July 24, 2025

HRSA Information Collection Clearance Officer
Room 14NWH04
5600 Fishers Lane, Rockville, Maryland, 20857
(submitted via https://www.reginfo.gov/public/do/PRAMain)

Re: Public Comment Request: Data System for Organ Procurement and Transplantation Network (OPTN), OMB No. 0915-0157-Revision

The Association of Organ Procurement Organizations (AOPO) appreciates the opportunity to provide comments in response to the *Public Comment Request: Data System for Organ Procurement and Transplantation Network (OPTN)*.

AOPO represents 46 federally designated, non-profit Organ Procurement Organizations (OPOs) in the United States, which together serve millions of Americans. As an organization, AOPO is dedicated to providing education, information sharing, research, technical assistance, and collaborating with OPOs, donor hospitals, transplant centers, patient advocacy organizations and other stakeholders, and federal agencies to continue this nation's transplantation success while consistently improving towards the singular goal of saving as many lives as possible.

AOPO endorses the recommendations contained in the OPTN Executive Committee's comments submitted in response to the Information Request. The Executive Committee's comments were based on the recommendations of the OPTN Member and Professional Standards Committee's (MPSC) paper, *Concepts for OPOs Referral and Evaluation Data Collection Process* ("MPSC Paper"). It was developed by donation and transplant professionals with expertise and experience working with the relevant data. AOPO encourages HRSA to review and incorporate the t MPSC paper as HRSA considers approaches to accurately measure and improve the donation and transplantation system.

Data Collection Related to Process Components

AOPO endorses the effort to collect performance data from OPOs and other system participants and stakeholders with the goal of developing performance measures that accurately assess member performance, drive system improvement and increase donation and transplantation. Data on specific process components will facilitate identification of both effective practices and areas for improvement. Accurately measuring specific performance points in the donation process will assist OPO professionals in identifying and implementing effective practices employed by high performing OPOs.

AOPO also supports the increased collection of data on process points, especially data that provides insight into the timeliness or tardiness of referrals from donor hospitals to OPOs, to inform efforts to optimize the donor referral process and increase the number of lives saved through transplantation.

Importantly, expanding data capture to include all ventilated referrals from a donor hospital will provide a wider lens on the number and disposition of potential donors. Currently, the ventilated referrals reported through the OPTN comprise approximately 5-10% of all ventilated referrals and does not capture referrals that do not become donors (e.g., they are ruled out medically, do not become asystolic in the timeframe necessary for donation). Even for referrals that do not become donors, OPOs must perform several steps in the donation process (e.g., initial screening, family approach, diagnostic testing), none of which are captured in the OPTN data for referrals that do not become donors. Capturing all ventilated referral data will provide an accurate view of the scope of OPO work, provide a data source to accurately assess OPO performance within the pool of potential donors in its DSA, and facilitate identification of process barriers to inform system performance improvement efforts.

Clarification and Standardization of Data Elements and Definitions

The proposed data collection tools include 48 main data points with limited definitions. Approximately 6 (13%) of the data points are not currently collected by all OPOs. An additional 13 (27%) could be collected with additional clarification and some data translation. Nine (19%) of the 48 are available for collection. The remaining 20 (42%) are currently being collected on existing forms. AOPO has identified barriers for OPOs to collect some of the data proposed for collection. We appreciate the exclusion of three fields identified as not currently collected but are disappointed that other substantive comments were not addressed in the revision. The form in its current state has challenges and will not meet the goals of the data collection effort due to not collecting data in a granular way. We urge HRSA to listen to the experts from AOPO and MPSC so that we can truly drive process improvement using this form.

Many of the proposed data elements lack definitions, creating a risk of inconsistent interpretations of the data requested and inconsistent reporting. Standardized definitions are critical to ensure consistent data collection to support performance improvement efforts. AOPO strongly encourages HRSA to adopt the data definition recommendations set forth in the MPSC Paper input from donation and transplant professionals with deep experience and knowledge of the donation and transplant process and associated data points. As the MPSC notes in its comments on the proposed rule, some of the questions and proposed response options lack the granularity required to make the data meaningful. For example, during the Terminal Step, the proposed response options for Case Disposition are not mutually exclusive nor complete. An authorized party can deny authorization prohibiting the OPO from moving forward. This is captured in a field, but not as a terminal step. Hospital interference is not mutually exclusive to the rest of the terminal steps in all cases. As an example, a referral could be made outside of timely requirement and still become a donor. A hospital can also interfere in ways that are ultimately overcome by the OPO. Having Hospital interference as a terminal step leaves the OPO to only report it if the case does not move forward due to that interference. Additionally, a significant problem with collecting interference data is that OPOs are collecting these instances and they follow up differently, so these data will not be consistent across OPOs.

Addressing Challenges to Data Collection

Implementation of standardized data collection, including some new data elements, will require collaboration with OPO software vendors to create fields for the OPOs to capture the required data. AOPO estimates it would take 6-14 months to develop specifications, test and implement this full dataset into the existing OPO electronic donor records systems. Once developed, OPOs must train staff and implement the changes. AOPO strongly recommends HRSA proactively consult with software vendors to identify and address software revisions necessary to capture the additional data.

Further, due to the volume of ventilated referrals, AOPO strongly recommends the OPTN work with software vendors to develop a way to electronically import data from the EDR to the OPTN system. This development time is included in the 6–14-month timeline stated above.

AOPO estimates approximately 60-90 minutes for OPOs to complete each form if entered manually.
Since the number of ventilated referrals in the US is not reported anywhere, AOPO used a surrogate to estimate this number. AOPO obtained the number of Imminent and Eligible referrals from the DonorNet Monthly Donation Data Report, as reported by each OPO. Based on a survey of a subset of OPOs, the total number of Imminent and Eligible referrals comprise approximately 7% of total ventilated referrals. Extrapolating this over 55 OPOs, AOPO believes the estimated time burden would equate to:

- 55 respondents
- 6195 responses per respondent
- 340,731 Total responses
- 1.0 h – Average burden per response
- 340,731 Total burden hours

Finally, the ventilated patient form with our comments and recommendations on specific, individual data fields for your consideration is attached below and available here. We hope that HRSA will reconsider some of the comments here as well as from the MPSC paper.

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Sincerely,

Jeffrey Trageser
AOPO President
Executive Director
Lifesharing

Field Label	Availability	Feedback
Status	-	no feedback
DonorNet Donor ID	Available, currently in DNR	no feedback
OPO Record ID	Available, currently in DNR	no feedback
OPO	Cascades from database unless no DonorNet Donor ID	no feedback
Patient Hospital	Cascades from database unless no DonorNet Donor ID	no feedback
Case detail/How did the OPO learn of this patient?	Available, currently in DNR	no feedback
Last Name	Cascades from database unless no DonorNet Donor ID	no feedback
First Name	Cascades from database unless no DonorNet Donor ID	no feedback
Middle Initial	Cascades from database unless no DonorNet Donor ID	no feedback
Home Zip Code	Cascades from database unless no DonorNet Donor ID	While a required field, this will be "Unknown" on the large number of ventilated patients ruled out early in the referral evaluation process.
Ethnicity	Cascades from database unless no DonorNet Donor ID	While a required field, this will be "Unknown" on the large number of ventilated patients ruled out early in the referral evaluation process.
Race	Cascades from database unless no DonorNet Donor ID	While a required field, this will be "Unknown" on the large number of ventilated patients ruled out early in the referral evaluation process.
Birth Sex	Cascades from database unless no DonorNet Donor ID	no feedback
Gender Identity	May be available from some OPOs; unlikely to have for all referrals.	This information is not collected routinely by hospitals and therefore will be unavailable on most patients who do not become donors. It is unclear to AOPO what clinical relevance this question has to donation.
Height	Cascades from database unless no DonorNet Donor ID	While a required field, this will be "Unknown" on the large number of ventilated patients ruled out early in the referral evaluation process.
Weight	Cascades from database unless no DonorNet Donor ID	While a required field, this will be "Unknown" on the large number of ventilated patients ruled out early in the referral evaluation process.
Age	Cascades from database unless no DonorNet Donor ID	AOPO recommends this field be calculated using date of birth. If the patient is unidentified, there should be an "unknown" option.
HIV Status	Cascades from database unless no DonorNet Donor ID	no feedback
Cause of Death	Cascades from database unless no DonorNet Donor ID	no feedback
Mechanism of Death	Cascades from database unless no DonorNet Donor ID	no feedback
Circumstance of Death	Cascades from database unless no DonorNet Donor ID	no feedback
Did patient legally document their decision to be an organ donor?	Cascades from database unless no DonorNet Donor ID	no feedback
First Person Authorization Restrictions	Available, currently in DNR	no feedback
Date and Time of Pronouncement of Death	Cascades from database unless no DonorNet Donor ID	AOPO recommends that this field not be required or add clarification to require for donors only. The majority of ventilated patient referrals are not dead at the time of referral. In many cases, these patients do not die. Further, many are ruled out prior to their determination of death. Due to a non-specific CMS regulation for death record review, there is wide variation in this process, which is where one might find the date of death. For many OPOs, it is not feasible to go back to all of the ruled out referrals to determine a date and time of death. To require OPOs to do so, would add substantial time burden.
KDPI	Available on donors only, but should cascade from DonorNet	This field is part of the DonorNet record for those for whom it is calculated. Recommend cascading this information from DonorNet.

Primary Insurance	Not available or captured by OPOs	AOPO recommends this field be removed. This information is not collected by OPOs. Gaining access to this information for all referrals would be an additional time burden for hospital personnel as well as OPOs. Asking for this information would potentially harm the relationship between the OPO and the hospital due to the sensitive nature of this information.

Field Label	Availability	Feedback
Date of Death Record Review	Available, currently in DNR	As stated above, there are no clear standards outlined in CMS regulations for this process. While this information is currently being collected for the DNR, as stated in the letter, the referrals included in the DNR capture represent only approximately 7% of total ventilated patient referrals. Death record review regulations states "an assessment of the medical chart of a deceased patient to evaluate potential for organ donation." If a patient has been ruled out early in the donation evaluation process, there may not be a full death record review. This would add significant time burden for the OPO, not only for this form completion. AOPO recommends better definition and standards for death record review process.
Was the patient referred by the hospital to the OPO?	Available, currently in DNR	AOPO recommends removal of this field as it is duplicate information to the question of how the OPO learned of the patient.
Date and Time of Hospital Referral	Available, currently in DNR	no feedback
OPO Onsite Response	Available, may need data configuration or transformation	no feedback
Date and Time OPO Onsite Response	May be available at some OPOs, others would need to build process and database for collection of discrete information.	no feedback
Remote EMR Access	Not collected on individual referrals	AOPO recommends removal of this field. OPOs do not collect this on a referral basis.
Advance Directive	Available, but may need data transformation	AOPO seeks clarification on the purpose of this question - Is this solely for first person authorization, or other purposes?
Patient Record Type	Available for donors, should cascade from DonorNet	AOPO seeks clarification on this question. This information may be available at some OPOs but will only be available once intent is organ recovery. This information could be provided as the 'donation pathway', again at the point where intent to recover organs is determined. This would only be able to be determined at the terminal step.
Was the patient medically ruled out by the OPO prior to approach?	May be available, but needs more clarification.	AOPO seeks clarification for the language "medically ruled out". OPOs rule out patients for neurologic reasons as well as medical suitability reasons. Additionally, from a data collection standpoint, it would also be important to clarify what type of medical suitability rule-out was made (i.e., infectious disease, cancer, organ function). Lastly, cases are sometimes ruled out after an approach. Clarification is needed if those cases are included in this question.
Method of Authorization Used by OPO	Cascades from database unless no DonorNet Donor ID	no feedback
Family Objection	May be available, may need data transformation and development of process points in database to capture this question.	Need clarification as to whether this field can be completed if donation moves forward as there are objections that are successfully navigated, as well as those that are not. "Family" should be replaced with "Legal next of kin".
Approaches	Available	no feedback
Date and Time of First Approach	May be available at some OPOs, others would need to build process and database for collection of discrete information.	no feedback
Modality of First Approach	May be available at some OPOs, others would need to build process and database for collection of discrete information.	no feedback
Language of First Approach	May be available	no feedback
Interpreter for Approach	May be available	no feedback
Authorization	Available	no feedback

Date and Time Authorization Obtained	Cascades from database unless no DonorNet Donor ID exists; "Date and Time Consent Obtained for Organ Donation"	no feedback
Date and Time of First OPO Hierarchy Approach for Authorization	Sub-question of Authorization	The instructions need revision for this question. Replace "time of OPO onsite response" to "time of approach".
Tissue Authorization	Available at some OPOs, but need clarification on research versus transplant.	no feedback

Field Label	Availability	Feedback
Case Disposition	Data could be available but would need transformation of data.	AOPO recommends revisiting this question, potentially breaking it into several questions to obtain information requested. Several of the choices are not mutually exclusive in a case setting. For example, there could be Hospital Interference for a case that proceeds to donation. Having this as part of the terminal step implies that this form is only looking for Hospital Interference when a case does not proceed to donation. Further, there could be a registry objection but proceed to donation. If the question is not changed, AOPO recommends clear definitions be outlined for each choice, and the determination as to whether this is a multi-select or single select.
Describe Hospital Interference	Not always available on individual referrals and needs significant work to define and develop a system for submitting this information.	AOPO seeks clarification as to whether the "interference" is only required to be reported when donation does not occur due to that interference. There is also a concern that reporting the interference would damage the relationship between the hospital and the OPO. "Timely" is defined differently across OPOs. Clarification needed for a single definition, or data will not be comparable. "Ventilated patient not referred" is obtained via death record review, and therefore since asked how OPO learned of the patient, this information is already captured. "Hospital blocked approach" - Is this only if donation does not proceed?
Report Provided to Hospital	Not always available on individual referrals and needs significant work to define and develop a system for submitting this information.	There is currently no standardized method to collect this information on the referral record level. Currently, OPOs have different methods of conducting follow-up, which may or may not be documented in their electronic donor record. Further, the follow-up with hospitals may not be on a case basis, but rather in aggregate of a particular issue (i.e., patients not referred, timeliness, approach interference). This aggregate follow-up may be conducted over a period of time (monthly, quarterly). AOPO believes that the inclusion of these questions should be revisited and a process for following up with the hospital regarding interference be outlined and standards set, prior to a requirement to report this information to the OPTN/CMS. Without such clarification, the value of the reported data will be lost.
Report to Hospital Accepted	Not always available on individual referrals and needs significant work to define and develop a system for submitting this information.	
Remediation Plan Provided to Hospital	Not always available on individual referrals and needs significant work to define and develop a system for submitting this information.	
Remediation Plan for Hospital Accepted	Not available on individual referrals and needs significant work to define and develop a system for submitting this information.	
Date and Time Case Close	Available in some form	Need clarification as to the definition of "close". For each OPO this may be defined differently (exit OR, end of allocation, end of documentation).