



## +Insight

# Organ Procurement and Transplantation Network: What's Next in Oversight and Reform

The Organ Procurement and Transplantation Network (OPTN) is a public-private partnership that manages the US organ donation and transplantation system. Today, more than 100,000 people are on the organ transplant waiting list, and 17 people die every day waiting for an organ to become available. Chronic performance problems related to technology, transportation and allocation, among other issues, have led to many congressional inquiries and oversight investigations. In March 2023, the Health Resources and Services Administration (HRSA) announced the OPTN Modernization Initiative, which aims to strengthen the OPTN in five areas: technology, data transparency, governance, operations and quality improvement and innovation. Read on as we explore recent developments with the Modernization Initiative and look ahead to what's next.

## OPTN OVERVIEW

The OPTN is a unique public-private partnership that links all professionals involved in the US organ donation and transplantation system and is responsible for establishing policies and procedures for organ donation and transplantation that ensure the equitable distribution of organs for transplantation. A board of directors runs the OPTN, and the board includes representatives from all sectors of the transplant community, including organ procurement organizations (OPOs), transplant hospitals and transplant recipients. The OPTN's mission is to increase the number of organs available for transplantation and to distribute them fairly to patients by developing and implementing policies and procedures for organ donation, allocation and transplantation. The OPTN board oversees policies and staff management, while committees focus on specific organ donation and transplantation aspects, such as ethics and organ allocation. Staff manage day-to-day operations, including the maintaining the database and assisting transplant experts.

The OPTN has 11 regions, each responsible for managing the organ transplant system within its area. The regions are run by advisory committees that consist of representatives from OPOs, transplant hospitals and transplant recipients. Each region has a member on the UNOS board of directors and a representative on every standing committee. The regional system facilitates communication among OPTN staff, the UNOS board of directors and the transplant community.

## UNOS CHALLENGES

UNOS is the private, nonprofit organization that manages the OPTN under contract with the federal government. It has been the sole holder of this contract for 40 years.

Many official congressional inquiries and reports cited in the press have identified significant mismanagement of UNOS technology, transportation and allocation for the organ procurement program.



## OUTDATED TECHNOLOGY

UNOS's information technology (IT) infrastructure is outdated, and the organization has had little incentive to modernize. Its IT system still relies on manual entry and is prone to crashing for hours at a time, which can leave providers without any information about the location or availability of life-saving organs. The US Department of Homeland Security has also expressed concerns about the privacy and cybersecurity of UNOS's technology.

Despite its status as a quasi-government agency, UNOS independently owns the technology that currently supports the entire national organ transplant system. Since this technology is private intellectual property, contracting with a new organization might require building a completely new IT system. While HRSA is carefully managing this transition, there are concerns that the time-sensitive process of matching deceased donor organs with the more than 100,000 people waiting for an organ transplant could be impacted.

## INEFFICIENT ALLOCATION

In 2021, 5,000 people died on the wait list while 5,912 organs were discarded. Some of this organ rejection was due to quality, but other reasons include increased costs for certain types of organs and logistical challenges. This problem is not inherent in other nations' organ transplant systems. In France, for example, about 62% of these discarded organs would have been used.

Changes in allocation practices have led to increases in transplants. As of May 2021, UNOS no longer allocates organs based on proximity of donor to patient. This resulted in a 16% increase of the transplant rate. This cannot all be attributed to the policy change because organ donations increased by 14% in the same period. Even a 2% transplant rate increase, however, shows that allocation policy makes a difference in how many patients receive organs.

## TRANSPORTATION FAILINGS

OPOs have delivered organs that are delayed, diseased or damaged. The current contract cannot require organs to be tracked, which makes it difficult to retroactively identify what happened to the missing or unusable organs.

In 2021, organs began to travel longer distances in an imperfect transportation system, increasing their likelihood of damage or delay. The organ discard rate increased after the de-prioritization of proximity in allocation decisions, despite an increased transplantation rate. The transplantation rate would increase more if the OPTN ensured that organs would get to their destination safely.

## RECENT KEY DEVELOPMENTS

### 2020

- **February 2020:** The Senate Finance Committee (SFC) began a series of inquiries by sending a [letter](#) to UNOS's CEO addressing concerns about OPTN oversight gaps, specifically related to UNOS and the 58 monitored OPOs. The letter questioned UNOS's oversight effectiveness, accountability and transparency, and whether gaps in these areas had led to OPO underperformance. The letter emphasized the need for improvement to ensure effective organ



## Organ Procurement and Transplantation Network: What's Next in Oversight and Reform

recovery and sought responses from UNOS pertaining to UNOS's role in overseeing OPOs' organ recovery and transplantation. SFC requested information on topics such as data accuracy, audits, patient safety, conflicts of interest, compensation and operational transparency.

- **October 2020:** SFC sent a [letter](#) to the US Department of Health and Human Services (HHS) addressing concerns raised by reports of patient safety and quality control lapses, financial misuse and inefficiencies within the OPTN. SFC requested responses concerning OPO certification records, complaints, standardization of organ acquisition costs, double billing of registration fees, financial operations, conflict prevention, safety coordination, IT system management and taxpayer fund usage for lobbying.
- **December 2020:** Shortly following SFC's letter to HHS, the Centers for Medicare & Medicaid Services (CMS) released a [final rule](#) to reform OPTN conditions for coverage. The rule addressed transparency and accountability issues because the previous standards lacked objectivity and had resulted in unrecovered organs and patient safety risks. The reforms aimed to save lives, increase organ transplantation rates and improve health equity for communities of color.

### 2021

- **February 2021:** SFC [issued](#) a subpoena to UNOS as part of its ongoing investigation into OPTN. The subpoena compelled UNOS to provide documents related to the investigation into OPOs and potential false claims submitted to government benefit programs.
- **March 2021:** SFC sent a [letter](#) requesting data from the OPO OneLegacy regarding the procurement of pancreata (organs responsible for producing insulin) for research. The SFC was concerned about the potential exploitation of a loophole in the CMS final rule that allowed OPOs to count pancreata procured for research in the same way they count organs procured for transplants, possibly leading to inflated performance metrics that would help OPOs maintain contracts with CMS. The letter sought specific information from OneLegacy, such as the number of pancreata recovered, placed for transplant and placed for research, to evaluate whether the loophole was being misused and to ensure compliance with regulations.
- **March 2021:** SFC expressed concern about delayed implementation of the final rule for OPOs and urged prompt implementation, given bipartisan support for the rule and endorsements from various experts and advocacy groups.
- **April 2021:** HHS [began](#) implementation.
- **July 2021:** SFC sent another [letter](#) to HHS urging that additional steps be taken to expedite the recently implemented rule's effectiveness. The SFC cited concerns that delaying the potential decertification of underperforming OPOs until 2026 would not timely address the increased organ demand and health disparities created by the COVID-19 pandemic.

### 2022

- **August 2022:** SFC released a [report](#) exposing severe mismanagement within the organ transplant system overseen by UNOS. The multi-year investigation revealed widespread errors and negligence leading to patient deaths and illnesses disproportionately affecting minorities, such as African



## Organ Procurement and Transplantation Network: What's Next in Oversight and Reform

Americans needing kidney transplants. The report found that outdated and insecure IT systems further compromised patient safety and data security. The report called for reform in leadership, policies and technology to rectify these life-threatening issues.

- **November 2022:** SFC sent a [letter](#) to the president of the National Academies of Sciences, Engineering, and Medicine (NASEM) requesting information related to the development of a recent report, including whether committee members involved in developing the report had any financial interests in entities involved in organ or tissue procurement or transplantation. The NASEM report was titled “[Realizing the Promise of Equity in the Organ Transplantation System](#).” It seemed to align with the lobbying positions of UNOS and the Association of Organ Procurement Organizations, and prompted a [letter](#) of thanks from OPTN.

### 2023

- **March 2023:** SFC sent another [letter](#) to OneLegacy expressing concern that OPOs might be reporting pancreas procurements that did not meet the standard of bona fide research consistent with regulation and statute. An increase in pancreata procurement signaled to SFC that many of these organs may not have been recovered for legitimate research purposes. SFC also reported receiving communications indicating that OPO employees were actively discussing how to exploit new regulations from CMS to increase their performance metrics. SFC proposed sending letters to 10 OPOs requesting data on the number of pancreata recovered and their purpose.
- **March 2023:** HRSA announced its OPTN Modernization Initiative, which sought to reform and strengthen OPTN in five areas: technology, data transparency, governance, operations, and quality improvement and innovation. The announcement included a statement of intent to not award the contract to UNOS without large-scale reform.
- **July 2023:** In response to HRSA’s announcement, SFC held a hearing titled “[The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System](#)” to discuss OPTN’s problems, reform efforts and proposed policy solutions. A summary of the discussion can be found [here](#).
- **September 2023:** To aid HRSA’s Modernization Initiative, Congress passed and the president signed into law the Securing the U.S. Organ Procurement and Transplantation Network Act ([H.R. 2544](#)). This legislation gives HRSA necessary flexibility by removing caps on the number of grants, contracts and funds HRSA can award for OPTN maintenance and separating these awards from any funds allocated to the OPTN’s board of directors. The legislation specifically requires that the OPTN board be supported by an organization that is separate from the organizations that support OPTN operations. It also requires the US Government Accountability Office to conduct a review of the OPTN’s historic financing. While the legislation increases HRSA’s flexibilities, it does not allocate necessary funding. The Administration has asked Congress to double the funds for OPTN to \$67 million and remove the cap on appropriations for contracts that HRSA can award. As Congress continues to work on its annual appropriations bills, this money has not yet been included in any of the short-term funding bills for FY 2024.
- **September 2023:** HRSA [announced](#) an inter-departmental collaboration with CMS. The Organ Transplantation Affinity Group (OTAG) aims to meet five goals: reducing variation in pre-transplant practices, increasing organ availability, enhancing accountability, promoting



equitable access, and engaging patients and families. OTAG's 2023–2028 Action Plan uses nine strategies to improve OPTN performance and equity:

- Improve transparency of pre-transplant and referral practices
  - Establish criteria for standardization and transparency of waitlist practices
  - Remove barriers to use of donated organs, including living and medically complex organs
  - Ensure organ acquisition payment policies promote equity and support organ procurement
  - Identify performance measures and incentives to drive accountability for systems change
  - Support US OPTN operations, including embedding Continuous Quality Improvement efforts across the system
  - Ensure OPTN policymaking processes and policies create equitable outcomes across populations
  - Improve transparency of referral and waitlist processes for patients, families and caregivers
  - Enhance patient, family and caregiver education and engagement.
- **November 2023:** The Office of Management and Budget received for review prior to publication in the *Federal Register* a CMS proposed rule titled Alternative Payment Model Updates; Increasing Organ Transplant Access (IOTA) Model (CMS-5535). The proposal would create a new mandatory Medicare payment model under section 1115A of the Social Security Act. This model would test ways to advance CMS's goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

## GOALS OF THE HRSA MODERNIZATION INITIATIVE

HRSA's [Modernization Initiative](#) aims to strengthen the OPTN in five key areas. HRSA notes its goals for each area and specifies how it will begin to achieve those goals:

- **Technology** – The OPTN IT system will be reliable, secure, patient-centered, user-friendly and reflective of modern technology functionality. There will be continuous focus on improved IT system functionality and security, while ensuring continuity of services, protecting patient safety and accelerating innovation in line with industry-leading standards.
  - The Next Generation contract will focus on modernizing OPTN's foundational IT systems.
- **Data Transparency** – OPTN data will be accessible, user-friendly and patient-oriented. The Modernization process will provide easily accessible, high-quality and timely data to enable informed patient, donor and clinical decisions; measure and evaluate program performance; inform oversight and compliance activities; and support the advancement of scientific research.
  - HRSA created a data dashboard to track and evaluate data for donor organ procurement, allocation, distribution and transplantation.
- **Governance** – The OPTN board of directors will be high-functioning and have greater independence. It will represent the diversity of communities and delivers effective policy development.



## Organ Procurement and Transplantation Network: What's Next in Oversight and Reform

- An OPTN board of directors, independent from the contractor, will be created to increase accountability and assist HRSA in oversight.
- **Operations** – The OPTN will be effective and accountable in its implementation of organ policy, patient safety and compliance monitoring, organ transport, OPTN member support, and education of patients, families and the public.
  - In upcoming requests for proposals, HRSA will move towards differentiating OPTN support functions by designating a different potential contractor to carry out OPTN operations than the contractor for the board and IT systems.
- **Quality Improvement and Innovation** – The OPTN will promote a culture of quality improvement and innovation across the network by leveraging timely data and performance feedback, collaborative learning and strategic partnerships.
  - The Administration's goals are to increase organ donations and improve procurement. The Administration will promote innovation through continuous competition among potential contractors.

This initiative is expected to lead to restructuring of the entire OPTN system and division of the current OPTN contract, on which UNOS has historically had a monopoly. OPTN's program management contract, which covers programming and strategic planning, was awarded to a joint venture between Guidehouse and the Poarch Band of Creek Indians in summer 2023. In early 2024, HRSA plans to release a solicitation to establish multiple new contracts for transition planning (transition contracts), followed by a solicitation to establish new contracts for implementation ("next-gen" contracts), in spring 2024. A more detailed timeline is outlined below.

### Phase 1: OPTN Modernization Design and Strategy Development

In summer 2023, HRSA, with the assistance of the program management contractors, began engaging with external stakeholders and conducting market research to develop the upcoming contract solicitations. Part of this outreach included a series of [industry days](#) in which interested parties gathered to speak with HRSA about their efforts to date and the upcoming contract solicitations.

Highlighted efforts taken by HRSA and the program management contractors in Phase 1 as of July 21, 2023, are listed below:

- **Collaborated with Industry** – HRSA provided information to and forums for potential vendors.
- **Provided Data** – HRSA created [public dashboards](#) for patients, clinicians and researchers to aid in decision-making.
- **Engaged with Diverse Stakeholders** – HRSA spoke to patients and their families, using their unique perspective to identify areas of need within the industry.
- **Built HRSA Capacity for Modernization** – HRSA used digital services to create stakeholder engagement in the Modernization Initiative.



## Organ Procurement and Transplantation Network: What's Next in Oversight and Reform

- **Secured Support for Modernization** – the President's FY 2024 Budget called for increased resources and authority for HRSA, including the ability to use different entities to enhance performance and innovation.

### Phase 2A: OPTN Transition Management

In early 2024, HRSA will release a multi-vendor solicitation for the operations transition contracts, referred to as the transition indefinite delivery, indefinite quantity (IDIQ) solicitation, which will ensure OPTN continuity as the next-gen contracts are implemented. The transition IDIQ presolicitation has been [noticed](#). An overview of the task areas of the transition contracts is provided below. HRSA has expressed its commitment to soliciting feedback from interested parties during the development and implementation of this work.

**OPTN Operations and Governance** – All other task areas rely on the operational stability provided by awardees in this area. This area includes the following:

- The transition to an independent OPTN board of directors supported by a nonprofit with HRSA oversight
- Management of OPTN finances, operations and member compliance
- Observation and correction of potential issues that could impact OPTN continuity
- Continuous implementation of OPTN protocols, policies and guidelines.

**IT System and Data Continuity, Maintenance and Compliance** – OPTN operations are enforced by standards and compliance measures created in this task area. This data infrastructure also aids in communication and research activities. This area includes the following:

- Maintenance of the IT system
- Continuous verification and updating of algorithms
- Implementation and monitoring of compliance with independent OPTN board policies and applicable laws
- Implementation of data continuity and security measures.

**Communications** – Communicating the operational activities and research findings to the broader audience, bridging the gap between OPTN and its stakeholders. This area includes the following:

- Patient and public engagement
- Regular stakeholder communication
- Management of the OPTN website
- Educational material development.





## Organ Procurement and Transplantation Network: What's Next in Oversight and Reform

**Research and Evaluation** – Research conducted in this task area informs operational changes, IT system updates and communication strategies. This area includes the following:

- Conducting state assessments and special studies to prepare HRSA for modernization while protecting patient safety
- Evaluating OPTN operations and functions
- Providing recommendations for improvements.

**General Requirements** – In all task areas, awardees will implement these general requirements to ensure legal compliance, effective coordination and smooth transition of responsibilities. Any entities bidding for any contract need to address this task area in their proposal. This area includes the following:

- Onboarding and expectation setting
- Vendor collaboration
- Support transition of any contract activities to new entities
- Compliance with the Federal Acquisition Regulation (FAR) and all applicable laws and regulations.

In early 2024, HRSA will also release a single-vendor IDIQ solicitation contract to oversee OPTN board support. This contract will be awarded to a nonprofit organization.

**Board Support** – This single vendor contract will be awarded to a distinct entity responsible for OPTN board policies, OPTN support, policy enforcement and regular reviews. The entity's responsibilities will include the following:

- Administrative services
- OPO member and executive director management
- OPO governance
- OPTN governance and oversight.

### Phase 2B: OPTN Modernization Implementation

In late spring 2024, HRSA will release a solicitation for the next-gen contract, which will ask vendors to enhance current infrastructure. Next-gen vendors will build and test modernization ideas using human-centered design practices, implement IT modernization, and carry out specific functions such as initial prototyping, testing, scaling, integration, deployment and adoption support.

For more information, please contact [Julia Grabo](#), [Erica Stocker](#) or [Karen S. Sealander \(McDermott Will & Emery—Counsel\)](#).





## Organ Procurement and Transplantation Network: What's Next in Oversight and Reform

McDermott+Consulting LLC is an affiliate of the law firm of McDermott Will & Emery LLP. McDermott+Consulting LLC does not provide legal advice or services and communications between McDermott+Consulting LLC and our clients are not protected by the attorney-client relationship, including attorney-client privilege. The MCDERMOTT trademark and other trademarks containing the MCDERMOTT name are the property of McDermott Will & Emery LLP and are used under license.