

House Energy and Commerce Oversight and Investigations Subcommittee

July 22, 2025, Hearing on Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System

Questions for the Record for Dr. Raymond Lynch (HRSA)

The Honorable John Joyce, M.D. (R-PA)

1. As HRSA's report indicates, there are many concerning features among the cases analyzed, and oversight is critical to ensure the system operates safely and in accordance with laws and regulations. Even if all policies and regulations were followed correctly, should we rethink how these guardrails are structured to prevent future harm to patients?

Response:

The Corrective Action Plan HRSA issued to the OPTN on May 28, 2025, includes directives for the OPTN to propose policies that improve safeguards to address the concerns around donation after circulatory death that were highlighted in HRSA's March 25, 2025, memo. In addition, HRSA has also taken several actions to strengthen patient safety safeguards with respect to organ procurement and will continue to modernize core OPTN safety systems to monitor and mitigate threats to patient safety.

- **Strengthened reporting of allegations of misconduct:** HRSA [instituted a new process](#) to report allegations of misconduct related to organ donation, organ procurement, or organ transplantation. Under the new process, as reports are received, HRSA directs oversight action, triages the complaint to the appropriate investigative body, multiple bodies, or as appropriate, to the OPTN.
- **New organ procurement organization (OPO) data for improved oversight:** HRSA has proposed novel federal data collection that requires OPOs to describe how, when, and where OPOs interact with patients referred for possible organ donation by hospitals. [This data collection is currently in a public comment period](#), and stems from [an HHS Secretarial Data Directive](#).
- **More comprehensive data files:** [HRSA notified the OPTN](#) to include patient records in data and analytic files for those patients from whom OPOs attempted to procure organs to increase transparency and inform system oversight and quality improvement.
- **New policies to safeguard innovative procurement techniques:** HRSA issued a [critical comment to the OPTN concerning the practice of normothermic regional perfusion \(NRP\)](#), especially as it relates to the safety of patients who may donate their organs.
- **Investigating allegations and creating responsive policies for OPOs:** HRSA and the OPTN conducted a special review of allegations of potential preventable harm to a patient under the care of a specific OPO. Additionally, HRSA identified a concerning pattern of risk across OPOs, often linked to staff practices, which included inconsistent assessments, coordination of care, data collection, and lack of clarity on roles and responsibilities within the care team.

In response, HRSA [directed the OPTN to develop a corrective action plan for the specific OPO](#) (Network for Hope (OPTN Code: KYDA), and directed the OPTN to develop safety standards and policies for the protection of all patients who may donate organs across the nation.

- **Strengthening patient-centric governance:** HHS recently oversaw the Special Election of a new OPTN Board of Directors that officially began their term on July 1, 2025. 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 and bylaws. This review includes both the policies that govern day-to-day OPTN operations and the management and membership bylaws that define administrative responsibilities and membership requirements.
- **Developing more robust patient safety and member compliance monitoring systems:** Historically, over 80% of the annual OPTN operational costs are covered by OPTN registration fees that transplant centers pay to the OPTN contractor for each patient they add to the transplant wait list. The OPTN Committees that make policies play an important role in patient safety. These Committees, such as the Membership and Professional Standards Committee that investigates complaints, make up a significant part of the cost of OPTN operations. The temporary fee authority included in the Full-Year Continuing Appropriations and Extensions Act, 2025 (P.L. 119-4) enables HRSA to collect and distribute OPTN patient registration fees. With this user fee authority, HRSA will be able to implement significant improvements to patient safety monitoring processes, and for the first time ever, hold a contract competition to select the best-in-class vendor to support this critical function.

2. The report notes that “because the records submitted to HRSA are only those in whom there was not a rapid progression to cardiac death, HRSA cannot conclude whether the same pattern of withdrawing care in patients under chemical paralysis or sedation is at least as frequent among the patients who did progress to recovery as DCD donors.” Can you elaborate on this portion of the report and its significance?

Response:

This statement in HRSA’s memo refers to the fact that the records requested from KYDA and received by HRSA are of patients for whom procurement was attempted but not completed. HRSA did not request or receive KYDA electronic medical records for patients whose organs were procured via DCD. Thus, this caveat in HRSA’s memo is intended to convey that from the records reviewed, HRSA cannot assess whether the same pattern of inaccurate neurologic assessments and failure to account for the psychoactive effects of illicit drugs or hospital sedation occurred in that population of patients.

3. Your written testimony mentions the passage of the Securing the U.S. Organ Procurement and Transplantation Network Act and HRSA’s launch of the OPTN Modernization Initiative. It also notes that HRSA has been able to make meaningful changes in a short period due to the changes to the structure of

the OPTN and the support provided by the passage of the Act. Can you elaborate on what those changes are?

Response:

For 40 years, the Board of Directors for HRSA's contractor supporting the OPTN also served as the OPTN Board of Directors, raising longstanding concerns about potential conflicts of interest. For example, the contractor that collected registration fees also oversaw policymaking and operated the IT matching system. In addition, the OPTN Board of Directors, which was the same as the contractor's Board of Directors, oversaw investigations of patient safety complaints. As a result, the Board had little motivation to update bylaws and policies that would identify member non-compliance or deficiencies and require increased accountability within the system they operated. Because of these potential conflicts, HRSA had challenges providing meaningful oversight.

Following the passage of the Securing the U.S. Organ Procurement and Transplantation Network Act, which removed the requirement for the OPTN to be a private, non-profit entity operated by a single contractor with expertise in transplant, eliminated the statutory cap on the amount of funding available for supporting the OPTN, and required separate contracts for OPTN governance and operations, HRSA announced the first-ever multiple contractor awards to support the OPTN. Five initial awardees were tasked with research and discovery work on the OPTN system. This information will help inform the necessary changes to core OPTN operations such as IT, policy development, patient safety monitoring, financial management and communications for a modernized OPTN that better serves patients and families. To implement the new law, HRSA also built its internal oversight capacity, including a robust internal data analytics and clinical team, enabling HRSA to analyze OPTN data and clinical information.

As a part of the OPTN Modernization Initiative, HRSA formally separated the OPTN Board of Directors from the contractor and conducted a national special election to seat an independent Board. This separation mitigated conflicts of interest and ensures more transparency and government oversight of the OPTN. The new Board members are prohibited from serving on the Board of any OPTN contractor and have not served on previous OPTN Boards in the past 10 years. The new OPTN Board of Directors began their term on July 1, 2025.

4. Your written testimony notes that historically, pre-waitlist and pre-donor groups were excluded from consideration by the OPTN in policy making and review, but over the last year HRSA has undertaken an effort to expand OPTN data collection to fully capture the outcomes and experiences for whom OPTN members provide procurement and transplant expertise. Can you elaborate on those efforts and the status of their implementation?

Response:

HRSA has proposed a novel federal data collection that will address critical gaps in our understanding of transplant system performance. The data directives address two areas of new or updated OPTN data collection:

- Information from transplant centers about when individuals are first referred to them for an organ transplant, as well as the results of their transplant evaluation and selection as a transplant candidate.
- Information from organ procurement organizations on all ventilated patients referred to them from hospitals in their donation service area, regardless of whether such individuals progress to organ donation and procurement. This data collection is designed to identify which patients are receiving adequate care, screening, and support as potential organ donors. This is a crucial step in HRSA's efforts to ensure patient safety and improve the quality of care for potential organ donors.

HRSA plans to begin implementation of these data collection in FY26.

The Honorable Russ Fulcher (R-ID)

1. How will HRSA make their reporting system both easy to access digitally and available for those with no prior experience with the organ donation system?

Response:

HRSA [instituted a new process](#) to report allegations of misconduct related to organ donation, organ procurement, or organ transplantation directly to HRSA. Under the new process, as reports are received, HRSA directs oversight action, triages the complaint to the appropriate investigative body, multiple bodies, or, as appropriate, to the OPTN. To improve transparency, HRSA also launched a separate [patient safety](#) webpage on the OPTN website for anyone looking for additional information regarding patient safety within the OPTN. This page is designed to provide easy access to information and resources related to patient safety. The patient safety page also includes a link to the page that describes the process for reporting.

The Honorable Frank Pallone, Jr. (D-NJ)

1. How does HRSA's new patient safety complaint portal allow HRSA to more efficiently triage the complaints it receives?

Response:

HRSA [instituted a new process](#) to report allegations of misconduct related to organ donation, organ procurement, or organ transplantation. Under the new process, as reports are received, HRSA directs oversight action, triages the complaint to the appropriate investigative body, multiple bodies, or, as appropriate, to the OPTN. The new approach will ensure HRSA is aware

of complaints and provides added protection for complainants by supporting direct government oversight and enhancing the requirements for OPTN awardees to report, review, and support adjudicating policy violations and misconduct within the network. We expect this approach to continue to allow more claims to surface so the requisite reviews can take place.

2. Does HRSA's portal show you whether there are multiple complaints about the same entity that may require additional investigation by HRSA?

Response:

Previously, UNOS did not maintain records or information on complaints in a manner that would allow for easy analysis by HRSA or OPTN members. Additionally, the previous system also was not designed to identify themes or trends in complaints across members to inform policymaking (e.g. similar complaints of improper procurement across OPOs). Instead, each complaint was received and investigated individually.

The new process, which makes it easier to submit reports directly to HRSA, will help ensure HRSA is aware of complaints regarding the same issues or entities. In addition, HRSA is independently monitoring OPTN and OPTN contractor compliance and implementing real-time tracking of specific issues of concern, such as organ allocations out of sequence allegations, through a central monitoring tool, marking a shift to proactive oversight of allocation practices. HRSA will continue to exercise its oversight authority to triage all complaints impacting safety within the OPTN appropriately, including assessing patterns for multiple complaints about the same entity.

3. As the OPTN transitions from a system that has only ever been controlled by the same single contractor to a multi-vendor structure, what has HRSA done to begin to prepare to move patient data from the UNOS system to new contractors that will need it to manage parts of the OPTN?

a. How will HRSA ensure safeguards are in place to protect patient privacy during that transition?

Response:

As HRSA works to create a more transparent, accountable and a higher-performing OPTN, HRSA is committed to ensuring that there are no disruptions to transplant access. HRSA is actively working on our IT modernization process, including the need to "dual track" legacy and modern systems during the design and build phases to ensure ongoing continuity of life-saving organ IT matching services. HRSA's focus on operations management, transition services, and technology modernization reflect the need to support multiple systems during the transition as we protect patient safety by responsibly phasing in a new IT system and operations.

HRSA's priority is that all future awardees understand and comply with federal security standards. The contract terms of agreement will ensure ongoing monitoring of IT system operability, real-time reporting, and compliance with all cybersecurity protocols. We are

committed to advancing the OPTN modernization efforts and having a transparent and accountable organ procurement and transplant system that best meets the needs of patients and families. As always, the speed and depth with which HRSA can execute these steps depend on our available authorities and resources.

4. Is HRSA doing more to protect whistleblowers from retaliation?

a. And is HRSA communicating any such efforts publicly to provide confidence to would-be whistleblowers that their disclosures will be protected and, where appropriate, investigated?

Response:

Through the Modernization Initiative, HRSA has taken steps to improve the reporting process so that misconduct can be reported directly to HRSA to be assigned for investigation by the appropriate entities. HRSA has highlighted the new process during public events and in newsletters reaching more than 50,000 people.

Because of HRSA's efforts to mitigate conflicts on the new OPTN Board, including supporting development of new conflict of interest policies for the OPTN Board members and volunteers, and HRSA's new mechanism to report allegations of misconduct, there are more avenues for individuals to speak up and more safeguards to protect individuals who may have been afraid to report issues under the previous process.

In addition, HRSA would welcome an opportunity to provide technical assistance on proposed legislation to strengthen the Secretary's authority to provide whistleblower protections to support safe reporting of misconduct across the system.

5. Are there any strategies that HRSA is considering aside from what is in the Corrective Action Plan to improve the interaction between OPO staff and hospital staff in their respective roles on donation after circulatory death (DCD) cases?

Response:

HRSA's role is to oversee the OPTN and its members, and OPTN contractors. The Centers for Medicare & Medicaid Services (CMS) also has authority over OPOs, and HRSA defers to CMS regarding oversight of the Medicare and Medicaid certification requirements for OPOs.

HRSA shared the May 28, 2025, Corrective Action Plan with CMS, and both agencies are collaborating to strengthen federal oversight and support of the organ transplantation system.

HRSA has also engaged critical stakeholders in the hospital and critical care communities in addition to the transplant and procurement community to ensure all health care professionals are clear on their roles, responsibilities and appropriate communication and handoffs given the importance of interdisciplinary, team-based care in organ donation and procurement.

6. How will HRSA help ensure that any entity involved in future patient safety investigations is transparent and thorough in its responses to inquiries related to the investigation?

Response:

HRSA takes patient safety investigations very seriously, including those identified to the OPTN, HRSA, and through CMS. With additional support from Congress through increased appropriations and the Securing the U.S. Organ Procurement and Transplantation Network Act (P.L. 118-14), HRSA is in a better position to monitor OPTN operations and direct the OPTN to undertake actions that protect public health and patient safety. This will help HRSA ensure accountability of entities involved in patient safety investigations. Furthermore, as part of the OPTN Modernization Initiative, HRSA is building up its internal data analysis and clinical capacity, enabling HRSA to analyze OPTN data and information for better oversight and compliance purposes.

Additionally, HRSA is working closely with CMS to investigate all patient safety issues and ensure that any entity under investigation is forthcoming in providing all requested information in a timely manner, including cooperation with other federal agencies, as appropriate.

The Honorable Greg Landsman (D-OH)

1. This is a first of its kind investigation by HRSA. What tools does HRSA need to continue investigating patient safety issues in the organ procurement space?

Response:

With additional support from Congress through increased appropriations and the Securing the U.S. Organ Procurement and Transplantation Network Act (P.L. 118-14), HRSA is in a better position to monitor and improve OPTN operations and direct the OPTN to undertake actions that protect public health and patient safety.

Across the nearly 40-year history of the OPTN, all functions of the OPTN were managed by a single contractor that collected the OPTN registration fee from transplant centers for each patient added to the transplant wait list. On average, over 80% of the annual OPTN operational costs, including the work of OPTN policymaking committees, are covered by these OPTN registration fees. The sole contractor that collected the fees oversaw policy making and investigated patient safety complaints, operated the IT matching system, and supported governance functions of the OPTN Board of Directors, which was the same as the contractor's Board of Directors. Because of this structure, HRSA had challenges providing meaningful oversight of the OPTN.

The temporary fee authority included in the Full-Year Continuing Appropriations and Extensions Act, 2025 (P.L. 119-4) enables HRSA to establish the necessary infrastructure for collecting and distributing OPTN patient waitlist registration fees. This user fee authority will help maintain the

reforms and oversight improvements Congress envisioned when passing the new law. HRSA appreciates Congress' strong support for monitoring compliance with OPTN policy to uphold patient safety, fairness, and trust in the system. HRSA would welcome the opportunity to work with Congress to improve OPTN policy compliance and enhance patient safety. Additionally, as reflected in testimony and previous briefings, the resources provided in the FY 2026 Budget, including the user fees, will strengthen HRSA's ability to fully investigate patient safety incidents and provide data-driven oversight for the OPTN.

2. How do the proposed FY26 budget cuts at HRSA impact HRSA's ability to investigate instances of patient safety issues within Organ Procurement and Transplantation Networks (OPTN)?

Response:

The FY 2026 President's Budget supports Organ Procurement and Transplantation Network (OPTN) system modernization, enhanced oversight, and expanded support for living organ donation. The Budget proposes to administer the OPTN under the planned Administration for a Healthy America. Key priorities in the budget include strengthening patient safety oversight by establishing new systems for monitoring, reporting, and intervening on safety issues; enhancing financial oversight to ensure transparency and accountability in using fees/funds; and continuing the multi-year effort to modernize the IT infrastructure. The speed and depth with which HRSA can modernize the OPTN and improve system performance for patients and families, depends directly on available authorities and resources.

3. How does HRSA plan to move forward after the conclusion of this investigation in the Kentucky OPO?

a. What changes will come as a result of this investigation?

Response:

Following the review of the Kentucky OPO, HRSA issued a Corrective Action Plan that requires the OPTN to monitor the Kentucky OPO and address identified patterns of risk to patients for potential donation after cardiac death. HRSA also identified a concerning pattern of risk across OPOs, often linked to staff practices, which included inconsistent assessments, coordination of care, data collection, and a lack of clarity on roles and responsibilities within the care team. In response, HRSA also directed the OPTN to enhance safeguards and policies to protect all patients who may donate organs nationwide. HRSA is actively evaluating next steps and has also referred this issue to other federal agencies, demonstrating our proactive approach to addressing these safety concerns.

Additionally, HRSA also recently [directed the OPTN](#) to include records for patients from whom OPOs attempted to procure organs in future OPTN data and analytic files. This direction aims to increase transparency and inform system oversight and quality improvement.

4. Based on this investigation, what changes are needed in the organ procurement and transplantation system?

Response:

HRSA has taken several actions to strengthen patient safety safeguards with respect to organ procurement and will continue to modernize core OPTN safety systems to monitor and mitigate threats to patient safety.

- **Strengthened reporting of allegations of misconduct:** HRSA [instituted a new process](#) to report allegations of misconduct related to organ donation, organ procurement, or organ transplantation. Under the new process, as reports are received, HRSA directs oversight action, triages the complaint to the appropriate investigative body, multiple bodies, or as appropriate, to the OPTN.
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Committee that investigates complaints, make up a significant part of the cost of OPTN operations. The temporary fee authority included in the Full-Year Continuing Appropriations and Extensions Act, 2025 (P.L. 119-4) enables HRSA to collect and distribute OPTN patient registration fees. With the user fee authority, HRSA will be able to implement significant improvements to patient safety monitoring processes, and for the first time ever, hold a contract competition to select the best-in-class vendor to support this critical function.

5. What does HRSA need, in addition to the Securing the U.S. Organ Procurement and Transplantation Network Act, to be able to ensure safety within the organ procurement space?

Response:

HRSA is in the process of reforming this nearly 40-year-old system. This is an iterative process, and as we continue this work, we may identify challenges or needs that require an updated approach to how we carry out this critical work. The collection and use of OPTN fees remains a top priority for HRSA as the agency continues enhancing its oversight of the OPTN. As HRSA has stated previously, these resources will improve the scope and speed for modernization. HRSA appreciates Congress' strong support for monitoring compliance with OPTN policy to uphold patient safety, fairness, and trust in the system. HRSA would welcome the opportunity to work with Congress to improve OPTN policy compliance and strengthen patient safety. Additionally, as reflected in the testimony, the resources included in the FY 2026 Budget, including user fees, will strengthen HRSA's ability to fully investigate patient safety incidents and provide data-driven oversight for the OPTN.

HRSA will continue to update and work with Congress to ensure we have the tools to modernize the system.