



Testimony of Dr. Maureen McBride, Ph.D.,
Chief Executive Officer, United Network for Organ Sharing,
before the U.S. House Committee on Energy & Commerce,
Subcommittee on Oversight & Investigations

"Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System"

July 22, 2025

Table of Contents

ONE PAGE SUMMARY.....	3
INTRODUCTION.....	4
THE ORGAN DONATION AND TRANSPLANT ECOSYSTEM.....	5
UNOS' ROLE AS A HRSA CONTRACTOR SUPPORTING THE OPTN.....	7
HRSA'S OPTN MODERNIZATION INITIATIVE.....	8
PATIENT SAFETY.....	9
MOVING FORWARD TO STRENGTHEN THE SYSTEM FOR PATIENTS.....	13
CONCLUSION.....	16

Summary

As CEO of the United Network for Organ Sharing (UNOS), I am honored to serve in a role that gives me the opportunity to support the federal government, organ donation and transplant professionals, patients, and families who make up the nation's organ donation and transplant system. Throughout my entire career, I have remained deeply committed to this mission and firmly believe in the life-changing power of organ donation. While the system is not perfect, it is strong, improving and worthy of trust.

UNOS has led meaningful innovations and improvements that benefit patients. We developed the Offer Filters tool to create a more efficient offer process and reduce the risk of organ non-use. We introduced a predictive analytics tool to increase organ use rates by providing physicians with information about the impact that accepting or declining an offer could have on a patient. UNOS worked with Congress and the Federal Aviation Administration (FAA) to enable safer and more efficient organ transportation on commercial airplanes.

UNOS is not the OPTN, and UNOS does not make clinical decisions or direct enforcement of OPTN policies. We are a contractor supporting the OPTN under HRSA's direction. In the Kentucky case, which prompted this hearing, UNOS carefully followed the process that HRSA approved for the OPTN Member and Professional Standards Committee (MPSC). The MPSC, through the OPTN Board of Directors, not UNOS, holds primary responsibility for monitoring and improving member performance. UNOS supports this role by developing and implementing HRSA-approved plans and metrics, which are subject to HRSA oversight. UNOS must submit detailed documentation, including plans, toolkits, and annual reports, and must revise these based on HRSA feedback. UNOS responsibilities are subordinate to the National Organ Transplant Act (NOTA; P.L. 98-507), the OPTN Final Rule (42 CFR Part 121), OPTN policies, OPTN bylaws, and HRSA's authority.

We support HRSA's OPTN Modernization Initiative, and UNOS seeks to partner with Congress to advance additional reforms. I recommend four key improvements to strengthen the organ donation and transplant system:

- The creation of a "no wrong door" patient-safety reporting system that allows anyone, including patients, providers, or family members, to report safety concerns easily and effectively.
- A nationwide implementation of automated deceased donor referrals to streamline and modernize the donor referral process.
- A robust tracking system for unaccompanied organs in transit to prevent loss, delays or damage.
- Migrating the OPTN computer system to the cloud.

The reforms that UNOS is leading and endorsing will bolster trust in the system through improvements that are meaningful and measurable to patients and donor families, including an increase in transplants, a reduction in the number of individuals who die while waiting for a transplant, and a decrease in organ non-use.

The system is built on trust. To preserve and strengthen that trust, we must work together — Congress, HRSA, CMS and all stakeholders — to ensure a fair, effective and safe organ donation and transplant system. UNOS will continue to be a partner in that effort.

Introduction

Thank you for the opportunity to testify today, and for your continued efforts to strengthen organ donation and transplant in the United States. My name is Maureen McBride, and I am the Chief Executive Officer for the United Network for Organ Sharing (UNOS).

I'm also a mother, a sister, a daughter, a wife and a friend who cares deeply about the lives of those around me. That's why I chose to register to be an organ donor. There is truly no more powerful, transformative and altruistic gift than the gift of life.

I've spent my entire professional career dedicated to improving organ donation and transplant and to increasing the number of people who can live longer and more complete lives because of that gift of life. Each day, I celebrate the milestones of my colleagues who are transplant recipients and who work for UNOS because they feel compelled by the alignment of their personal journey and our mission. They are living full lives – taking their kids to swim practice, going on walks with their dogs, having dinner with friends, and traveling. I carry these stories of transplant recipients with me, and the immeasurable gift of more time.

Donation and transplant touch our lives at every turn. Consider the experience of one colleague whose father passed away in 2023 at the age of 54. Walking alongside him to the operating room during his honor walk was the most difficult moment of her life. Yet today, she shares his story openly to inspire others to become organ donors. Generous people like him allowed more than 48,000 recipients to have another chance at life last year. The steady, annual increase in transplant is evidence that the system is working – and it's working well. There are opportunities to strengthen it and to save more lives.

I applaud Congress, and particularly this Committee, for its focus on ensuring the nation's organ donation and transplant system, which includes the Organ Procurement and Transplantation Network (OPTN), continues to be the best in the world. By taking the time to understand this complex system, this Committee can direct meaningful reforms that improve the system for patients and donor families.

While the system is not without its flaws, we have a moral responsibility, as long as a waitlist for organs exists, to drive progress and expand access to lifesaving transplants. Patients and their families are counting on our nation's leaders to champion reforms that enhance transparency, strengthen accountability, and ultimately save more lives. I fully support efforts focused on patient-centered improvements, and UNOS has consistently demonstrated its commitment to being part of the solution.

Before diving into an overview of this complex network, I want to share a few essential truths about my organization. UNOS is driven by a mission that is both urgent and deeply meaningful: to save and improve lives through innovation, research, and collaboration. For nearly 40 years, we have played a central role in managing much of the nation's highly regulated OPTN under a federal contract with HRSA. **At UNOS, we believe every American deserves access to an organ donation and transplant system that is fair, effective and safe — both for donors and the patients whose lives depend on it.**

UNOS has increased efficiencies in the system, introduced cutting-edge innovations, and brought together stakeholders to improve organ donation and transplantation. UNOS created, built and implemented Organ Offer Filters to ensure that the right organ reaches the right patient at the right time, streamlining the matching process and reducing unnecessary delays. We also implemented predictive analytics to equip physicians with critical insights, allowing them to estimate how long a patient might wait for another offer if the current one is declined. This tool, powered by machine learning, was developed to increase offer acceptance and reduce waitlist mortality. UNOS has also enhanced clinical decision-making by providing physicians with high-resolution medical imaging, improving the evaluation of organ viability. Additionally, UNOS has led stakeholders across the donation and transplant community to partner with Congress and the FAA to enable organ transport above the wing, to reduce the risk of damage, delay, or loss to organs. The next crucial step is to fully implement the FAA's recommendations, which requires cooperation among government agencies and stakeholders.

Since I became chief executive officer two years ago, UNOS has focused on two primary objectives: making improvements in areas that are within our control and driving systemic reforms that cannot be achieved without action from Congress, HRSA and other federal agencies. Congress plays a critical role in advancing policy to strengthen the organ donation and transplant system.

The nation's organ donation and transplant system is founded on trust, and to continue to earn and keep that trust, we must work together to keep improving the system. UNOS remains committed to partnering with Congress, the federal government, the dedicated stakeholders and volunteers in the organ donation and transplant community, including patients, living donors and donor families, to ensure the nation's donation and transplant system is fair, effective, and safe for all.

The Organ Donation and Transplant Ecosystem

The nation's complex, multi-stakeholder organ donation and transplant ecosystem depends on public trust. That's why each participant in the system – hospitals, organ procurement organizations (OPOs), histocompatibility laboratories, transplant hospitals, HRSA, the Centers for Medicare & Medicaid Services (CMS), the OPTN, and all paraprofessional organizations like federal contractors – must maintain the highest standards and continuously seek to improve. To do that, however, it's crucial to understand the distinct roles and responsibilities of each entity with a shared responsibility for the system's successes and opportunities. Recent events in Kentucky have highlighted the importance of clearly understanding these different roles.

Hospitals

Title XI of the Social Security Act¹ and CMS' conditions for participation² require all hospitals to report to OPOs information about patients whose death is imminent or who have died in the hospital. This is how OPOs are made aware of potential deceased organ donors. CMS oversees approximately 5,000 hospitals, which are referred to as donor hospitals, that are not overseen by the OPTN or HRSA (unless they are also transplant programs). Donor hospitals are responsible for:

¹ Social Security Act § 1138, 42 U.S.C. § 1320b–8 (2018).

² 42 CFR § 482.45 ; 42 CFR Part 486, Subpart G.

- Saving a patient's life as their primary focus.
- Identifying and referring patients who may become organ donors (potential donors) to OPOs.
- Identifying potential donors (this process could be improved and standardized across the country using existing technology to automate electronically donor referral).
- Making determinations of death, whether it be brain death or circulatory death, in accordance with state law. Hospital physicians do this.
- Making determinations, in consultation with the patient's family and loved ones, about withdrawing life support.

Organ Procurement Organizations (OPOs)

OPOs are local and regional not-for-profit organizations responsible for recovering organs from deceased donors for transplantation in the United States. Organs that can be donated include the heart, kidneys, lungs, pancreas, liver, intestines, and vascularized composite allografts. There are 55 OPOs, each mandated by federal law to perform this life-saving mission in their assigned donation service area. CMS issues Requirements for Certification and Designation and Conditions for Coverage for OPOs.³ OPOs are responsible for:

- Educating the public about organ donation.
- Working directly with hospitals on organ donation protocols.
- Coordinating with families regarding deceased donation decisions and securing authorization for deceased donation.
- Entering data into the OPTN Computer System regarding deceased donor organs so that they can be matched to potential recipients.
- Recovering organs from deceased donors.
- Working with transplant hospitals to place organs with patients.
- Transporting donated organs to the transplant hospital.

Histocompatibility Laboratories

A histocompatibility laboratory is a specialized facility that performs tests to determine the compatibility of tissue and organs for transplantation. These tests include, but are not limited to, Human Leukocyte Antigen (HLA) typing, antibody screening, compatibility testing, and crossmatching. Histocompatibility laboratory members are either independent, or hospital based. CMS regulates all laboratory testing, including histocompatibility testing (an integral component of organ donor and recipient matching) performed on humans through the Clinical Laboratory Improvement Amendments (CLIA).

Transplant Hospitals

Transplant hospitals are specialized medical facilities that perform organ transplantation procedures. Transplant hospitals provide pre- and post-transplant care supported by multidisciplinary medical teams. A condition of

³ 42 C.F.R. §§ 486.301–486.348 (2025).

participation in the Medicare program for transplant programs is membership in the OPTN. As of July 2025, there are 251 active transplant hospitals.⁴ These transplant hospitals are responsible for:

- Evaluating transplant candidates and adding them to the waitlist.
- Facilitating living donation.
- Providing pre-transplant care and management of a patient's disease and comorbidities.
- Evaluating organ offers and accepting or declining on behalf of patients.
- Performing transplant surgeries.
- Providing post-transplant care to patients.

The Organ Procurement and Transplantation Network (OPTN)

The OPTN is a unique public-private partnership that links most of the health care organizations involved in the U.S. donation and transplantation system. It is a membership-based organization established by NOTA. HRSA is responsible for the oversight and direction of the OPTN. A driving force of the OPTN is to improve the U.S. system so that more life-saving organs are available for transplant. Patient safety is at the forefront of activities at transplant hospitals, OPOs and laboratories.⁵

The OPTN makes OPTN policy decisions through its Board of Directors and committees, who bring a wealth of technical knowledge and lived experience to their decision making. The OPTN Board, committees, review boards, and ad hoc groups are made up of approximately 1,000 volunteers who lend their clinical and professional expertise as physicians, surgeons, nurses, organ procurement professionals, and transplant hospitals program directors as well as the lived experience from transplant patients and families, living donors and donor families to develop and approve organ allocation policies, establish and maintain OPTN bylaws, policies and membership requirements, and monitor OPTN member compliance with the OPTN bylaws, OPTN policies, NOTA and OPTN Final Rule.

UNOS' Role as a HRSA Contractor Supporting the OPTN

UNOS is one of several HRSA contractors supporting the work of OPTN volunteers. **To be clear, UNOS is not the OPTN. UNOS supports the OPTN's operations. UNOS does not make clinical decisions regarding patient care and lacks the authority to unilaterally implement changes to the OPTN's processes or systems without HRSA's review and approval.**

The work UNOS performs as a HRSA contractor to support the OPTN is outlined in a contractual agreement with HRSA. UNOS acts as directed by and with oversight from HRSA to support the OPTN's operations in accordance with NOTA, the Final Rule, OPTN Policies, and OPTN Bylaws. Our work as a HRSA contractor includes:

⁴ Organ Procurement and Transplantation Network. *About OPTN membership*. U.S. Department of Health and Human Services. <https://optn.transplant.hrsa.gov/about/about-optn-membership/>

⁵ Organ Procurement and Transplantation Network. *About the OPTN*. U.S. Department of Health and Human Services. <https://optn.transplant.hrsa.gov/about/>

- Managing the national transplant waiting list and organ matching system 24/7/365.
- Providing support to OPTN volunteers during the policy development and compliance oversight processes.
- Monitoring compliance through data reporting systems and supporting the OPTN volunteers' investigations of reported patient safety incidents.
- Collecting and maintaining OPTN data on behalf of HRSA.

Our work as a HRSA contractor supporting the OPTN **does not** include:

- Making any clinical decisions. The patient's physician, the transplant team, and OPO professionals do this.
- Conducting oversight over hospitals. CMS, and HRSA in the case of a transplant hospital, does this.
- Directing OPTN investigations or deciding the outcome of OPTN investigations.

With support from UNOS as one of HRSA's contractors supporting the OPTN, the nation's complex organ donation and transplant system has been incredibly successful and has enabled more than 1 million people to receive the gift of life. In 2024, a record 48,000 transplants were performed, and the average waitlist deaths per day decreased to 13 in 2023 compared to 16 per day in 2021.⁶ More than 100 life-saving transplants occur every day through our national network.⁷ Multiple countries across the globe have modeled their systems on the U.S.'s world-class system, including South Korea and Japan.

HRSA's OPTN Modernization Initiative

HRSA announced its OPTN Modernization initiative on March 22, 2023, with the aim of improving OPTN technology, data transparency and analytics, governance, operations, quality improvement and innovation. UNOS supports the OPTN Modernization Initiative and increasing competition because we agree the system can be strengthened.

HRSA's efforts to modernize the system were bolstered by the enactment of the Securing the U.S. Organ Procurement and Transplantation Network Act of 2023 (P.L. 118-14). The law specifically authorized: (1) for-profit organizations to be eligible to bid on OPTN contracts; (2) the OPTN Board support contract to be distinct from contracts awarded for OPTN operations; (3) increased appropriations by removing the \$7 million annual cap on appropriations; and (4) a Government Accountability Office (GAO) report on OPTN financing due to Congress by September 2025.

President Biden's Fiscal Year (FY) 2024 and 2025 budget requests included more than double the federal funding, \$67 million total, for the OPTN to support the OPTN Modernization Initiative. UNOS supported these requests.⁸ Congress appropriated an additional \$23 million in FY 2024 for a total of \$54 million for the OPTN.

⁶ United Network for Organ Sharing. (2025, April 14). *Waitlist deaths decrease under UNOS' operation of nation's organ system*. <https://unos.org/news/waitlist-deaths-decrease-under-unos-operation-of-nations-organ-system/>

⁷ United Network for Organ Sharing. (n.d.). *UNOS Data and Transplant Statistics*. <https://unos.org/data/>

⁸ United Network for Organ Sharing. (2024, April 26). *FY2025 OPTN funding stakeholder letter*. <https://unos.org/wp-content/uploads/FINAL-Stakeholder-FY25-HRSA-OPTN-Appropriations-Letter.pdf>

The FY 2025 funding for the OPTN remains at the FY 2024 level, as the federal government is operating under a Continuing Resolution until September 30, 2025. Federal funding provides only a small portion of the funds used to operate the OPTN. The majority of the OPTN funding is provided by transplant hospitals through OPTN registration fees paid for each patient added to the transplant waitlist.

Some progress has been made in HRSA's Modernization Initiative, most notably the separation of the OPTN Board of Directors from UNOS' Board of Directors. The original National Organ Transplant Act of 1984 required that the OPTN be operated as a single non-profit entity; hence, to comply with the law, UNOS' board had to also serve as the OPTN's board. The OPTN Board of Directors became independent after the 2023 revisions to the National Organ Transplant Act required the separation, and after HRSA changed the OPTN contract with UNOS to remove the requirement that the OPTN Contractor's Board of Directors serve as the OPTN Board of Directors,⁹ and the OPTN Board of Directors approved corresponding changes in the OPTN Bylaws on March 26, 2024.¹⁰ Specifically, the OPTN Board eliminated the requirement in the OPTN Bylaws for the OPTN Board of Directors and the OPTN Contractor's Board of Directors to have identical membership. The OPTN contract changes and OPTN Bylaws changes were effective on March 30, 2024.

UNOS took the initiative in establishing its own independent UNOS Board of Directors, effective March 30, 2024. HRSA established an independent OPTN Board on July 24, 2024, and awarded the contract to support them to the American Institutes for Research (AIR) in August 2024. I am committed to collaborating with the U.S. Department of Health and Human Services, HRSA, CMS, Congress and other stakeholders to continue to support the OPTN Modernization Initiative.

Patient Safety

At UNOS, our top priority is and always has been patients. UNOS wants potential organ donors to be confident in the hospitals making decisions with their family about their care at the end of life. It is clear, based on recent reports of patient safety incidents, that additional efforts to bolster patient safety at hospitals are necessary, inside and outside of the OPTN's authority. UNOS is ready to work with HRSA, CMS, Congress, and other stakeholders to advance necessary patient safety reforms.

Kentucky Investigations

This hearing was prompted by the Committee's interest in understanding several OPTN and HRSA investigations into a patient safety incident first raised at a House Energy & Commerce Committee hearing on September 11,

⁹ HRSA's contract with UNOS for OPTN support previously stated: The Contractor shall support **and maintain** (*emphasis added*) an OPTN BOD governance structure that focuses on meeting the requirements of NOTA, the OPTN final rule, and the OPTN contract.

¹⁰ Organ Procurement and Transplantation Network. (March 26, 2024). *OPTN Board of Directors Meeting Summary*. https://optn.transplant.hrsa.gov/media/1ddiojnl/20240326_board-of-directors_meeting-summary.pdf; Organ Procurement and Transplantation Network. (n.d.). *Proposal to Address the Relationship of the OPTN and OPTN Contractor Boards*. <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/proposal-to-address-the-relationship-of-the-optn-and-optn-contractor-boards/>

2024. The details of the story, as alleged in that hearing, are deeply disturbing. But UNOS alone could not have prevented this incident because UNOS does not and cannot:

- Make death determinations — only physicians can do that.
- Direct day-to-day operations at local hospitals or override medical decisions.
- Force hospitals to make donor referrals.
- Control individual patient care protocols.

It is also important to clarify that UNOS is not a health care provider. UNOS does not create organ allocation policy, regulate OPOs, transplant hospitals, or physicians, nor does it participate in clinical decision-making, death determination, or the physical recovery or transport of organs. UNOS is also not a federal investigatory, oversight or law enforcement authority. It has no subpoena power and cannot compel documents or past case records from any party. UNOS supports the government's right to take these steps under law, but insinuations that UNOS has somehow failed by not taking these actions reflect a misunderstanding of the law and federal oversight authority.

OPTN Investigations

The OPTN, with oversight and participation from HRSA, conducted two investigations into the case from September 2024 through March 2025. UNOS, as a HRSA contractor supporting the OPTN, worked throughout the investigative process as directed by the OPTN volunteers and authorized by HRSA and approved processes. HRSA was involved in every step of each investigation and had direct oversight of the process. UNOS did not have a decision-making role in any of these processes, including the decision to close a review or investigation.

To investigate the Kentucky incident, the OPTN volunteers evaluated the individual patient case, as well as more expansive patient records from October 2021 to December 2024 that were provided by the OPO.

The OPTN Membership & Professional Standards Committee (MPSC), a committee of 41 volunteers, is responsible for reviewing OPTN members for compliance with OPTN obligations and reviewing events identified as potentially presenting a risk to patient safety, public health, or the integrity of the OPTN. The MPSC conducts its work under peer review.

1. MPSC Review Participants

The MPSC review team for this case was comprised of clinical experts in donation and transplant, including nephrologists, surgeons, OPO leadership, and others. The OPTN Board president also joined some MPSC leadership calls regarding the investigation. UNOS staff, as the HRSA contractor supporting the OPTN, assisted these volunteers, as established in the MPSC policies approved by HRSA. UNOS, at no point, was able to direct or determine the outcome of the investigation. HRSA had several HRSA employees in the MPSC's initial investigation. Further, HRSA had independent authority, on behalf of the Secretary, to make decisions and to assist the investigation throughout its entirety, and to supplement any investigatory actions requested by the OPTN (for example, by compelling the production of records, as UNOS and the MPSC can only request records).

2. Ad-Hoc Review Participants

The OPTN Board president also established an ad hoc group of eight volunteers from the OPTN Board, MPSC, and other volunteers for a special review, as directed by HRSA. HRSA actively engaged in the review and approval of all the ad hoc group members, as well as the UNOS staff supporting the group. The OPTN volunteers in the ad hoc group also included surgeons, OPO leadership, as well as patient and donor family representation. This group was supported by UNOS staff, who – again - possessed no decision-making authority. HRSA also had several HRSA employees in the ad-hoc group's additional investigation. Further, HRSA had independent authority, on behalf of the Secretary, to make decisions and to assist the investigation throughout its entirety, and to supplement any investigatory actions requested by the OPTN.

3. HRSA's Report

HRSA's independent investigation, conducted separately from the OPTN, resulted in a report to the HRSA Health Systems Bureau Associate Administrator on March 24, 2025. UNOS received a copy of this report on July 9, 2025. UNOS is not aware if HRSA has shared the March 24, 2025, report with the OPTN. The report was provided to UNOS by HRSA's Office of Legislation staff after UNOS met with the Energy & Commerce Oversight & Investigations Subcommittee staff on July 8, 2025.

In the report, HRSA criticized UNOS for perceived conflicts of interest after some UNOS leadership and staff signed an open letter calling for full investigations. The open letter was a call for the community to act to enhance the broader integrity of the transplant system amid intense public scrutiny, rather than an attempt to obstruct oversight. In response to HRSA's concerns, UNOS took steps to exclude staff who signed the letter from supporting the ongoing investigation, demonstrating a willingness to adapt and maintain impartiality. Similarly, community members who signed the letter were prohibited from participating in the investigation. UNOS' cooperation with HRSA's directives and its role in facilitating a transparent review process underscore its commitment to accountability.

While HRSA's findings highlight areas where OPTN oversight could be strengthened, they also reflect the inherent challenges of managing a national transplant system established by law as a public-private partnership. UNOS' actions throughout the investigation demonstrate prompt engagement, compliance with federal directives, and support for OPTN and MPSC responsibilities.

Summary

At each point that UNOS was involved in supporting the investigations, UNOS acted as directed by HRSA and in accordance with established processes to support the MPSC, the OPTN, and HRSA, following the requirements in the OPTN contract, the OPTN policies, the OPTN bylaws, the Final Rule and NOTA.

HRSA has the responsibility to direct and participate in the case review and investigations, as it has regulatory authority over the OPTN. UNOS carried out its role as a contractor following HRSA's direction, and UNOS fulfilled its obligation as a contractor by executing the investigative plan that the OPTN approved with HRSA's oversight.

Despite being present for all discussions related to the investigative plan, which included discussion of the materials to be requested from the OPO, after initial investigation, HRSA called the OPTN experts' investigation insufficient. HRSA made this determination after the experts initially determined there was no apparent OPTN policy violation. **The most concerning behavior identified by MPSC leadership was by the hospital, which is not an OPTN member and therefore not subject to OPTN policies.**

Thereafter, HRSA directed the expansion of the investigation beyond the incident, and into a fuller review of potential systemic issues at the OPO.

The OPTN policy standard against which the MPSC reviewed the case initially was whether the OPO was: "Acting to avoid risks to patient health or public safety." This is not an objective, black-and-white standard; the standard is applied by the OPTN reviewers with their clinical knowledge and experience to evaluate whether, in any given instance, an OPTN member is acting to avoid such risks. Doing so also requires the OPTN volunteers to acknowledge that the field of donation and transplant, and indeed the entire field of medicine, is never completely risk-free. Therefore, the OPTN Final Rule establishes the process that HRSA used for the Secretary's designees (HRSA employees) to conclude differently, according to the above standard, than the organ donation and transplant professionals and patient and donor families on the OPTN committees and Board of Directors and to broaden investigations.

Since the Kentucky investigations concluded, steps have been taken by UNOS consistent with HRSA's direction to address the allegations. In April 2025, HRSA announced¹¹ it would take an expanded focus on investigating patient safety issues as part of its OPTN Modernization Initiative. In a letter dated May 28, 2025, HRSA directed the OPTN/MPSC to monitor the OPO on various clinical criteria for a year. UNOS has already begun supporting the requirements outlined in that letter from HRSA. HRSA also developed its own report separate from the OPTN investigations, dated March 24, 2025, which UNOS received on July 9, 2025. The report was provided to UNOS by HRSA's Office of Legislation staff after UNOS met with the Energy & Commerce Oversight & Investigations Subcommittee staff.

On July 1, 2025, an incident similar to the Kentucky case was shared at the OPTN Board of Directors meeting. AIR runs these meetings to support the OPTN Board as a HRSA contractor. Upon hearing about the incident during the meeting, UNOS reported it to HRSA within 24 hours as required by contract. HRSA indicated it is "coordinating internally and has sufficient information to determine what actions, if any, we will direct UNOS to undertake on this matter."

This incident, as well as the event described during the September 2024 hearing, highlights a serious gap in the ability of patients and families to report concerns. Patients, families and other stakeholders in the system deserve a reporting mechanism that they trust and understand.

¹¹Health Resources & Services Administration. (April 2025). *Recognizing Donate Life Month: Expressing Gratitude for Those Who Give, and Honoring the Resilience of Those Who Wait*. <https://www.hrsa.gov/optn-modernization/updates/april-2025>

Moving Forward to Strengthen the System for Patients and Donor Families

There is no greater priority for UNOS than a fair, effective, and safe organ donation and transplant system. The federal government has existing authority to make changes to improve organ donation and transplantation in the U.S. – inclusive of the OPTN as well as beyond the OPTN. In addition to Congress, HRSA and CMS, agencies including the FAA, the U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and Department of Transportation (DOT) all have a role in improving the organ donation and transplant system. UNOS is eager to make necessary reforms to the system, and UNOS cannot do so without leadership from Agency partners.

To strengthen the U.S. organ donation and transplant system, UNOS proposes four key reforms to enhance patient safety, transparency, and efficiency. These include several key improvements: The creation of a “no wrong door” patient safety reporting system that allows anyone, including patients, providers, or family members, to report safety concerns easily and effectively; a nationwide implementation of automated deceased donor referrals to streamline and modernize the donor referral process; a robust national tracking system for unaccompanied organs in transit to prevent loss, delays, or damage; and moving the OPTN computer system to the cloud.

In addition to these four key reforms outlined above, UNOS also recommends additional reforms to improve transparency, patient empowerment, in-cabin airplane transport for organs, and Medicare incentives for transplant hospitals to accept medically complex organs to ensure more donated organs are used effectively.

All these reforms aim to close critical gaps in oversight, improve patient outcomes, and ensure that the system is centered on the needs and voices of patients and donor families.

Key Reforms

“No Wrong Door” Patient Safety Reporting

Congress should direct HRSA and CMS to create a comprehensive, “no wrong door” patient safety reporting system to ensure that patient safety events are quickly reported by providers, patients, family members, or anyone who has witnessed or learns of a potential safety incident. Since most hospitals in the U.S. are not OPTN members and therefore fall outside the OPTN patient safety reporting requirements, CMS and HRSA must work together to close that gap. Without a comprehensive reporting system, patient safety incidents can fall through the cracks. Any patient safety reporting system must be well understood by the American public to ensure its effectiveness.

Optimize the Donor Referral Process with Automated Donor Referrals (ADR).

Successful organ transplants depend on information-sharing with OPOs. This reporting is often undertaken manually by overworked hospital staff. It is antiquated and inefficient. An automated referrals system using electronic health records is being piloted by several OPOs and hospitals. Determining best practices and how to adopt this technology across the country would ensure OPOs are automatically alerted about every potential organ donor when a dying patient meets predetermined clinical criteria. Small studies have found a 49 percent

increase in donor referrals and a 333 percent increase in organ donors upon implementation of ADR. U.S. Representatives Wittman, Miller-Meeks, McClellan, Costa introduced legislation referred to Energy and Commerce, H.R. 330, the Organ Donation Referral Improvement Act, to require a study to determine how to implement this nationally. U.S. Representatives Van Duyne, Del Bene, Miller, and Costa introduced legislation referred to Ways and Means, H.R. 4470, Removing Burdens From Organ Donation Act, to improve the donor referral process from hospitals to OPOs with software tools. UNOS endorses both of these important pieces of legislation.

Implement a National Tracking System for Unaccompanied Organs in Transit

There is no federally required national tracking system for organs in transit to prevent them from being lost, delayed or damaged. A national, centralized, and compulsory system-wide tracking system would give key organ transplant stakeholders maximum visibility into the transportation of life-saving organs, while enabling thorough investigations of lost or delayed organs, which is critical to implementing systemwide improvements. This concept has been discussed for several years but needs action. In response to Congressional hearings noting that Americans can track their online orders and pizza deliveries but not the whereabouts of lifesaving organs in transit, HRSA can and should direct the OPTN to establish an OPTN policy that mandates the use of tracking devices, at the very least for unaccompanied organs. The technology to do so exists; the policy does not.

Migrate the OPTN Computer System to the Cloud

The OPTN Computer System is secure, stable and reliable, providing OPTN members 99.9% uptime. Migration to a modern cloud-based infrastructure is important to making necessary modifications to the system, such as interoperability, modern APIs, and other technology like artificial intelligence which would improve features and functions for OPTN members and researchers which ultimately improves organ donation and transplant for patients.

Additional Reforms

Transparency

Increased transparency is critical to drive greater public and community trust in the nation's organ donation and transplant system. As a HRSA contractor supporting the OPTN, UNOS developed and published the Lung Monitor Dashboard — a first-of-its-kind organ-specific monitoring dashboard that was previously only available to transplant professionals and not the public. The dashboard reports data on key allocation measures. It can also monitor the impact of policy changes based on the geography of where transplant hospitals are located and if they are in rural or urban areas. It serves as an important complement to the static monitoring reports for continuous distribution of lungs. The dashboard became publicly available in November 2023 following HRSA approval.

UNOS, as a HRSA contractor, also developed interactive OPO organ recovery and usage maps, which display both OPO and hospital-level recovery and transplant information. This information is based on donor characteristics selected by the user, as well as an organ usage map that displays which programs are

transplanting the organs from those same donors. UNOS is advocating that HRSA make additional dashboards available to deliver at-a-glance information to the public, patients, providers, and policymakers.

Patient Empowerment

Given the importance of ensuring a patient-centered organ donation and transplant system, UNOS is advocating that HRSA require the OPTN to offer additional expansive consumer empowerment tools to enable patients to make choices regarding their care, as well as education and resources for patients, donors, caregivers, parents, and their families.

Future iterations of the OPTN contract should require, in collaboration with the patient community, the development of consumer choice tools that include information to assist patients in finding appropriate care for their needs, timely updates about new patient benefits or care programs, emerging medical innovations, and a candidate's status on the waitlist to help patients navigate through the donation and transplant process. Including these enhanced offerings as part of the OPTN Contract would ensure that the OPTN serves as a centralized resource to patients and their loved ones during their journey.

In-Cabin Airline Transportation for Organs

Life-saving organs should never be relegated to airline cargo bays, where they are more prone to damage, loss, or delay because of cargo staffing limitations. It should not take an act of Congress for HRSA and other federal agencies and departments to convene to address the challenge of unaccompanied organs being transported in the cargo of commercial airlines – but it did. UNOS advocated for a provision in the most recent Federal Aviation Administration (FAA) reauthorization legislation (P.L. 118-63, Section 1102) that would mandate that the Department of Transportation convene relevant agencies and stakeholders to make recommendations regarding best practices to transport organs in the cabin of commercial aircraft to avoid delays, damage, or loss of these life-saving gifts. The FAA released the Organ Transportation Working Group's final report on May 12, 2025. The report included 20 recommendations for airlines, OPOs and couriers, HRSA, the Transportation Security Administration (TSA), and FAA to support the above-wing transportation of donated organs. These recommendations are viewed as a foundational first step and are advisory in nature. UNOS calls on all associated stakeholders to implement FAA's recommendations as soon as possible, as no statutory or regulatory barriers to their implementation were identified by the working group.

Medicare Incentives for Transplant Hospitals to Accept Medically Complex Organs

More kidneys are recovered for transplant every year, in part because OPOs are increasingly pursuing more medically complex donors. The changes in the health of the donor population, including increased history of hypertension, diabetes, and cancer, largely explain the increase in non-use of these hard-to-place kidneys. Last year, 9,266 deceased donor kidneys were recovered for transplant but not ultimately transplanted. In many cases, this was because they could not be paired in time with a hospital willing to take on the clinical and financial risks that come with accepting organs from more medically complex donors. Kidneys from these donors may have delayed graft function, and patients receiving these kidneys may require dialysis after their transplant until the transplanted kidney starts working. This treatment and monitoring may require longer hospital stays.

However, evidence shows that kidneys from more medically complex donors can still result in successful transplant outcomes with appropriate post-transplant care, and that patients will live longer if they receive a transplant – even from a more complex kidney - than if they wait on dialysis. One study estimates that 62 percent of kidneys that were not transplanted in the U.S. between 2004-2014 would have been successfully transplanted in France¹². A policy change to Medicare to compensate transplant hospitals at a higher rate for transplanting more medically complex kidneys would encourage more hospitals to accept these kidneys for their patients. This could save more than 5000 avoidable deaths annually. Currently, 13 patients die each day awaiting organ transplant, a 23.5% decrease from 2021. This change could potentially reduce that number to zero.

Conclusion

The nation's organ donation and transplant system is founded on trust. To continue to earn and keep that trust, all stakeholders, Congress and the federal government must work collaboratively to continuously improve the system for the benefit of patients and donor families, who deserve a fair, effective and safe organ donation and transplant system. UNOS is eager to work with the Energy & Commerce Committee to strengthen this vital system that serves as a beacon of hope for patients and families across America.

¹² Aubert, O., et al. (2019). Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased US Acceptance. *JAMA internal medicine*, 179(10), 1365–1374.
<https://doi.org/10.1001/jamainternmed.2019.2322>