

February 5, 2024

Maureen McBride PhD  
OPTN Executive Director  
United Network for Organ Sharing  
700 North 4<sup>th</sup> Street  
Richmond, VA 23219

Dianne Rudow-LaPointe PhD, RN  
OPTN President  
United Network for Organ Sharing  
700 North 4<sup>th</sup> Street  
Richmond, VA 23219

Dear Drs. McBride and Rudow-LaPointe:

I am writing to inform you that HRSA, per authority of 42 CFR 121.11, is directing the Organ Procurement Transplantation Network (OPTN) and the OPTN contractor to take the following actions regarding OPTN data collection:

1. Expand OPTN Transplant Center data collection to begin at the time that a patient is referred for an organ transplant to increase information regarding those patients referred for transplantation prior to listing on the OPTN waitlist. Pre-waitlist data will provide insight into who gets referred and by whom, who gets evaluated, and who gets placed on the organ transplantation waiting list. These data will also facilitate the OPTN's ability to address disparities in care processes, improve access to organ transplantation, and assess overall system performance. This expansion includes:

Development and implementation of a new organ specific data collection form (or forms), the "Referral and Evaluation Registration Form (RERF)," to be completed by OPTN member transplant programs for all patients referred to OPTN transplant programs. The RERF should be completed at least three points in time: the point of patient referral to the transplant program, points of first (and subsequent) visit(s) to the transplant program for evaluation, and the date at which the transplant program selects the patient as a transplant candidate.

The RERF will be based on the existing Transplant Candidate Registration (TCR) form, with revisions to remove TCR elements related to candidate listing and add new elements related to referral and evaluation dates including, but not limited to:

1. date of referral,
2. date of evaluation visit,
3. date of formal transplant selection, and
4. referring provider number (CMS Certification Number, or CCN).

HRSA revised the TCR to assist with development and implementation of the new RERF (see Attachment A). The RERF form(s) should include a patient identifier to allow referral, evaluation, candidate selection, and candidate registration data to be linked for the patient.

2. Expand OPTN Organ Procurement Organization (OPO) data collection to address the Centers for Medicare & Medicaid Services (CMS) OPO Condition for Coverage 42 CFR § 486.328 that requires OPOs to report certain data to the OPTN. HRSA and CMS have determined that additional data are needed to meet the requirements of the Condition. HRSA is directing the OPTN to develop and implement a new data collection form, the Ventilated Patient Form, based upon the existing OPTN Death Notification Registration (DNR) form. The Ventilated Patient Form is attached (see Attachment B).

Implementing systematic collection of information on all ventilated patients reported to OPOs from donor hospitals will provide a more objective source of information on procurement practices, management of donor patients, and how these practices affect the supply of deceased donor organs available for transplant. These data may also help to improve monitoring of OPO performance and facilitate quality assurance and performance improvement efforts to reduce the variation in OPO management and support provided to ventilated patients, donors, and donor families.

The OPTN Contractor must develop and incorporate the new RERF and Ventilated Patient Forms, associated instructions, and burden calculations into the contract deliverable for the 2024 30-day Information Collection Request package and Federal Register Notice for the Data System for Organ Procurement (OMB. 0915-0157) due to HRSA by **March 22, 2024**.

If you have any questions, please contact Christopher McLaughlin, Senior Advisor and OPTN Contract Officer's Representative, Division of Transplantation, Health Systems Bureau, HRSA, at 301-443-0036, 240-674-8444, or [cmclaughlin@hrsa.gov](mailto:cmclaughlin@hrsa.gov).

Sincerely,

Suma Nair PhD, MS, RD  
Associate Administrator  
Health Systems Bureau

cc: Chris McLaughlin

OPTN Contract Officer's Representative  
Attachment A "Kidney Referral Evaluation Registration Form - DRAFT.xlsx"  
Attachment B "Ventilated Patient Form - DRAFT.xlsx"