

July 11, 2025

John Magee, MD
President, Board of Directors
Organ Procurement and Transplantation Network
[REDACTED]

Dear Dr. Magee,

Modernizing the OPTN is essential to ensuring a system that is safe, fair, and effective for the more than 170 million registered organ donors and over 100,000 patients awaiting life-saving transplants. As part of our commitment to strengthening public trust and improving outcomes, the Health Resources and Services Administration (HRSA) is prioritizing data analytics and increased transparency across the OPTN. In our efforts to better understand the data OPTN members share to support OPTN operations, we have discovered opportunities to provide more data with the community to support compliance and safety oversight, quality improvement, and research. These efforts are critical to building a more responsive and effective transplant system for patients, families, and organ donors.

As you know, HRSA has received multiple reports of instances in which patients who were prospective organ donors may have received suboptimal care through interactions with OPOs. This is in addition to public reports of similarly concerning events¹ and in the context of a directive from HRSA to the OPTN to increase safeguards for patients who are entered into the donation after circulatory death (DCD) pathway by OPOs.

The current analytic files which contain data pertaining to potential and actual deceased organ donors are filtered to exclude or otherwise do not contain complete records for patients who did not progress to organ procurement. In the creation of analytic files as listed below, the OPTN and Scientific Registry of Transplant Recipients (SRTR) contractors remove patient records for which 1) a Donor ID exists, and 2) there were no organs procured. This filtering or removal of data from the analytic files produced by the OPTN and SRTR contractors precludes full visibility into the totality of organ procurement interactions with patients who are assigned a Donor ID.

The OPTN, OPTN members, OPTN contractors, oversight bodies, researchers, and stakeholders who engage in oversight, quality improvement and research need comprehensive data to inform system, organizational, and provider-level improvements and innovations. Data collected and

¹ Christensen, J. (2024, October 28). *A man was wheeled into surgery to harvest his organs. Weeks later, he left the hospital alive.* CNN. <https://www.cnn.com/2024/10/28/health/organ-donor-surgery-kentucky-investigation>

disseminated by the OPTN for “the government, the scientific community, and the public”² should be complete, reliable, and valid.

HRSA believes that remediating this data gap in the analytic file(s) will improve visibility into the care provided to patients who may become deceased organ donors, and the activities of OPOs. OPOs operate as healthcare facilities comprised of healthcare providers with a significant number of interactions between patients and providers, including in cases in which the OPO attempts procurement, but no organs are ultimately procured.

To address this limitation, and ensure transparency into which patients interact with or receive care through the organ procurement system, HRSA is notifying the OPTN that we will direct the OPTN and SRTR contractors to take the following actions by September 1, 2025:

1. Update deceased donor analytic files to include all individuals with a Donor ID. This will be a superset of the files as they exist today. This should include files in the following datasets:
 - a. Standard Transplant Analysis and Research (STAR) files,
 - b. Standard Analytic Files (SAFs), and
 - c. Government analytic files.
2. Draft, for HRSA review and approval, a communication about logic that researchers can use to filter these files to yield the files as they were before the change.
3. Draft, for HRSA review and approval, a communication to the Board and all committees and OPTN community regarding the change to files and the rationale for including more information about patients who are assigned a Donor ID but who do not progress to organ procurement.
4. Draft, for HRSA review and approval, associated data dictionary materials including descriptive language presented on websites and corresponding language within Data Use Agreements (DUAs), as applicable, so that changes to language or information reflect (1) and (2) above.

Given our shared interest in robust, data-driven policymaking, evaluation, and system oversight, HRSA invites the OPTN Board (and its relevant committees) to provide feedback or request additional information to be added to the analytic files. If you have any questions, please contact the HRSA Data and Analytics Team at HSBDAT@hrsa.gov.

Sincerely,

/Suma Nair/

Suma Nair, PhD, MS, RD
Associate Administrator

² See: <https://optn.transplant.hrsa.gov/data/about-data/uses-of-data/>