UNOS
Life without limits

[redacted]
tel: [redacted]
fax: [redacted]
www.unos.org

Maureen McBride, Ph.D. — CEO

August 27, 2025

The Honorable John Joyce, M.D.
U.S. House of Representatives
Chairman, Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

The Honorable Yvette Clarke
U.S. House of Representatives
Ranking Member, Subcommittee on Oversight and Investigations
Committee on Energy and Commerce

Dear Chairman Joyce and Ranking Member Clarke,

Thank you for the opportunity to testify before the Subcommittee and respond to additional questions for the record. I look forward to continuing to work together to improve the organ donation and transplant system for patients.

Sincerely,

Maureen McBride

Maureen McBride, PhD
Chief Executive Officer, United Network for Organ Sharing (UNOS)

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

1. **Your testimony outlines what OPOs are responsible for, but it seems to omit much of OPOs' role in practice. Would you agree that an OPO is more involved in the process between when an OPO is contacted by a hospital about a potential organ donor and when the organs are transported to the transplant hospital than what your written testimony outlines?**

The role of organ procurement organizations (OPOs) is outlined in federal law[1] and guided by the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA). CMS and HRSA share responsibility for overseeing organ donation, procurement, and transplantation in the U.S. This is accomplished through CMS' oversight of OPOs and transplant programs, along with HRSA's oversight of the Organ Procurement and Transplantation Network (OPTN)[2]. CMS issues Requirements for Certification and Designation and Conditions for Coverage for OPOs[3]. CMS Conditions for Coverage[4] require OPOs to be members of the OPTN, and HRSA has oversight over the OPTN.

The way my testimony characterizes the general role of OPOs in the organ donation and transplant system and is accurate from UNOS' limited role as a HRSA contractor supporting the OPTN. Specific questions about OPO operations or processes are best answered by the OPO present at the July 22, 2025, hearing, Network for Hope, the Association of Organ Procurement Organizations (AOPO), CMS, and HRSA.

2. **Your written testimony notes that UNOS staff, as the HRSA contractor supporting the OPTN, assisted OPTN's MPSC volunteers in their review. How did UNOS assist the MPSC in its review?**

The OPTN Membership and Professional Standards Committee (MPSC) is a group of volunteer clinicians and professionals focused on improving member performance, ensuring patient safety, and monitoring compliance with policies. Reporting to the OPTN Board of Directors, the MPSC provides annual briefings, shares effective practices from their meetings, and regularly updates the transplant community through regional meetings and community messages, aiming to foster continuous improvement and address system-wide issues.

Promoting and maintaining patient safety is the foundation of the donation and transplant system. To support this priority, all reported suspected patient safety events are investigated by the OPTN. The patient safety reporting and investigation process is a collaborative effort between the OPTN MPSC, the

[1] 42 U.S.C. §273 - Organ procurement organizations.
[2] Centers for Medicare & Medicaid Services. (2023, April 28). The Transplant Eco-System: The Role of Data in CMS Oversight of Organ Procurement Organizations. CMS Blog. Retrieved from https://www.cms.gov/blog/transplant-eco-system-role-data-cms-oversight-organ-procurement-organizations
[3] 42 C.F.R. §§486.301–486.348 (2025).
[4] 42 C.F.R. § 486.320 (2024).

OPTN Contractor (organization awarded a HRSA contract to manage suspected patient safety events, which is currently UNOS), and HRSA.

When a suspected patient safety event is received by the OPTN, it is assigned to a UNOS patient safety staff member who specializes in healthcare investigations to determine whether the event constitutes a HRSA-Required Reporting Event. If a suspected event is determined to be a HRSA-Required Reporting Event, UNOS is required to notify HRSA within 24 hours of becoming aware of the event. HRSA coordinates with CMS as needed. HRSA required reporting events are[5]:

- Transplant of the wrong organ into an organ recipient
- Near-miss transplant of the wrong organ into an organ recipient
- Transplant of the wrong organ recipient
- Near-miss transplant of the wrong organ recipient
- Suspected or confirmed HIV transmission from a deceased or living donor to a recipient
- Any complaint, issue, or concern that may pose a serious or time-sensitive threat to public health or patient safety (including failure to provide a safe environment to patients), regardless of whether there is a suspected or actual violation of OPTN policy or the OPTN final rule
- Living donor death, regardless of the time period after surgery and regardless of the cause of death
- Failure of a native organ in a living organ donor
- Evidence of an attempt to deceive the OPTN or the Department (e.g., falsifying medical records)
- Use of a device for a condition, diagnosis, or procedure that is contraindicated by the Food and Drug Administration (FDA)
- Any "Never Event," as included in the Centers for Medicare and Medicaid Services' (CMS) policies for selected hospital-acquired conditions (HACs), in an OPTN member hospital that impacts transplant patients or living organ donors (including those under evaluation for living organ donation)
- Suspected or significant potential of non-HIV disease transmission from a donor to a recipient
- Any sanction taken by a state medical board or other professional body against a transplant professional working for an OPTN member

UNOS, as the HRSA contractor supporting the OPTN, assisted the MPSC volunteers in their investigation of the Kentucky OPO incident according to contractual requirements with HRSA and established OPTN procedures. Throughout the investigative process, UNOS worked as directed by the MPSC and HRSA. Upon learning of the allegations during the House Energy & Commerce Committee hearing on September 11, 2024, UNOS notified HRSA of the allegation within 24 hours, as required by our OPTN contract, and began planning the investigation. On behalf of the MPSC, at the direction of the MPSC Chair, UNOS sent letters to the involved parties, Network for Hope, and to the hearing witnesses, to

[5] Organ Procurement and Transplantation Network (OPTN). *OPTN Member Monitoring Processes*. U.S. Department of Health and Human Services. Published March 13, 2025. Available at: https://optn.transplant.hrsa.gov/media/gqrbxjba/monitoring_processes_20250313.pdf

request case details and documentation. UNOS staff provided all documentation received from the involved parties to the MPSC, including HRSA representatives. HRSA serves on the MPSC as an ex-officio member, was involved in every step of the MPSC's investigation, and had direct oversight of the process. During MPSC leadership calls, UNOS provided summaries of the investigation and opened discussions for MPSC and HRSA. The MPSC did not find an OPTN Policy violation and therefore closed the case.

In summary, UNOS staff assisted the MPSC by facilitating communication, gathering and providing necessary documentation, submitting investigative plans, and ensuring compliance with HRSA's directives, all while acting under the direction of HRSA and the MPSC.

In general, HRSA and the OPTN Board hold final authority over all major decisions, including investigations, policy changes, and enforcement actions. UNOS is not authorized to make these decisions on behalf of HRSA or the OPTN.

3. **How does UNOS handle the complaints that it receives, particularly complaints about patient safety issues?**

At UNOS, we are committed to a culture of safety, transparency, and accountability across the national transplant system. We recognize that meaningful improvement begins with the ability to report concerns without fear.

For complaints about patient safety issues, UNOS follows the MPSC process as required by OPTN policy. The policies UNOS staff followed are detailed on pages 11-12 of the OPTN Member Monitoring Processes and included below[6]:

> Intake, Triage, and Containment
>
> When an event is reported by an individual and the reporter's email or mailing address is known, patient safety staff send an acknowledgment of the report. The acknowledgment explains that the OPTN Contractor will not disclose the reporter's identity to the subject of the report and will not disclose the outcome of the investigation to the reporter. Patient safety staff then review and triage the report to determine whether:
>
> - Readily available information suggests the report is accurate
> - The potential incident meets any of the criteria requiring it to be reported to HRSA according to OPTN contract requirements (see "HRSA-required event reporting" below)
> - The potential incident involves issues such as actual, or the potential for, direct harm to patients, a risk to patient health or public safety, or a risk to the integrity of the OPTN If the incident appears to involve any of these risks, staff notify HRSA, MPSC leadership,

[6] Organ Procurement and Transplantation Network. (2025, March 13). *OPTN member monitoring processes*. U.S. Department of Health and Human Services, Health Resources and Services Administration. https://optn.transplant.hrsa.gov/media/ggrbxjba/monitoring_processes_20250313.pdf

and/or OPTN Contractor leadership and work with the member to implement an immediate containment plan as needed.

Incident Investigation

Once any necessary containment plans have been implemented, patient safety staff send inquiry letters to all relevant parties involved to gather complete information about the incident. At a minimum, patient safety staff request:

- A detailed explanation of what occurred and why it happened
- Findings of any root cause analyses or post-case reviews
- A description of any corrective actions developed as a result of the incident
- Copies of policies, procedures, medical records, and other supporting documentation, as needed

Parties may receive additional inquiries requesting clarifying or supporting documentation as needed to supplement information obtained through the initial inquiries. A potential OPTN policy noncompliance does not have to be present for staff to request information or documentation related to an event.

Post-investigation Assessment

At the conclusion of the investigation, staff present findings to a multi-disciplinary team that determines whether a potential policy or bylaw noncompliance occurred, or if there is an ongoing risk to patient safety or public health. If a potential noncompliance does not exist, there is no threat to patient safety or public health, and the reported event is not a living donor event as defined by OPTN policy, staff close the case and the member(s) receives a closure letter. If the team identifies a potential noncompliance threat to patient safety or public health, or a threat to the integrity of the transplant system, the member receives a notification letter explaining the potential OPTN Policy, Bylaw, or Membership and Management Policy noncompliance and staff refer the case to the MPSC for review. The MPSC may review any event, even without a specific OPTN policy citation. If the reported event is a living donor event as defined by OPTN Policy, staff will refer the case to the MPSC for review according to Policy 18.5.B: Reporting of Living Donor Events.

Any reports that are not immediately referred to the MPSC are provided to the MPSC in a retrospective report multiple times per year. HRSA also receives this report. The MPSC may choose to investigate these reports at any time. UNOS staff and HRSA meet weekly to ensure HRSA is aware of all investigative progress on cases deemed a serious patient safety risk. Data integration and case management systems have further improved the ability to track complaints in real time, coordinate peer review activities, and monitor the status of investigations efficiently.

Cases referred to the MPSC for review are assigned, by UNOS staff, to a subset of MPSC members with relevant expertise. The MPSC reviewers receive a summary of the OPTN member's compliance history along with the case details. They review the material, recommend a member action, or suggest that the case be brought before the full MPSC for further discussion. After the MPSC review concludes and the MPSC votes on an appropriate member action, the OPTN member receives a resolution letter with the MPSC's decision, signed by the MPSC Chair, and the next steps. At the direction of the MPSC, UNOS patient safety staff will begin ongoing monitoring of the OPTN member as needed to ensure sustained compliance and improvement.

UNOS provides monthly and quarterly reports to both the MPSC and HRSA. The MPSC makes the decision to release an OPTN member from ongoing monitoring only after sustained improvement is demonstrated.

Following HRSA approved practices[7], cases are not immediately referred to the MPSC if they do not present a potential OPTN policy violation, do not present a risk to public health, patient safety or integrity of the OPTN, do not meet criteria for reporting to the MPSC as defined by the MPSC, or otherwise do not contain sufficient information to corroborate the initial allegations.

Historically, the MPSC reports to the OPTN Board of Directors during the June and December meetings with metrics on investigations and patient safety complaints are publicly available on the OPTN website[8].

a. Is this true of all the complaints it receives?

Yes.

i. If not, how is it determined when UNOS investigates and/or reports a case versus when it does not?

See responses above.

4. Your written testimony notes that UNOS proposes the creation of a "no wrong door" patient safety reporting system that allows anyone to report safety concerns easily and effectively. Would you agree that such a system is entirely dependent on a culture that encourages reporting and takes concerns that it receives seriously?

Yes.

---

[7] Organ Procurement and Transplantation Network. (2025, March 13). Patient safety and non-routine compliance reviews. In OPTN member monitoring processes (pp. 10–13). https://optn.transplant.hrsa.gov/media/gqrbxjba/monitoring_processes_20250313.pdf

[8] Organ Procurement and Transplantation Network. (n.d.). MPSC resources. U.S. Department of Health & Human Services. https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/mpsc-resources/

a. Do you believe that UNOS has a culture that encourages the reporting of complaints or concerns – historically and currently? Why or why not?

Yes. UNOS as an organization encourages the reporting of complaints or concerns. Our staff complete training during onboarding and annually about how to report complaints and concerns, and we have a non-retaliation policy to protect anyone who reports a complaint. UNOS maintains a safe, ethical, and legally compliant workplace where employees are empowered to speak up.

b. Are you aware that HRSA already has a mechanism by which anyone may file a complaint reporting an allegation of misconduct?

While the OPTN currently has a procedure in place for reporting patient safety issues, we believe more can, and should be done to ensure every patient safety concern is captured, not just those directly reported to the OPTN. That's why UNOS is calling on Congress to urge The Department of Health & Human Services (HHS) to create a comprehensive "no wrong door" patient safety reporting system across all HRSA and CMS programs to ensure patient safety events can be effortlessly reported by providers, patients, family members, or anyone who has witnessed or learns of a potential safety incident.

Following the patient safety allegations made during the September 11, 2024, U.S. House Committee on Energy and Commerce Oversight & Investigations Subcommittee hearing, CMS and HRSA took actions to initiate better processes for filing complaints against transplant centers and OPOs.

CMS issued a blog post in November 2024 that listed what the appropriate reporting contacts were at CMS, HRSA, and the OPTN for patient safety concerns. This post has since been archived[9] and has not been replaced.

In April 2025, seven months after the September 2024 hearing, HRSA announced[10] direct collection on the OPTN website for patient concerns, but this assumes individuals are aware of the OPTN. Simple Google searches of phrases like "HRSA report patient safety event" or "report organ donation problem" do not bring up HRSA's reporting mechanism, demonstrating that it is not easy to locate for the public[11].

While these reporting improvements are positive, they fall short of the robust and unified reporting systems that are necessary because they assume individuals are aware of CMS, HRSA, the OPTN, and each of their distinct roles in our nation's organ donation and transplant system. This is an unrealistic

[9] U.S. Department of Health and Human Services. (2024, November 12). *How we're making the organ transplant system more safe and equitable* [Blog post]. HHS.gov. Archived at Pagefreezer. https://us.pagefreezer.com/en-US/wa/browse/0a7f82bb-be6e-448a-ae11-373d22c37842?find-by-timestamp=2025-01-10T05:49:59Z&url=https:%2F%2Fwww.hhs.gov%2Fblog%2F2024%2F11%2F12%2Fhow-were-making-organ-transplant-system-safe-equitable.html&timestamp=2025-01-10T05:50:26Z

[10] Health Resources and Services Administration. (2025, April). Recognizing Donate Life Month: Expressing gratitude for those who give, and honoring the resilience of those who wait. U.S. Department of Health and Human Services. https://www.hrsa.gov/optn-modernization/april-2025

[11] Per Google searches completed on August 19, 2025, at 10:21am EST.

expectation for patients, families, or providers experiencing safety concerns during a time of trauma and loss.

Anyone who has witnessed or experienced poor care should have a clear path for reporting their concerns. Since more than 95 percent of hospitals in the U.S. are not OPTN members, CMS and HRSA must work together to close the reporting gap.

c. What is stopping UNOS from creating a similar mechanism by which anyone can file a complaint reporting an allegation of misconduct?

UNOS recommends that HHS develop a central reporting mechanism because it is the federal agency with the appropriate authority and oversight over all aspects of organ donation and transplant.

UNOS is a private nonprofit 501(c)(3) organization and does not have authority over the organ donation and transplant system. In its role as one of HRSA's contractors supporting the OPTN, UNOS works at the direction of HRSA and is only able to complete work that is contractually authorized by HRSA. UNOS would be pleased to support the creation of such a mechanism if HRSA or HHS authorized us to do so.

5. Are you aware of any instances in which any individuals affiliated with the UNOS, or the OPTN, retaliated against individuals who tried to report concerns in the nation's organ procurement and transplant system, particularly patient safety concerns?

No, UNOS is not aware of UNOS or OPTN-affiliated individuals retaliating against individuals who tried to report concerns.

UNOS is aware of past claims made in Congressional Hearings and the media that UNOS or the OPTN is retaliatory towards whistleblowers. UNOS has continuously attempted to gather information about these claims and has been unable to secure any evidence to substantiate them.

When generic retaliation claims were made, UNOS, in our role as a HRSA contractor supporting the OPTN, implemented improvements to the OPTN's processes to ensure greater transparency, more rapid investigations, and stronger protections for individual reporters within the OPTN. These updates are available on the OPTN website[12].

a. If so, please provide details about those instances of retaliation and what, if anything, UNOS did to address both the concerns that were reported and the retaliation that occurred.

See above.

[12] Organ Procurement and Transplantation Network. (2024, July 1). Notice of OPTN bylaws changes: Establish code of conduct and whistleblower protection bylaws. https://optn.transplant.hrsa.gov/media/uzlfxnfp/code-of-conduct-_ec_policy-notice.pdf

6. **What was UNOS's contribution to the development of the "Critical Pathway for Donation After Cardiac Death" guide document?**

UNOS, as the OPTN contractor, delivers final information and records to HRSA as requested. UNOS retains non-records up to 2 years from the last modified date. Non records include drafts, notes and copies. UNOS's contribution to the final guide document, which is from the early 2000s, would have been captured in preliminary drafts; and therefore, is no longer available.

   a. **Were your additions to the document made in consultation with medical professionals?**

All policy-related work completed by UNOS in our role as a HRSA contractor supporting the OPTN is deliberated by OPTN Committees, which are comprised of healthcare professionals, medical doctors, patient and donor family representatives, and other experts in the field of organ donation and transplant. All final OPTN policy projects must be approved by the OPTN Board and HRSA.

   b. **Why is there no mention of steps to take in the case of previously administered medications, particularly sedatives, in the medication section of this document?**

See above.

7. **UNOS' website previously included press releases regarding a collaborative project to share information and effective practices related to DCD organ recovery and increasing the number of transplants beginning in October 2020. When was this information removed, and why was it removed?**

In support of HRSA's OPTN Modernization initiative, UNOS has begun removing OPTN-specific content from the UNOS website to help establish a clear difference between UNOS and the OPTN. UNOS is not the OPTN, nor are we the only contractor supporting the OPTN; therefore, UNOS should not host OPTN-specific content on our organization's website. UNOS had conversations with HRSA about the website changes, and HRSA is aligned with the approach. Removal of OPTN-specific content began in November 2024 and has continued on a rolling basis. The information that has been removed from the UNOS website is available on the OPTN website[13].

[13] Organ Procurement and Transplantation Network. Collaborative improvement projects. U.S. Department of Health and Human Services. https://optn.transplant.hrsa.gov/professionals/improvement/collaborative-improvement/collaborative-improvement-projects/

Questions Submitted by The Honorable Neal P. Dunn, M.D. (R-FL)

1. **You asserted that UNOS followed all HRSA-approved processes for the Kentucky investigation, yet UNOS never even spoke with TJ Hoover or his family about what happened, nor to the former KODA staff who were either in the room with Mr. Hoover, or were otherwise involved in the case and shared information with Congress. Does it follow HRSA-approved processes to avoid speaking to patients, families, and frontline workers?**
    a. **If so, how does this allow UNOS or the OPTN to have even a basic understanding of the facts of a case?**

UNOS was not aware of the incident involving Mr. Hoover until a witness referenced it during the House Energy & Commerce Committee hearing on September 11, 2024. We heard about it for the first time in that moment. Neither that witness, nor any other party, had brought the incident to UNOS for the OPTN to investigate before that date. Once UNOS heard the witness's allegations, however, UNOS notified HRSA within 24 hours, as required by our OPTN contract, and began planning the investigation. On behalf of the MPSC and at the direction of the MPSC Chair, UNOS sent letters to the involved parties, Network for Hope, and to the hearing witnesses, to request case details and documentation. UNOS staff provided all documentation received from the involved parties to the MPSC, including HRSA representatives. HRSA serves on the MPSC as an ex-officio member, was involved in every step of the MPSC's investigation, and had direct oversight of the process. During MPSC leadership calls, UNOS provided summaries of the investigation and opened discussions for MPSC and HRSA. The MPSC did not find an OPTN Policy violation and therefore supported closure of the case.

UNOS followed the MPSC process as required by the OPTN policies. The policies UNOS staff followed are detailed on pages 11-12 of the OPTN Member Monitoring Processes and included below[14]:

> Intake, Triage, and Containment
>
> When an event is reported by an individual and the reporter's email or mailing address is known, patient safety staff send an acknowledgment of the report. The acknowledgment explains that the OPTN Contractor will not disclose the reporter's identity to the subject of the report and will not disclose the outcome of the investigation to the reporter. Patient safety staff then review and triage the report to determine whether:
>
> - Readily available information suggests the report is accurate
> - The potential incident meets any of the criteria requiring it to be reported to HRSA according to OPTN contract requirements (see "HRSA-required event reporting" below)
> - The potential incident involves issues such as actual, or the potential for, direct harm to patients, a risk to patient health or public safety, or a risk to the integrity of the OPTN If the incident appears to involve any of these risks, staff notify HRSA, MPSC leadership,

[14] Organ Procurement and Transplantation Network. (2025, March 13). OPTN member monitoring processes. https://optn.transplant.hrsa.gov/media/gqrbxjba/monitoring_processes_20250313.pdf

and/or OPTN Contractor leadership and work with the member to implement an immediate containment plan as needed.

Incident Investigation

Once any necessary containment plans have been implemented, patient safety staff send inquiry letters to all relevant parties involved to gather complete information about the incident. At a minimum, patient safety staff request:

- A detailed explanation of what occurred and why it happened
- Findings of any root cause analyses or post-case reviews
- A description of any corrective actions developed as a result of the incident
- Copies of policies, procedures, medical records, and other supporting documentation, as needed

Parties may receive additional inquiries requesting clarifying or supporting documentation as needed to supplement information obtained through the initial inquiries. A potential OPTN policy noncompliance does not have to be present for staff to request information or documentation related to an event.

Post-investigation Assessment

At the conclusion of the investigation, staff present findings to a multi-disciplinary team that determines whether a potential policy or bylaw noncompliance occurred, or if there is an ongoing risk to patient safety or public health. If a potential noncompliance does not exist, there is no threat to patient safety or public health, and the reported event is not a living donor event as defined by OPTN policy, staff close the case and the member(s) receives a closure letter. If the team identifies a potential noncompliance threat to patient safety or public health, or a threat to the integrity of the transplant system, the member receives a notification letter explaining the potential OPTN Policy, Bylaw, or Membership and Management Policy noncompliance and staff refer the case to the MPSC for review. The MPSC may review any event, even without a specific OPTN policy citation. If the reported event is a living donor event as defined by OPTN Policy, staff will refer the case to the MPSC for review according to Policy 18.5.B: Reporting of Living Donor Events.

UNOS, in our role as a HRSA contractor supporting the OPTN, has no authority to compel the direction of an investigation. In the context of this case, UNOS staff acted in accordance with the information available at the time and followed all HRSA-approved processes. It is not typical for UNOS to contact a patient unless the patient themselves submitted the report. UNOS speaks to frontline workers if the OPTN MPSC directs us to when coordinating the investigation. OPTN members have an obligation to respond to OPTN inquiries; however, thousands of hospitals that care for potential organ donors in the U.S. are not OPTN members and are not obligated to respond to OPTN requests.

It is important to clarify that UNOS does not have subpoena power, nor the power to issue a civil investigative demand. As such, UNOS cannot compel an OPTN member, or anyone else for that matter, to turn over documents. UNOS does not possess regulatory authority and is not empowered to act as an agent for the government, nor does UNOS have access to attorneys general or federal law enforcement capabilities. Our role during OPTN investigations is to support the MPSC by facilitating fair, evidence-based evaluations. We operate within the scope of the Performance Work Statement (PWS) within our contract with HRSA, and under the oversight of HRSA.

HRSA is the federal government and has federal investigative powers. We understand and expect that HRSA has more investigative resources than UNOS, and more authoritative weight, as the federal government, to compel actions from a member.

In the context of the Kentucky case, HRSA was aware that the OPTN member did not respond robustly to the OPTN's documentation requests, because HRSA personnel were present for all stages of the MPSC deliberations regarding this matter.

If HRSA was not satisfied with the OPTN's investigations regarding the Kentucky case, or if it wanted UNOS, the MPSC, or the OPTN to take additional investigatory steps, HRSA could have assisted with those steps contemporaneously, or it could have intervened and performed the steps itself[15]. HRSA did intervene at one point, as it directed UNOS to follow up with the OPTN member after the member's first production of documents to enforce the initial request. Again, however, while UNOS could follow up on the request, it could not compel the OPTN member to produce documents. UNOS welcomes HRSA's use of its government authority to successfully compel production of documents from OPTN members. We note that HRSA's subsequent reviews were informed by documents that were not made available to the OPTN.

2. **You called for a "no wrong door" approach to reporting a patient safety concern. How can UNOS itself possibly have any credible role in investigating or enforcing patient safety after you and 26 other UNOS Executives signed a public letter suggesting that patient safety concerns raised under oath in a bipartisan Congressional hearing count as "spreading misinformation based on conspiracy theories and hearsay?"**

We stand by the contents of the full letter, and believe that reporting based on snippets, taken out of context, grossly misrepresent the content. The letter was signed by more than 1,100 members of the organ donation and transplant community, including members of the OPTN Board, both before and after the special election. The letter does not call the patient safety concerns raised at the hearing "misinformation" or "hearsay." Rather, it specifically references allegations that UNOS operates as a "monopoly" and engaged in whistleblower retaliation, a federal crime. These allegations about UNOS are false. UNOS provided links to further information discrediting those allegations on its website, which are linked in the online posting of the community letter.

[15] Pursuant to 42 CFR 121.10(a); *See also* 42 C.F.R. §121.10(b)(3).

At no point has UNOS ever alleged that the patient safety allegations raised in the hearing were misinformation or hearsay, nor does the letter say that. Further, UNOS first heard about the patient safety concern the witness during the hearing. UNOS brought the concern referenced at the hearing to HRSA as soon as it heard it, and awaited direction from the Agency regarding investigation of the matter. In the meantime, the letter asked that the public await a full and fair investigation before jumping to conclusions. At the time the letter was issued, the concerns referenced were still hearsay to the signers, because those concerns had not yet been investigated, nor were they known by UNOS to exist prior to the hearing. If the witness brought them to HRSA and law enforcement's attention behind the scenes as he stated that he did, then those parties did not bring them to UNOS' attention or ask for our support in an investigation prior to the hearing.

UNOS strongly disagrees that the letter represented a conflict of interest, or that it was in any way harmful or obstructive to any investigation. In fact, its call for fairness and a full investigation shows the opposite intent. We further disagree that the efforts to call out UNOS staff for otherwise protected public speech were necessary or warranted. Nonetheless, to respect HRSA as our client, UNOS took measures to ensure that none of the UNOS staff who signed the letter were involved in related OPTN investigations going forward.

I signed the letter because I believe in our nation's organ donation and transplant system, and I believe in thorough investigations that consider all the facts.

As a contractor with a duty to assist in investigating potential member incidents, UNOS has an interest in ensuring all investigations are completed appropriately and according to the terms of the contract that UNOS holds with HRSA. UNOS has nothing to gain from obstructing, impeding, or insufficiently supporting the investigation of a potential OPTN member incident.

More than 100,000 patients are in need a lifesaving organ transplant in the U.S. Their lives are reliant upon public trust in the system. To protect that trust, patient safety concerns should receive thorough and objective investigations in which facts are determined and measures to prevent them from happening again are identified. That is how trust is built and maintained. I stand by my signature.

Questions Submitted by The Honorable Russ Fulcher (R-ID)

1. **In your testimony you suggested a "no wrong door patient safety reporting system" so that anyone, regardless of status could report safety concerns for patients of organ donation. If you were to design this form, what information would you recommend this form collect in order to most effectively report concerns?**

Before HRSA took over the complaint collections process, UNOS maintained a fulsome complaint reporting form and process that collected a variety of material information and also allowed for anonymous whistleblowing. This electronic form submission system has since been replaced by a statement on the HRSA website that persons who wish to submit complaints should send an email to OPTNComplaints@hrsa.gov or call 911 if they are experiencing an emergency[16].

UNOS envisions a system with broader usability that can cut across all HHS programs and reach patients and caregivers at multiple levels. A "No Wrong Door" patient safety reporting system would more likely be used by patients, families, friends, and members of the public, not necessarily an OPTN member institution. UNOS recommends that any such form be developed with strong input from the public, including patients and donor families, physicians, hospital staff, and other professionals involved in the organ donation and transplantation process. Such a form should collect enough detail for reviewers to establish a full understanding of the event and know which oversight body the report should be routed to. UNOS recommends that a form include fields that capture the following case-specific details.

- Name of institution where event occurred (Institution Name, City/ State) ***required
- Date the event occurred (Day, Month, Year) ***required
- Names of involved persons ***required
- Timeline of events ***required
- Impact on patient(s)
- Waitlist ID (if known)
- Donor ID (if known)

[16] See Reporting Allegations of Misconduct, available at: https://hrsa.unos.org/about/reporting-allegations-of-misconduct/

Questions Submitted by The Honorable Greg Landsman (D-OH)

1. **How do we improve public trust in the organ transplantation system?**

The system is built on trust. To preserve and strengthen that trust, all aspects of the system must work together — Congress, HRSA, CMS and all stakeholders — to ensure a fair, effective, and safe organ donation and transplant system by advancing impactful improvements and reforms.

In the week after the July 22, 2025, House Energy and Commerce Oversight and Investigations Subcommittee Hearing, national donor registry removals increased approximately 700 percent according to Donate Life America. This trend was maintained at the state level. For example, Donate Life California recorded 5,423 removals between July 20 and July 27, including a record 841 people on July 22. Colorado, Texas, Tennessee, Florida and Arizona also saw significant increases in registry removals during the week following the hearing[17].

This sharp increase in registration removals puts the patients who are waiting for a life-saving transplant at greater risk, and all aspects of the system must work together to combat the fear and mistruths circulating about the system. In doing so, Congress, HRSA, CMS, and stakeholders must move forward with a proactive, solutions-oriented approach.

To increase public trust, when I became CEO, I recommended many reforms to HRSA and to Congress that supported cost-effectiveness, efficiency, transparency and fairness. I would welcome the opportunity to work with you on the reforms listed below to increase trust in the system.

Recommendations to HRSA

- HRSA should work with UNOS to enhance technology to integrate the OPTN computer system with OPTN members' medical record systems and provide a modern IT experience including migration to the cloud.
- HRSA should require that organs in transit be tracked in real-time so that logistical travel challenges can be triaged and addressed to ensure no organ is lost, delayed, or damaged due to transportation problems.
- HRSA should support the development of a patient app to offer individualized support for patients on the waitlist.
- HRSA should provide more robust public data dashboards about OPTN member OPTN performance.
- HRSA should authorize increased data collection, reporting, and analysis of transplant patients before they are added to the waitlist to inform data-driven policy improvements for access.

Recommendations to Congress

[17] Miller, J. R. (2025, August 7). Mass exodus from organ donor registries following New York Times coverage. Newsweek. https://www.newsweek.com/thousands-remove-organ-donor-registries-nyt-coverage-2109940

- Nationwide implementation of automated deceased donor referrals to streamline and modernize the potential deceased organ donor referral process. Widespread use of these software tools would build off the investment Congress has already made in the interoperability for electronic health records to ensure every potential donor is referred, which could increase the number of Americans who are able to receive lifesaving organ transplants. It would also reduce the burden of standard manual reporting for busy hospital staff across the nation, allowing them more time to focus on direct patient care. The U.S. House Energy and Commerce Committee should advance two bills that would support the national implementation of automated donor referral, the Organ Donation Referral Improvement Act (H.R. 330) and the Removing Burdens from Organ Donation Act (H.R.4470). Introduced by Representatives Rob Wittman (R-VA), Jennifer McClellan (D-VA), Mariannette Miller-Meeks (R-IA), and Jim Costa (D-CA), H.R.330 would require HHS to study best practices for national implementation of automated donor referral technology. Introduced by Representatives Beth Van Duyne (R-TX), Suzan Del Bene (D-WA), Carol Miller (R-WV), and Jim Costa (D-CA), H.R.4470 would modernize and streamline the organ donation process by improving communication between hospitals and OPOs using automated donor referral technology.
- Ensuring in-cabin airline transportation for organs. After the terrorist attacks on September 11, 2001, broad security changes for air travel were instituted, including relegating organs to under the wing instead of in the cabin under the care of the airline crew as was the previous practice. Life-saving organs should never be relegated to airplane cargo bays, where they are more prone to be damaged, lost or delayed because of cargo staffing limitations. The Federal Aviation Administration (FAA)'s Organ Transportation working group, authorized by a provision in the bipartisan FAA Reauthorization Act of 2024 (Pub. Law No: 118-63), has made recommendations for the above-wing transportation of donor organs. Congress should direct HRSA to implement FAA's recommendations that apply to HRSA as included in report language accompanying the FY2026 Senate Labor, HHS Appropriations bill.
- Congress should align Medicare incentives for transplant hospitals to accept hard-to-place organs from OPOs to increase transplants performed and decrease organ non-utilization rates. A hard-to-place organ is a donated organ that is considered difficult to transplant due to factors like significant damage, anatomical abnormalities, or a high level of incompatibility with potential recipients. This means it may take longer to find a suitable match and could be rejected by multiple transplant centers before being accepted. There are some transplant hospitals that successfully transplant hard-to-place organs with positive outcomes for patients. These transplants may require longer hospital stays or otherwise more care immediately after surgery. Medicare should not disincentivize the transplants of life-saving organs due to such short-term issues.
- Congress should act to create a "no wrong door" patient safety reporting system that allows anyone, including patients, providers, or family members, to report safety concerns easily and effectively. This "no wrong door" approach must allow any individual at any location to report safety concerns without having to navigate the complex bureaucracies within our organ donation and transplant system. Congress should direct HHS to establish this "no wrong door"

patient safety reporting system to route all reported patient safety concerns to the correct authority. This "no wrong door" system should be widely promoted and understood by the public, guarantee anonymity for individuals who make reports, and track and publicly disclose the outcomes of safety investigations to build trust and accountability.

UNOS proposes these reforms to build trust in the system. Patients deserve a transparent and accountable system that works collaboratively in pursuit of a common mission: saving more lives.

Our nation's organ donation and transplant system is not perfect, and it is the responsibility of the organ donation and transplant community, federal agencies, and Congress to address problems as they arise and implement appropriate reforms. As reforms are implemented, it is important that there is transparency about their impact on the system and how they are benefiting patients and donor families.

UNOS will continue to be a partner in this effort and looks forward to collaborating with the Committee, federal agencies, and other stakeholders to advance critical reforms to the system that directly benefit patients and improve public trust in the system.

2. What does UNOS need from HRSA to improve the partnership between the two?

UNOS has served as a HRSA contractor supporting the operations of the OPTN for more than forty years. Now, as part of the OPTN Modernization Initiative, HRSA is undertaking a reorganization of the OPTN contracting model to include multiple contractors. HRSA has named 15 contractors to support the OPTN Board and the OPTN operations, which does not count the subcontractor requirements for the small business set-asides. UNOS supports the OPTN Modernization Initiative and is dedicated to ensuring the transition to a modern OPTN with multiple contractors goes smoothly and does not harm the system or patients and donor families that it serves. As HRSA continues to implement their OPTN Modernization Initiative, it is imperative that HRSA:

<u>Ensure that OPTN Contracts are Current, Clear, and Accurate</u>

UNOS recognizes that as HRSA advances changes to the OPTN, contractor expectations may change as well. HRSA must work with UNOS to agree on appropriate contract modifications that ensure clarity of roles and expectations going forward.

For example, HRSA awarded a contract to the American Institutes for Research (AIR) in August 2024 to support the OPTN Board of Directors. As of August 2025, HRSA has not modified UNOS' ongoing board support role within our Contract to transition the OPTN Board Support work to AIR. As the OPTN Board Support work is still in UNOS' contract, both UNOS and AIR are operating in parallel, which has led to confusion. It is also costing the U.S. taxpayer additional funding to pay two contractors for similar workstreams. UNOS would welcome HRSA giving us the chance to offer our insights on how transition can occur safely and effectively, when the government decides to trigger that transition process.

<u>Ensure Timely Responses and Engagement.</u>

Recognizing HRSA is taking a more active oversight role, our team looks to HRSA for guidance and clarity with respect to work, such as new directives, to ensure we are completing work in accordance with HRSA's direction. HRSA's timely response and engagement with our staff is critical, especially regarding matters of patient safety. HRSA must also provide timely information from other HHS agencies, like CMS, that impact OPTN operations.

For example, CMS recently approved waivers to allow transplant hospitals to partner with different OPOs than the ones currently servicing their area. UNOS learned of CMS' approval through a news article and not from HRSA. Changes to the OPTN Computer System were required and could have been made in a timelier manner if HRSA had communicated these changes to contractors.

Collaboration is key for advancing HRSA's OPTN modernization goals.

3. **How can Congress work with UNOS to improve the organ transplantation process?**

UNOS welcomes the opportunity to work with Congress to improve organ donation and transplantation processes. Please refer to our answers to your first question for specific proposals.

Questions Submitted by The Honorable Jennifer McClellan (D-VA)

1. **What reforms are most necessary to improve our nation's organ donation and transplantation system for patients moving forward?**

To strengthen the U.S. organ donation and transplant system, UNOS proposes four key reforms to enhance patient safety, transparency, and efficiency. 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.

Implement a "No Wrong Door" Safety Reporting System.

Under HHS' leadership, CMS and HRSA must work together 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. This "no wrong door" approach must allow any individual at any location to report safety concerns without having to navigate the complex bureaucracies within our organ donation and transplant system.

CMS and HRSA share responsibility for organ donation and transplantation oversight, creating confusion and gaps in accountability. Most hospitals caring for potential organ donors are not a part of the OPTN overseen by HRSA, making reporting organ donation concerns even more difficult. Individuals experiencing safety concerns during times of trauma and loss should be able to report those issues without needing to understand complex health systems or oversight structures. UNOS calls on HHS to launch a unified reporting system that routes all safety concerns to the correct authority—regardless of where the incident occurred. This "no wrong door" system should be widely promoted and understood by the public, guarantee anonymity for individuals who make reports, and track and publicly disclose the outcomes of safety investigations to build trust and accountability.

Optimize the Donor Referral Process with Automated Donor Referrals.

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 donor referral 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[18,19] have found a 49 percent increase in donor referrals and a 333 percent increase in organ donors upon implementation of automated donor referrals.

[18] Levan, M. L., Trahan, C., Klitenic, S. B., et al. (2022). Short report: Evaluating the effects of automated donor referral technology on deceased donor referrals. Transplantation Direct, 8(8), e1330. https://doi.org/10.1097/TXD.0000000000001330

[19] Zier, J. L., Spaulding, A. B., Finch, M., et al. (2017). Improved time to notification of impending brain death and increased organ donation using an electronic clinical decision support system. American Journal of Transplantation, 17(8), 2186–2191. https://doi.org/10.1111/ajt.14312

Thank you for joining U.S. Representatives Wittman, Miller-Meeks, and Costa in introducing 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 also 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 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.

As it stands today, the OPTN Computer System is secure, stable and reliable. In 1999, HRSA included in the OPTN contract a requirement for UNOS to build a contractor-owned, contractor-operated (COCO) computer system to support the OPTN's functions. The resulting product is UNet, which UNOS has continued to use, in support of the OPTN and as required by the OPTN contract, ever since. UNOS and the OPTN have worked together over the last 25 years to continue to improve and evolve UNet to keep up with the OPTN's needs. Moving the OPTN Computer System to a modern cloud-based infrastructure is an important step yet to be authorized by HRSA for incorporating necessary modifications to the system, like enhanced interoperability, modern APIs, and other technology like artificial intelligence which would improve features and functions for OPTN members and researchers. Moving the OPTN Computer System to a cloud-based infrastructure would enable UNOS to leverage modern infrastructure to further secure and stabilize the technology to ultimately improve organ donation and transplant for patients and donor families. UNOS urges HRSA to authorize UNOS to begin moving the OPTN Computer System to the cloud.