant center if a patient does not respond to communication. Recommend reconsidering required fields to only include the three patient identifiers mentioned above.

Field label	Feedback on Field	Feedback on Instructions
Organ	Recommend excluding multi-organ options. Data collection should occur for each organ individually, thereby requiring a referral for each organ. If the patient becomes a multi-organ candidate after initially being referred for a single organ, another referral should be placed.	
Middle name	Recommend removing. Frequently is not provided at the time of referral nor is it required on any other TIEDI form.	
Ethnicity	Recommend removing. Not patient reported at time of referral, risk of inaccurate data.	
Race	Recommend removing. Not patient reported at time of referral, risk of inaccurate data.	
Primary phone number	Recommend removing. Patient will not be contacted from this data collection.	
Permanent street	Recommend removing. Patient will not be contacted from	

address	this data collection.	
City of permanent address	Recommend removing. Patient will not be contacted from this data collection.	
State of permanent address	Recommend removing. Patient will not be contacted from this data collection.	
Source of payment/primary	Rename to Primary Payment Source	
Source of payment/secondary	• Rename to Primary Payment Source • Use of Pending as an option Options still TBD, could utilize options in primary.	
Referral date	• Recommend broadening the definition as provided at top of table. Please note that format of communication varies (fax, phone, note, medical record notification, etc.) and can come from a variety of sources. • Recommend including another element of Referral source (patient, healthcare provider)	
Referring provider NPI	• Not always collected. • Referring provider is not always in the EHR system and can take weeks to be added. • Burdensome to gather, increases difficulty to automate the form. • Need option for self-referral, dialysis center social worker	
Referral status	• Recommend 3 options: Active, Moved to Evaluation, Closed • Details of referral closure are not applicable for lung because referrals stay open for significant time.	
Referral status/Referral closure reason *(Conditional, if Referral Status is Closed)*	• Remove: Closure due to evaluation started if adding a 3rd reason for Referral Status. Include the Evaluation started reasons under that option. • The reasons should be broader to discretely pull from an EMR. • Include 'Insurance denied' separate from Financial. • Include 'Medical complexity' separate from Too sick for transplant. • Cancelled due to error – include "duplicative referral received within the last 30 days". • Recommend removing Patient age. This is noncompliant with the Affordable Care Act Section 1557. • Recommend removing Patient unable to adhere – there is no data to collect at time of referral. • Recommend removing Refusal to vaccinate – there is no data to collect at time of referral. Collecting this information would place increased burden on referring providers and transplant centers. • Recommend removing Surgical complexity – there is no data to collect at time of referral. Collecting this information would place increased burden on referring providers and transplant centers. •	• Financial/insurance issues option needs to be better defined. • Options 'active mental/behavioral health barriers' and 'patient unable to adhere' have overlap and should be combined. • The financial/insurance issues reason should not include immigration status and/or homelessness. • Allow multi-select capability.
Referral status/ Referral closure date *(Conditional, if Referral Status is Closed)*	Recommend making this required only if the patient dies, the date is available, and occurs before the referral closes.	
Referral status/Death date *(Conditional, if Referral Closure Reason is Patient*	• Referral closure date before Death date on the form.	

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Please consider adding these additional fields:

Field label
Evaluated and declined by another center for transplant: yes/no/unknown

Pre-waitlist Evaluation Form – Field and Instructions Feedback
We recommend including a definition and start and end points for what constitutes an evaluation. **Proposed Evaluation definition**: In the evaluation phase, medical and non-medical information is gathered about the patient so that the multidisciplinary selection committee can determine whether the patient is suitable for transplant surgery. The organ transplant evaluation phase begins when the patient consents to complete this review process after either arriving for their first appointment associated with their transplant evaluation, as authorized by their insurance, or by completing evaluation testing prior to being seen for the transplant evaluation – whichever occurs first. The evaluation phase ends with the date of the first final decision from the multidisciplinary selection committee – either Approved to List or Denied.

Field	Feedback on Field
Organ	Recommend excluding multi-organ options. Data collection should occur for each organ individually, thereby requiring an evaluation for each organ. If the patient become a multi-organ candidate after initially being evaluated for a single organ, another evaluation should be started and would align with its corresponding referral.
Middle Name	Recommend removing. It is not required on any other TIEDI form.
Primary Phone Number	Recommend removing. Patient will not be contacted from this data collection.
Permanent Street Address	Recommend removing. Patient will not be contacted from this data collection.
Source of Payment/Primary	• Rename to Primary Payment Source • Recommend removing “Pending” as authorization for transplant evaluation has already been obtained at this point in the process.
Source of Payment/Secondary	• Reword to "Secondary Payment Source" • Options are listed as TBD.
Working for Income	• Recommend clarifying intention for data collection. • Recommend clarifying the need to differentiate between the different categories. Would working for income: yes/no meet the same need? • Recommend clarifying the difference between part-time vs. casual vs. seasonal employment.
Height	• Recommend removing since BMI is captured. • If it will not be removed, then recommend adding a not available option (if patient drops out or is declined prior to measurements being collected).
Weight	• Recommend removing since BMI is captured. • If it will not be removed, then recommend adding a not available option (if patient drops out or is declined prior to measurements being collected). • Since full evaluations can take time to complete, recommend clarifying the timeframe for this variable, i.e. weight at time of initial evaluation visit or most recent.
Primary Diagnosis	• Recommend reconsidering definition and removing “If the candidate has had a previous transplant for the same organ type, use Retransplant/Graft Failure as the primary diagnosis for that organ”. If retransplant and graft failure are variables that would be helpful to collect, consider adding additional data collection fields. • There are no listed values provided. Recommend that these options match diagnosis options used in other TIEDI forms. • Recommend removing “unknown” as an option as this is not clinically applicable.
Selection Committee Date	• Recommend altering definition to the date of the first final decision from the multidisciplinary selection committee – either Approved to List or Denied.
Selection Committee Decision/Declined Reason *(Conditional, if Selection Committee Decision is Denied)*	• Consider renaming section to align with previously use language: Selection Committee Decision/Denied Reason • Reasons for denying a patient can be multifactorial. Consider allowing multiple options to be selected. • Recommend removing Patient Age for same reasons shared in Referral section. • Active mental/behavioral health barriers: recommend that the section about adherence be moved to reason "patient unable to adhere" as these fields might otherwise be used interchangeably leading to poorer data collection.

	• Consider removing “immigration status and/or homelessness” from Financial/insurance issues. • Consider removing “transition to hospice” from patient choice.

Please consider adding these additional fields:

Field label
Evaluated and declined by another center for transplant: yes/no
Initial Evaluation Appointment Completion Date: As defined by UNOS Data Advisory Committee recommendations.
Evaluation Status/Evaluation Cancellation Reason: How will cancelled evaluation be managed in this data collection?

Thank you again for the opportunity to provide this feedback.

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