



Modernization in Action: Advancing Oversight and Policy Reform

Effective policies and regulations are essential to driving the performance, transparency, and continuous improvement of the Organ Procurement and Transplantation Network (OPTN). The timely development and revision of these policies ensure that the system remains responsive to scientific advances, operational needs, and the critical needs of patients and families.

As part of its congressionally mandated oversight responsibilities, the Health Resources and Services Administration (HRSA) has taken important steps to [strengthen policymaking within the OPTN](#). Recent actions include finalizing a special election, seating a new Board of Directors, investigating reported instances of policy noncompliance, issuing a corrective action plan to address identified issues, and initiating a transition to a modernized process for collecting OPTN registration fees. These efforts reflect HRSA's commitment to a more accountable and effective national organ procurement and transplant system.

A New Chapter: New Board of Directors Begins Comprehensive Policy Review

HRSA is pleased to share the results of the recent election for the five Board Officer positions: president, vice president, vice president of patient and donor affairs, treasurer, and secretary. These elected officers will serve on the [OPTN Executive Committee](#), which is responsible for carrying forward the work of the Board, including timely decisions on policy development, committee actions, and other urgent matters.



2025 OPTN Officers

President - John C. Magee, MD, Attending Surgeon, Division of Transplantation, Jeremiah & Claire Turcotte Professor of Transplant Surgery, Professor of Internal Medicine and Pediatrics, University of Michigan

Vice President - Shelley Hall, MD, Chief of Transplant Cardiology, Congestive Heart Failure and Mechanical Circulatory Support, Baylor University Medical Center

Vice President of Patient and Donor Affairs - William (Bill) Ryan, MBA, Founder, President, and Chief Executive Officer of Transplant Life Foundation; Family Member of a Deceased Donor

Treasurer - Alan Reed, MD, MBA, FACS, Professor and Chief of Transplant and HPB Surgery, Iowa Carver College, Director, Iowa Health Care Organ Transplant Center, and Adjunct Professor of Accounting, Henry B. Tippie School of Management, University of Iowa

Secretary - Justin Wilkerson, MBA, Deputy Director of Human Services, Illinois Army National Guard; Liver Transplant Recipient

OPTN members also recently elected (1) the third Organ Procurement Organization (OPO) Representative on the OPTN Board of Directors and (2) the Associate Regional Councillor for Region 8.

Full election results can be found on the [OPTN Special Election web page](#).

Policy Development: A Collaborative and Data-Driven Process

The new OPTN Board of Directors officially began their term on July 1, 2025. They will serve staggered terms of two to four years, depending on their role on the Board. As one of their first actions, in addition to addressing system-wide fairness and safety concerns, the newly appointed Board will review existing [OPTN policies](#). This review includes both the policies that govern day-to-



day OPTN operations and the management and membership policies that define administrative responsibility and membership requirements.

While the OPTN Board of Directors is responsible for approving official policies, policy development is a collaborative effort involving many stakeholders across the transplant community. Ideas for new or revised policies can be proposed by OPTN committee members, OPTN members, regulatory bodies, or other interested stakeholders. To move forward as a committee project, each proposal must be supported by credible data, research, and evidence demonstrating its relevance and potential impact on the transplant system.

Once an idea advances, an OPTN committee drafts a proposal, which is then shared publicly for feedback. The public comment period provides a vital opportunity for the transplant community to help shape policy. After careful review of all input, the Board of Directors votes on whether to adopt the policy.

Effective policies are critical to the OPTN's success, and policy development relies on the expertise and engagement of the broader transplant community. HRSA strongly encourages participation in this process whenever appropriate. Learn more about [OPTN committees](#) and how to get involved. Individuals interested in serving on a committee can submit a [Volunteer Interest Form](#).

Modernizing the OPTN policymaking process presents a critical opportunity to enhance efficiency and transparency. Strengthening public engagement at every stage will improve trust, ensure accountability, and lead to better policy outcomes that reflect the needs of patients, clinicians, and the broader transplant community. As part of this effort, HRSA engaged contractors to study the current policymaking process and identify opportunities for meaningful improvement. HRSA looks forward to sharing key insights from this work in the coming months and collaborating with the OPTN to implement enhancements that support a stronger, more responsive national transplant system.

To learn more about the policy development process visit: [Policy development - OPTN](#).

Addressing Patient Safety Concerns with Policy Reform

Patient safety is, and must remain, at the core of organ procurement and transplantation efforts. As HRSA leads the ongoing modernization of the OPTN,

[safeguarding patients](#) throughout the donation, procurement, and transplant process remains a top priority. Achieving this requires a system that operates not only efficiently and transparently, but also one that is responsive to emerging clinical, ethical, and operational challenges. Meaningful and timely policy reform is essential to ensure that the system evolves to meet these challenges, strengthens accountability, and consistently centers the needs and safety of patients and their families.

Driving Reform for Allocation Out of Sequence

As part of its oversight responsibilities, HRSA recently completed a comprehensive review of the OPTN's proposed approach to allocation out of sequence (AOOS). Following this review, HRSA [provided formal feedback](#) to support improvement and ensure accountability.



To promote transparency and public engagement, HRSA launched a [dedicated AOOS web page](#) in late June. This page serves as a centralized resource, offering background on AOOS, ongoing updates, and opportunities for stakeholders and the public to submit questions and provide input.

HRSA commends the work of the AOOS Analytic Definition Work Group for their swift and thoughtful development of these operational and analytic definitions. Their efforts, particularly the significant contributions of members from the Patient Affairs and Data Advisory Committees, demonstrated a strong commitment to both technical rigor and patient-centered values and reflect a clear understanding of the complexity of AOOS-related challenges and a shared resolve to address them with urgency and care.

HRSA will continue to monitor implementation efforts closely to ensure that resulting policy and operational changes lead to meaningful improvements for patients, families, and the transplant community.

Prioritizing OPTN Efforts to Remediate AOOS

As the OPTN undertakes actions to comply with HRSA's directive on AOOS remediation, HRSA has determined it is both prudent and responsible to prioritize policy work focused on implementing effective, evidence-based AOOS policies that uphold fairness and integrity with the organ allocation system. AOOS impacts all organ types, reviewing known challenges with existing allocation policy before developing new allocation policy will be critical. As a result, the OPTN will pause all new policy work related to continuous distribution (CD). This pause will



allow the OPTN to focus on implementing effective, evidence-based AOOS policies that uphold fairness and integrity across the system.

This decision reflects a commitment to ensuring that future allocation policies are developed with transparency, supported by robust and reliable data, and grounded in accountability to the patients the system is meant to serve. Once the AOOS remediation work is meaningfully advanced, policy development on CD can resume with greater confidence in the system's ability to deliver fair outcomes.

Investigation into Donation after Circulatory Death Procurement Practices

Over the last several months, HRSA and the OPTN conducted a special review of allegations of potential preventable harm to a patient with neurological injuries under the care of a specific OPO. As part of this investigation, HRSA identified opportunities for corrective action.



As part of HRSA's oversight of the OPTN, [HRSA issued a corrective action plan \(CAP\)](#), which is an accountability tool used by HRSA to require an OPTN member to take specific actions to address identified violations of OPTN policies or bylaws. In this instance, the CAP directs the OPTN to develop and implement a monitoring plan to address the concerns found during the special review and to immediately develop enhanced safety standards.

HRSA and the OPTN will continue to work together to increase oversight and accountability to maintain the highest quality of care and safety for all patients and families.

New Data Standards for Increased Patient Safety

The OPTN Final Rule grants HRSA the regulatory authority to oversee and direct OPTN data collection. HRSA and the OPTN Board of Directors use this data to develop transplant, procurement, and allocation policies; to determine whether institutional members are complying with policy; to determine member-specific performance; to ensure patient safety; and to fulfill the requirements of the OPTN Final Rule.



Recently, the Office of Management and Budget (OMB) published two Information Collection Requests (ICR) submitted by HRSA for public comment:

- [Data System for Organ Procurement and Transplantation Network](#)
- [Process Data for Organ Procurement and Transplantation Network](#)

Both requests seek to update the current OPTN data collection to gather information that can improve the organ matching and allocation process.

All interested individuals may submit comments and recommendations for the proposed ICRs directly to OMB [here](#). HRSA values all feedback and strongly encourages stakeholders directly affected by the proposed policy changes to provide input on the potential impacts of these proposals.

Implementing a New Collection Process for OPTN Registration Fees

This spring, Congress passed the 2025 Full-Year Continuing Appropriations and Extensions Act ([Sec. 1904 in P.L. 1968](#)) 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. These fees are paid by transplant programs for each candidate they add to the national transplant waiting list and help fund the operations of the OPTN.



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; and
- Strengthen oversight, performance, and accountability across the network.

The new law also introduces new transparency measures, providing the transplant community and the public with greater visibility into how registration fees are allocated and spent. These measures ensure registration fees support OPTN operations and, ultimately, improve outcomes for patients and families.

HRSA has initiated this transition by reaching out to transplant hospitals to confirm their billing points of contact. During this period, transplant hospitals should continue to pay the fees to the OPTN contractor until HRSA provides further instructions. HRSA anticipates beginning to invoice transplant hospitals for OPTN patient registration fees for transplant candidates added to the waiting list between October 1st through 31st, 2025.

HRSA anticipates collecting registration fees via Pay.gov, a secure, no-cost federal payment platform used by many U.S. government agencies. HRSA will keep transplant hospitals informed with timely updates, detailed guidance, and clear timelines to support a smooth transition. If you are a transplant hospital with questions regarding registration fees, please contact OPTNFeeSupport@hrsa.gov.

Looking Ahead: Meaningful Policy Reform

As HRSA continues to lead the [modernization of the OPTN](#), advancing oversight and meaningful policy reform remains central to building a more effective and patient-centered procurement and transplant system. Strengthening governance, improving transparency, and ensuring accountability are essential to building public trust and improving outcomes for patients and families. Through collaborative engagement with the transplant community, a commitment to data-driven decision-making, and a renewed focus on timely and enforceable policies, HRSA is laying the foundation for a system that is not only operationally sound but also worthy of the lives it is entrusted to serve.

ICYMI

A Round-Up of Previously Announced Items

- **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.