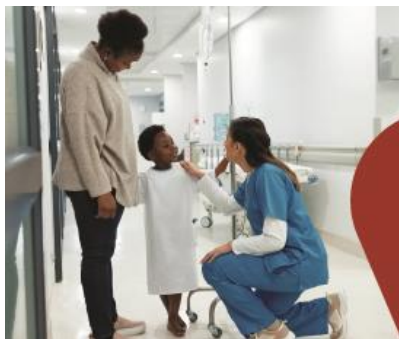




OPTN Modernization Monthly Update

Strengthening Systems: Advancing Accountability, Safety, and Public Trust

The national organ donation, procurement and transplantation system depends on its ability to evolve with integrity, prioritize safety, and earn the confidence of the people it serves. HRSA continues to [make significant progress](#) on modernizing the Organ Procurement and Transplantation Network (OPTN), including reinforcing financial stewardship, improving patient safety, modernizing governance, and expanding public engagement. By focusing on transparency, collaboration, and evidence-based practices, these efforts not only enhance the OPTN but also ensure that patients and their families continue to be served with the highest standards of care.

Improving Patient Safety through Historic Actions

The U.S. Department of Health and Human Services (HHS) announced it is [moving to decertify a major organ procurement organization \(OPO\)](#), marking the first time an OPO has been decertified mid-contract. Following a comprehensive investigation, the OPTN recommended that Secretary Robert F. Kennedy, Jr. revoke certification of the Life Alliance Organ Recovery Agency, a division of the University of Miami Health System. The decision comes after years of documented unsafe practices, poor staff training, chronic underperformance, understaffing, and repeated paperwork errors, including an incident in which a surgeon declined a donated heart due to a clerical mistake. HHS emphasized that such failures directly endanger patients waiting for lifesaving transplants and undermine public trust in

the nation's organ procurement system. Life Alliance, in a statement to on their [website](#), said it does not plan to appeal the decision and that it will “cooperate fully with HHS to ensure a smooth transition.”

To strengthen accountability and proactively protect patients, Secretary Kennedy directed the OPTN to establish a new policy requiring every OPO to appoint a [dedicated Patient Safety Officer](#). These officers will play a central role in protecting patients by monitoring and investigating safety events in real time; serving as the first point of contact for families, hospital partners, and HRSA; documenting and reporting incidents to OPTN; conducting root cause analyses; and ensuring corrective actions are carried out promptly. This announcement builds on the ongoing reforms HHS, and specifically HRSA, have undertaken to ensure that the organ donation, procurement and transplantation system operates safely, fairly and effectively.



Increasing Oversight through Clear,
Transparent Financial Management

Most of the operating costs of the OPTN are paid for by [patient registration fees](#). These fees are paid by transplant programs for each candidate they add to the national transplant waiting list. The fee amount is set each year by the OPTN Board and approved by HRSA.



In March 2025, Congress passed the 2025 Full-Year Continuing Appropriations and Extensions Act (Sec. 1904 in P.L. 116-260) which includes a key provision affecting the organ transplantation community. Section 1904 grants HHS explicit legal authority to directly collect and distribute registration fees from OPTN member institutions. For decades, UNOS, as the sole OPTN contractor, has managed this fee collection process.

Under the new law, HHS will now assume responsibility for collecting these fees, a shift designed to:

- Enhance transparency in how fees are collected and used;
- Expand opportunities for multiple best-in-class contractors to support the operations of the OPTN;
- Strengthen oversight, performance, and accountability across the network.

The Board of Directors voted to increase the registration fee in order to set aside dedicated funds for HRSA directives (i.e., [allocation out of sequence](#), [donation after circulatory death policy](#), and [normothermic regional perfusion](#)); Secretarial Data Directives; and enhancing the security and stability of the OPTN IT system. HRSA anticipates beginning to invoice transplant hospitals in October 2025 for OPTN patient registration fees for transplant candidates added to the waiting list after August 31, 2025 via Pay.gov, a secure, no-cost federal payment platform used by many U.S. government agencies.

On August 25, 2025, HRSA approved the OPTN Board of Directors' recommended Fiscal Year (FY) 2026 Patient Registration Fee of \$1,036 per transplant candidate. This fee will go into effect on October 1, 2025.

For more information, or to view a Pay.gov user guide, please visit the [OPTN Patient Registration Fee webpage](#).

An Ongoing Focus on Patient Safety

The Membership and Professional Standards Committee (MPSC) is responsible for monitoring member performance, reviewing compliance with OPTN policies, and identifying areas for policy development and improvement. As part of its oversight role, the MPSC continues to evaluate emerging clinical and ethical issues that may impact transplant safety and system integrity, including:



- Normothermic regional perfusion (NRP): A technique used to restore blood flow to organs after circulatory death, raising ethical considerations related to the Dead Donor Rule.
- Donation after circulatory death (DCD): Organ recovery from donors whose heart and breathing have permanently stopped, requiring strict protocols to confirm death and suitability for donation.
- Rabies transmission: HRSA is working with OPTN and the Centers for Disease Control and Prevention (CDC) to reduce the risk of donor-derived rabies transmission. Policy updates aim to improve screening and reporting.

These topics were discussed during the July 2025 MPSC meeting and are under active review for future policy development. [Notes from the July 2025 MPSC meeting](#) are available online.

These [directives and critical comments](#) reflect HRSA's oversight of the OPTN and outline required actions, policy clarifications, and system improvements. They are published online to promote transparency and accountability across the transplant system.

Progress to Reduce Allocation Out of Sequence

Reducing the frequency of organ allocation out of sequence (AOOS) remains a critical area of focus for HRSA and the OPTN. Since August 2024, HRSA and the OPTN have worked together to define AOOS, close compliance gaps, and implement a remediation plan to strengthen fairness, transparency, and accountability in the national organ allocation system.



Recent actions include:

- Launch of a dedicated [AOOS webpage](#) with FAQs, definitions, and compliance tools
- Development of an [AOOS Oversight Dashboard](#) to monitor member-level and system-wide patterns
- Direction to the Membership and Professional Standards Committee (MPSC) to review AOOS data and strengthen member education

HRSA also established an [AOOS Workgroup](#) composed of representatives from multiple OPTN committees. This enables OPTN to modify existing policies or create new ones to further reduce out of sequence allocation as needed. This Workgroup will play a key role in gathering stakeholder input, including feedback from transplant professionals, OPOs, and patient advocates. [Learn more](#) about the AOOS Workgroup from Chair Justin Wilkerson.

Laying the Groundwork for Data-Driven Transformation

To strengthen oversight and improve transparency in the national transplant system, HRSA issued a [data directive](#) aimed at expanding the types of information collected from transplant centers and organ procurement organizations (OPOs). This directive is part of HRSA's broader modernization strategy and responds to long-standing gaps in data that limit HRSA's ability to evaluate system performance. The directive was published in the [Federal Register](#) and made available for public comment to gather input from stakeholders across the transplant community. The public comment period closed on July 31, 2025.



Key data proposed for collection includes:

- Referral data from transplant centers before waitlist placement, which will help HRSA improve access to organ transplantation, assess overall system performance, and identify potential disparities in care
- Referral data from OPOs for ventilated patients: 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, interactions with patients who may become organ donors, and how these practices affect the supply of deceased donor organs available for transplant.

HRSA will use feedback from the public comment period to refine the directive and develop an implementation plan. These efforts will support more consistent data reporting, better policy development, and a clearer picture of how the organ donation and procurement system functions for patients, families, and providers.



Discovery Task Order Recommendations

At the end of 2024, HRSA launched OPTN discovery task orders to provide insights on the current state of OPTN operations across key areas of patient safety, communications, financial management, and policymaking. Based on these valuable [insights and proposed recommendations](#), HRSA and the OPTN have already started to implement changes while laying the groundwork for long-term solutions.

Improving Governance Through Public Engagement

Summer 2025 Public Comment Period

OPTN invites all members of the transplant community to participate in the [Summer 2025 public comment period](#), which is open through October 1, 2025.



Public comment is a key part of the OPTN policy development process. All feedback is reviewed by the sponsoring committee and considered by the OPTN Board of Directors before any proposal is finalized. HRSA encourages input from patients, donor families, caregivers, transplant professionals, and members of the public.

You may comment on the following six proposals. Click on the topic below to learn more:

- [Establish A Comprehensive Multi-Organ Allocation Policy](#)
- [Require Patient Notification for Waitlist Status Changes](#)
- [Update And Improve Efficiency in Living Donor Data Collection](#)
- [Require West Nile Virus Seasonal Testing for All Donors](#)
- [Histocompatibility HLA Table Update](#)
- [Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage](#)

Register for Regional Meetings

OPTN regional meetings are being held throughout September 2025 and are free and open to the public. These meetings offer a forum to discuss proposed policy changes and hear perspectives from across the transplant community. HRSA encourages participation from patients, donor families, caregivers, and professionals involved in organ donation, procurement, and transplantation. [Learn more and register for Regional Meetings.](#)



December 2025 OPTN Board of Directors Meeting

HRSA will convene the [OPTN Board of Directors](#) for its upcoming in-person meeting on December 12, 2025. This meeting will bring together OPTN leadership, HRSA officials, and key stakeholders from across the transplant community to advance shared priorities for the nation's organ donation and transplantation system.

This meeting serves as an important forum for open dialogue, transparency, and collaboration—reinforcing HRSA's commitment to strengthening the organ donation, procurement, and transplantation system for patients and families nationwide.

Looking Ahead: Continuing Progress and Building Momentum

HRSA continues to focus on sustaining the progress we have achieved and building the momentum needed to meet the challenges that lay ahead. By strengthening accountability, advancing patient safety, modernizing governance, and deepening public engagement, we are laying the foundation for a system that is more transparent, resilient, and trusted. Continued collaboration, innovation, and commitment will ensure that progress carries forward, driving lasting improvements for patients and families nationwide.

ICYMI

A Round-Up of Previously Announced Items

- **September 2025:** [HHS to Close University of Miami's Failing Organ Agency](#)

- **August 2025:** [Strengthening the OPTN Through Data-Driven Decision Making](#)
- **July 2025:** [Modernization in Action: Advancing Oversight and Policy Reform](#)
- **June 2025:** [Purposeful Change, Shared Vision: HRSA's Commitment to Stakeholder-Driven OPTN Reform](#)
- **June 2025:** [HRSA Announces New OPTN Board of Directors](#)
- **May 2025:** [Strengthening Oversight to Improve Patient Outcomes: Recent Advances in OPTN Governance and Transparency](#)
- **April 2025:** [Recognizing Donate Life Month: Expressing gratitude for those who give, and honoring the resilience of those who wait](#)

Quick Links

[We Want to Hear from You:](#) Your voice is essential as we work to ensure equitable access to care, improve health outcomes, and empower the larger organ donation and transplantation community with data and transparency.

[More Donors, More Hope:](#) Every registered organ donor offers hope to people who need transplants – and to the families who love them.

[Ways to Get Involved:](#) Every 8 minutes, someone is added to the transplant waiting list. As a member of the donation and transplant community you have an impact on the lives of these people every day. But there is more you can do.

[OPTN Data Dashboard:](#) HRSA makes available to the public both data and data visualizations on organ donation and transplantation. The aim of this information is to improve transparency around organ transplantation activities across the nation for the public.



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5600 Fishers Lane | Rockville, MD 20857
