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ONE HUNDRED NINETEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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July 18, 2025

MEMORANDUM

TO: Members of the Subcommittee on Oversight and Investigations
FROM: Committee Majority Staff
RE: Subcommittee on Oversight and Investigations Hearing on July 22, 2025

I. INTRODUCTION

The Subcommittee on Oversight and Investigations will hold a hearing on Tuesday, July 22, 2025, at 10:15 a.m. (ET), in 2123 Rayburn House Office Building. The hearing is entitled, "Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System."

II. WITNESSES

Panel I

- **Raymond Lynch, MD, MS, FACS**, Chief, Organ Transplant Branch, Health Resources and Services Administration, U.S. Department of Health and Human Services.

Panel II

- **Barry Massa**, Chief Executive Officer, Network for Hope;
- **Maureen McBride, PhD**, Chief Executive Officer, United Network for Organ Sharing;
- **Richard Formica, MD**, Former President, Organ Procurement and Transplantation Network Board of Directors; and
- **John C. Magee, MD**, President, Organ Procurement and Transplantation Network Board of Directors.

III. BACKGROUND

A. Overview of the U.S. Organ Procurement and Transplantation System

The National Organ Transplant Act of 1984 (NOTA) set forth the creation of the Organ Procurement and Transplantation Network (OPTN) to institute a national registry system for

organ procurement and donor matching in the U.S.[1] The OPTN functions as a public-private partnership operating under a federal contract with the Health Resources and Services Administration (HRSA), a subagency within the U.S. Department of Health and Human Services (HHS).[2] According to the Congressional Research Service (CRS), "[a]lthough NOTA was enacted in 1984, creating the OPTN, among other policies, HHS did not promulgate regulations to establish the structure and operations of the OPTN until 1998."[3] The OPTN "final rule" officially went into effect on March 16, 2000.[4] Today, HRSA is the primary agency responsible for overseeing the OPTN contract.[5] HRSA is also responsible for administering grant funding[6] and providing policy guidance to ensure that organ procurement and transplantation programs adhere to national standards.[7]

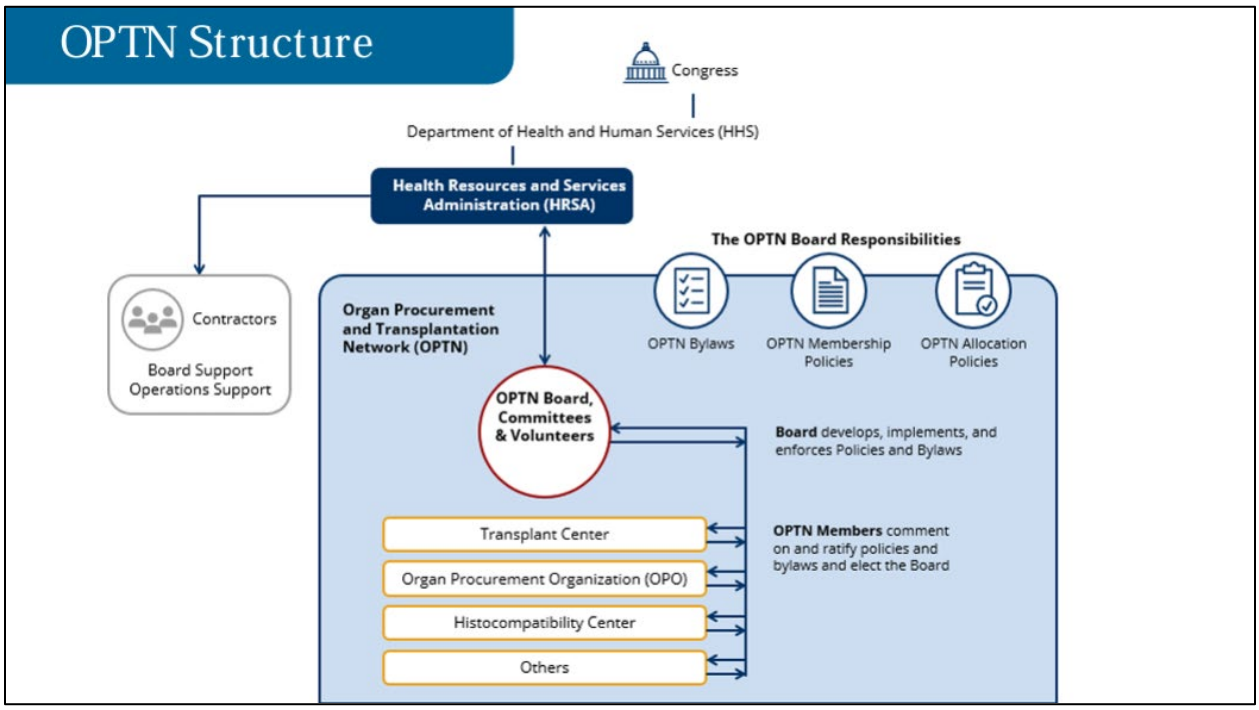

Figure 1: "OPTN Structure."[8]

[1] National Organ Transplant Act, 42 U.S.C. § 273 et seq.
[2] History & NOTA, Organ Procurement and Transplantation Net., HEALTH RESOURCES AND SERVICES ADMIN., *available at* https://optn.transplant hrsa.gov/about/history-nota/.
[3] MARCO A. VILLAGRANA, CONG. RESEARCH SERV., R48426, ORGAN PROCUREMENT AND TRANSPLANTATION: ADMINISTRATION, OVERSIGHT, AND POLICY ISSUES, 6 (Feb. 14, 2025).
[4] *Id*. at 3.
[5] *Id.* at 14.
[6] Find Grant Funding, Living Organ Donation Reimbursement Program (LODRP), Health Resources and Services Admin., U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *available at* https://www.hrsa.gov/grants/find-funding/HRSA-25-082.
[7] Guidance, Health Resources and Services Admin., U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *available at* https://optn.transplant hrsa.gov/professionals/by-topic/guidance/.
[8] Presentation by Macey Levan, *OPTN Update: New York State Transplant Council Meeting* 8, *available at* https://www health ny.gov/professionals/transplant_council/docs/2024-09-18_executive_update.pdf.

The United Network for Organ Sharing (UNOS), a nonprofit organization, has been the sole federal contract holder responsible for operating the OPTN since 1986.[9] Under this contract, the OPTN works with local or regional nonprofit organizations, known as Organ Procurement Organizations (OPO), to procure organs from donors for transplantation.[10] As of July 2025, there are currently 55 OPOs in operation across the U.S.[11] According to CRS, "all OPOs, transplant programs, and histocompatibility laboratories (that perform testing used to match organs with transplant candidates) are members of the OPTN."[12]

The Centers for Medicare and Medicaid Services (CMS) is responsible for regulating and certifying both OPOs and transplant centers to ensure compliance with health and safety regulations for patients.[13] OPOs must adhere to Conditions for Coverage (CfC) to receive Medicare and Medicaid reimbursement for covered services.[14] OPOs are also evaluated on performance by CMS using a tiered system ranging from Tier 1 (highest) to Tier 3 (lowest).[15] CMS recertifies OPOs on a four-year basis, with specific recertification requirements dependent on performance tier level.[16]

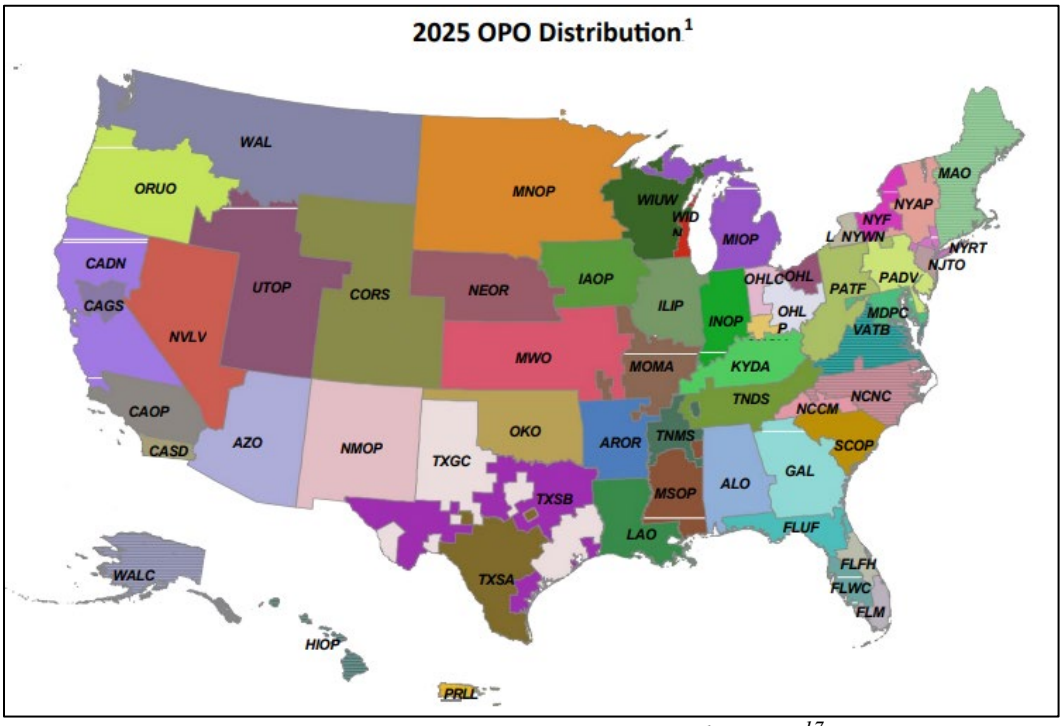

Figure 2: "2025 OPO Distribution"[17]

[9] *Supra* note 3, at 3.
[10] *Id.*
[11] Center for Medicare and Medicaid Services, Quality, Certification and Oversight Reports (QCOR), 2025 OPO Distribution, *available at* https://qcor.cms.gov/documents/2025%20Maps%20of%20OPO%20DSAs%20and%20Tier%20Status.pdf.
[12] *Supra* note 3, at 3.
[13] *Supra* note 3, at 18.
[14] *Id*.
[15] *Id*.
[16] *Id*.
[17] *Supra* at 11.

As Figure 1 illustrates, the OPTN is governed by the Board of Directors which establishes bylaws, policies, and other governing mechanisms such as committees.[18] In 2024, HRSA instituted reforms to separate OPTN's Board of Directors from that of their federal contractor, UNOS.[19] Previously, these entities were "one-and-the-same" as prescribed by OPTN bylaws, which raised concerns about the potential for conflicts of interest.[20] These changes went into effect on March 30, 2024.[21] On June 5, 2025, HRSA announced OPTN's new 34-member Board of Directors which began their new terms on July 1, 2025.[22]

Last year, the organ procurement and transplantation system in the U.S. performed over 48,000 transplants; however, there are over 103,000 people still on the transplant waiting list.[23] The OPTN is comprised of 440 total members, including "transplant hospitals, organ procurement organizations, histocompatibility laboratories, medical scientific organizations, public organizations, business members, and individual members."[24] Together, these entities help facilitate the procurement and transplantation of six main types of organs, including kidney, pancreas, liver, heart, lung, and intestine transplants.[25] Organ transplants have increased 23.3 percent in the past five years with 3.3 percent of this growth occurring between 2023 and 2024.[26]

B. Management Challenges and Patient Safety Concerns

The state of Kentucky falls under the regional jurisdiction of the OPO "Network for Hope."[27] It was previously under the jurisdiction of Kentucky Organ Donor Affiliates (KYDA, also referred to as "KODA") which was founded in 1987.[28] In October 2024, KYDA merged with another OPO, LifeCenter Organ Donor Network (LifeCenter), to form Network for Hope.[29]

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[18] *Supra* note 3, at 8.
[19] OPTN, *Public Comment Proposal: Revised Bylaws and Management and Membership Policies* 2, *available at* https://optn.transplant hrsa.gov/media/g1hfngvs/specialpc_invest_combineddoc.pdf.
[20] *Id.* at 3.
[21] *Id*.
[22] Press Release, Health Resources and Services Admin., *HRSA Announces New OPTN Board of Directors* (June 5, 2025), *available at* https://www.hrsa.gov/optn-modernization/board-of-directors.
[23] Organ Donation Statistics, Health Resources and Services Admin., U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *available at* https://www.organdonor.gov/learn/organ-donation-statistics.
[24] About, Organ Procurement and Transplant Network, Health Resources and Services Admin., U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *available at* https://optn.transplant.hrsa.gov/about/.
[25] Kathleen Doheny, *What You Need to Know About Organ Transplants*, WEBMD (Mar. 20, 2024), *available at* https://www.webmd.com/a-to-z-guides/organ-transplant-overview.
[26] Press Release, OPTN, Health Resources and Services Admin., *Organ transplants exceeded 48,000 in 2024; a 3.3 percent increase from the transplants performed in 2023* (Jan. 15, 2025), *available at* https://optn.transplant hrsa.gov/news/organ-transplants-exceeded-48-000-in-2024-a-33-percent-increase-from-the-transplants-performed-in-2023/.
[27] Network for Hope, *Who We Are*, *available at* https://www.networkforhope.org/about-us/.
[28] *Id*.
[29] LifeCenter, *Network for Hope - A New Era in Organ Donation Advocacy*, PR Newswire (May 9, 2024) *available at* https://www.prnewswire.com/news-releases/network-for-hope---a-new-era-in-organ-donation-advocacy-302141222.html.

On March 24, 2025, HRSA completed a report (Attachment 1) detailing findings of an investigation originating from allegations by a former KYDA employee.[30] The allegations were detailed in a letter shared by the House Committee on Energy and Commerce.[31] The employee alleged that "in 2021, a patient had been inaccurately pronounced brain dead and was pursued as an organ donor by KYDA" and that the patient displayed "clear signs of life at multiple points, but KYDA senior staff directed that organ recovery proceed."[32] HRSA's review—prompted by these allegations—found the following patterns related to KYDA's operations:

1. Failure to recognize neurologic function inconsistent or unfavorable for DCD organ recovery on initial patient assessment or subsequent follow up.
2. Failure to work collaboratively with patients' primary medical teams, including instances of potential violation of separation of roles in patient care.
3. Failure to respect family wishes and appropriately safeguard the decisionmaking authority of legal next of kin.
4. Failure to follow professional best practices as well as policies and guidelines for collection of patients' medical data.

Figure 3: Excerpt from HRSA's March 24, 2025 Information Memo to the Associate Administrator[33]

HRSA's report provides a detailed overview of its investigation, actions taken by the OPTN and KYDA at HRSA's direction following the initial complaint, and details concerning the index case.[34] The report also provides background and statistics related to KYDA's organ procurement in recent years[35] and reviews additional cases provided to HRSA.[36] Finally, the report summarizes these findings, notes relevance to other policy and practice concerns,[37] and includes an appendix consisting of OPTN's findings following the HRSA-directed review.[38]

The Index Case

In the index case (KYDA-001), the patient was found to be experiencing "cardiovascular collapse after an unintentional overdose" and was "intubated at the time of arrival at the hospital."[39] After the patient did not initially show signs of improvement, it was determined that the patient had signed the donor registry and steps were taken to obtain consent from next of kin to proceed with donation by cardiac death (DCD) procurement.[40] In the days following, hospital

[30] Report from Division of Transplantation, Health Resources and Services Admin., to Suma Nair, PhD, MS, RD, Associate Admin., HSB, 2 (Mar. 24, 2025).
[31] *A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation: Hearing Before the H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations*, 118th Cong. 2 (Sept. 11, 2024).
[32] *Supra* note 30.
[33] *Id*. at 4.
[34] *Id*. at 1.
[35] *Id*. at 9.
[36] *Id*. at 11.
[37] *Id*. at 20.
[38] *Id*. at 22.
[39] *Id*. at 5.
[40] *Id*.

staff noted signs of improved neurologic function displayed by the patient despite the use of sedatives, yet the decision to pursue organ recovery was not reversed.[41] The KYDA coordinator documented concerns from the hospital staff, stating: "*[h]opsital [sic] staff was extremely uncomfortable with the amount of reflexes patient is exhibiting . . . Hospital staff kept stating that this was euthanasia and [KYDA staff member] explained to them that it is not*."[42]

Despite this acknowledgement, HRSA's report notes that no additional neurological assessments were documented by the OPO prior to proceeding to the operating room (OR).[43] Once in the OR, "[t]he patient spent approximately 45 minutes in the operating room before the palliatitive care physician ended the attempted recovery" with documentation that "*she felt that this was inhumane and unethical and she would not participate in this process*."[44] KYDA-001 survived the attempted withdraw of life support and organ procurement, yet KYDA maintained that it was "*satisfied and confident in the donation process*."[45]

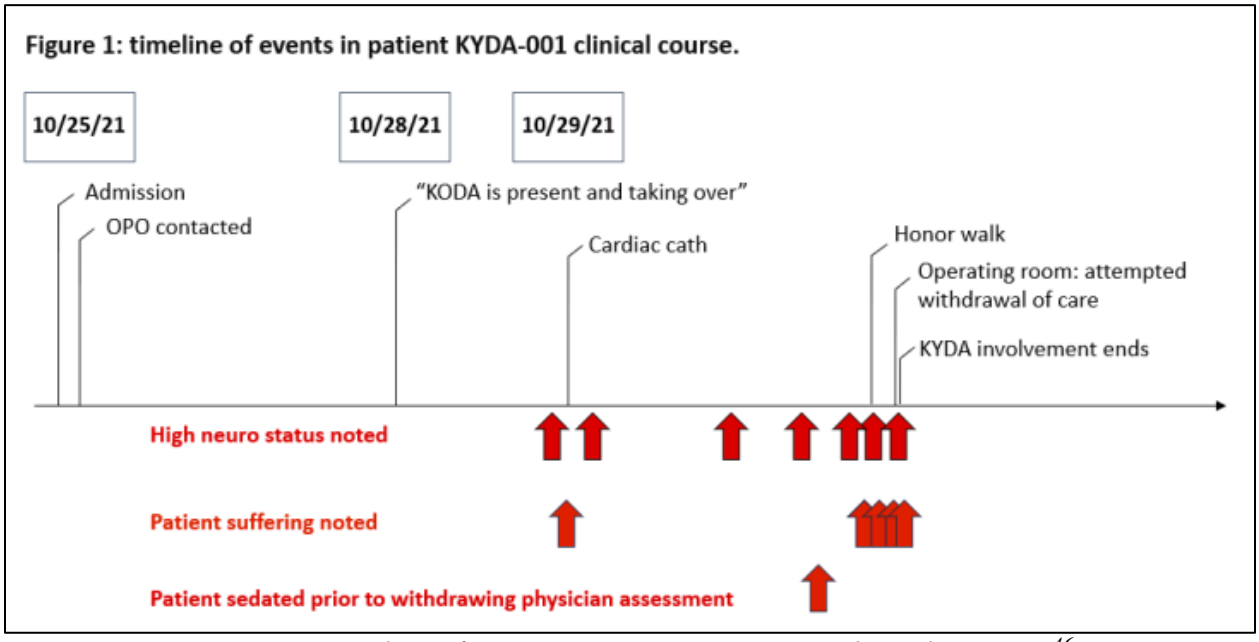

Figure 4: "timeline of events in patient KYDA-001 clinical course."[46]

Additional Cases

HRSA's report contains details of additional cases submitted by KYDA. Of the 351 unique cases with sufficient documentation pertaining to HRSA's request, 103 (or 29.3 percent) of the cases had "concerning features."[47] Some of these features include "issues with patient family interactions" when obtaining consent to proceed with organ procurement from next of

[41] *Id*. at 6.
[42] *Id*.
[43] *Id*. at 7.
[44] *Id*.
[45] *Id*.
[46] *Id*. at 8.
[47] *Id*. at 11.

kin[48] and "fractured communications and inflexible decision-making" with healthcare team interactions.[49] The report notes that the most common feature among these cases was the "failure to recognize preserved neurologic function that made successful DCD recovery unlikely."[50] HRSA also finds that the impacts of chemical paralysis or sedation may also contribute to the errors in neurologic assessments.[51] Below is an excerpt summarizing the full findings of this report:

> Beyond the concerning patient-level interactions, KYDA has also failed to accurately report relevant data to the OPTN, has sought to minimize to the OPTN and HRSA the degree and type of errors in the case of patient KYDA-001, and is alleged to have retaliated against a Congressional whistleblower…OPTN and UNOS leadership signed on to a letter condemning oversight activities and citing KYDA-001's case as an example of misinformation and hearsay. After a four month investigation, the OPTN failed to identify patterns of unsafe care, connect KYDA practice decisions with observed outcomes, or make specific recommendations to prevent further harm.[52]

Moreover, according to OPTN policies, protocols must be established between OPOs and donor hospitals to ensure that roles and responsibilities are clearly defined.[53] HRSA reiterates in the report that "a central tenant of DCD procurement is that until the patient has passed, they remain under the care of the hospital's medical team."[54] In one of the cases contained within the report, it is unclear who (the hospital team or the OPO) was in control of making decisions regarding patient care. In case KYDA-049, records reflect that a KYDA coordinator requested for testing to be ordered prior to receiving family consent to donation and that "*[the MD] has no problem ordering test per KODA request after family consents to donation, but has ethical concerns with this occurring prior to consent."*[55]

Corrective Action Plan

On May 28, 2025, HRSA issued a corrective action plan (CAP) (Attachment 2) to Dr. Richard Formica, the then-President of the OPTN Board of Directors, and Rexanah Wyse Morrissette, the Interim Executive Director.[56] The CAP included an overview of many of the key findings contained within the broader report, but also included specific corrective actions for OPTN to be addressed by specific deadlines, the first of which by June 27, 2025, and the second

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[48] *Id*. at 12.
[49] *Id*. at 14.
[50] *Id*. at 15.
[51] *Id*.
[52] *Id*. at 20.
[53] OPTN Policy 2.15.B, *available at* https://optn.transplant hrsa.gov/media/eavh5bf3/optn_policies.pdf.
[54] *Supra* note 30, at 13.
[55] *Id*.
[56] Letter from Suma Nair, PhD, MS, RD, Assoc. Admin., HSB, to Richard N. Formica, Jr., MD, Pres., Board of Directors, Organ Procurement and Transplantation Network, and Rexanah Wyse Morrissette, Esq. Interim Executive Dir. (May 28, 2025).

by November 24, 2025.[57] As noted in the CAP, "[f]ailure to comply with corrective action requirements as described above will prompt review by the Secretary for further actions to protect patient safety and public health in the KYDA [donor service area]."[58] The CAP further notes that "HRSA has received reports of similar patterns of high risk DCD procurement practices at multiple other OPOs" and that the "high frequency of DCD procurement and concern for variation in the quality and safety of care across the country merit immediate development of minimum safety standards[.]"[59]

C. Donation after Cardiac Death (DCD)

There are two primary methods by which organs may be procured from deceased donors: (1) **donation after brain death (DBD);** and (2) **donation after cardiac (or circulatory) death (DCD)**. DBD is defined as "the organ recovery process that may occur following death by irreversible cessation of cerebral and brain stem function; characterized by absence of electrical activity in the brain, blood flow to the brain, and brain function as determined by clinical assessment of responses."[60] CMS defines DCD as "an individual who donates after his or her heart has irreversibly stopped beating," and notes that "[a] donor after cardiac death may be termed a non-heartbeating or asystolic."[61] DCD means that the donor is unable to survive without the assistance of life support systems, yet still has minimal brain activity which disqualifies them from the DBD classification.[62] There are additional differences between DCD "controlled" versus "uncontrolled" donation:

- **Controlled DCD (cDCD)** occurs when a patient experiences an anticipated cardiac arrest while in a hospital.[63] Typically, these cases are intensive care unit (ICU) patients who suffer from catastrophic brain injury, and the patient's family and doctors decide to withdraw life support.[64]

- **Uncontrolled DCD (uDCD)** occurs when a patient suffers an unexpected refractory cardiac arrest, typically outside of a hospital.[65] Following cardiac arrest, physicians attempt resuscitation, but if these attempts are deemed a failure, action will be initiated to preserve the patient's organs for donation.[66] This includes continuing cardiac compressions and ensuring the patient is on a ventilator.[67]

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[57] *Id*.
[58] *Id*. at 6.
[59] *Id*. at 6.
[60] Organ Procurement and Transplantation Network, Clarify Requirements for Pronouncement of Death, *available at* https://optn.transplant hrsa.gov/policies-bylaws/public-comment/clarify-requirements-for-pronouncement-of-death/.
[61] 42 C.F.R. § 486.302 (2025).
[62] Nat'l Kidney Found., *Donation After Circulatory Death: A Basic Explanation for Donor Families* 4 (2014), *available at* https://www kidney.org/sites/default/files/03-60-0119_FBE_CirculatoryDeath_Bro_v5.pdf.
[63] Iván Ortega-Deballon et. al., *Protocols for uncontrolled donation after circulatory death: a systematic review of international guidelines, practices and transplant outcomes*, CRIT CARE (June 24, 2015), *available at* https://pmc.ncbi nlm nih.gov/articles/PMC4495857/.
[64] *Id*.
[65] *Id*.
[66] *Id*.
[67] *Id*.

According to the National Kidney Foundation, a patient becomes eligible for DCD if they experience "a permanent neurological injury, or disease that results in necessary life-sustaining medical treatment or ventilated support."[68] Once a determination is made by the hospital medical team that the patient will neither survive nor experience meaningful improvement, the family or next of kin may begin taking steps to discontinue further medical intervention.[69] At this point, conversations about possible organ donation begin and the regional OPO is notified to determine whether the patient is suitable for donation.[70]

As noted in HRSA's report, "the number of organ donors recovered by KYDA has grown by 80% in the past five years, compared to 58% overall growth in the United States."[71] The report also notes that "[t]he gain in organ donors recovered by KYDA came almost entirely from increases in DCD" and that "KYDA's shift to majority-DCD practice now places it at the 82nd percentile among OPOs in terms of DCD vs. brain dead procurement."[72] UNOS and the OPTN have taken steps to increase DCD donations, most notably through a joint project to increase procurement beginning in October 2020.[73] The stated goal was to "support organ procurement organizations (OPOs) in increasing recovery of donation after circulatory death (DCD) organs."[74] Initially beginning with 26 participating OPOs,[75] the initiative expanded to 30 of the then 57[76] national OPOs by January 2022, with an increased goal to raise DCD donations by yet another 28 percent by April 2022.[77]

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[68] *Supra* note 62.
[69] *Id*.
[70] *Id.* at 5.
[71] *Supra* note 30, at 9.
[72] *Id*.
[73] UNOS, *26 OPOs join new UNOS-led collaborative to increase DCD donor recoveries* (Apr. 13, 2021), *available at* https://web.archive.org/web/20250421141740/https://unos.org/news/26-opos-join-unos-dcd-donor-project// (This information has since been removed from the official UNOS website as of July 13, 2025).
[74] *Id*.
[75] *Id*.
[76] At the time, there were a total of 57 OPOs nationwide. There are currently 55 as of July 2025. *See* https://qcor.cms.gov/documents/2025%20Maps%20of%20OPO%20DSAs%20and%20Tier%20Status.pdf.
[77] UNOS, *30 OPOs participating in national project to increase procurement of DCD donors* (Jan. 20, 2022) *available at* https://web.archive.org/web/20250622114615/https://unos.org/news/30-opos-project-increase-dcd-donors/ (This information has since been removed from the official UNOS website as of July 13, 2025).

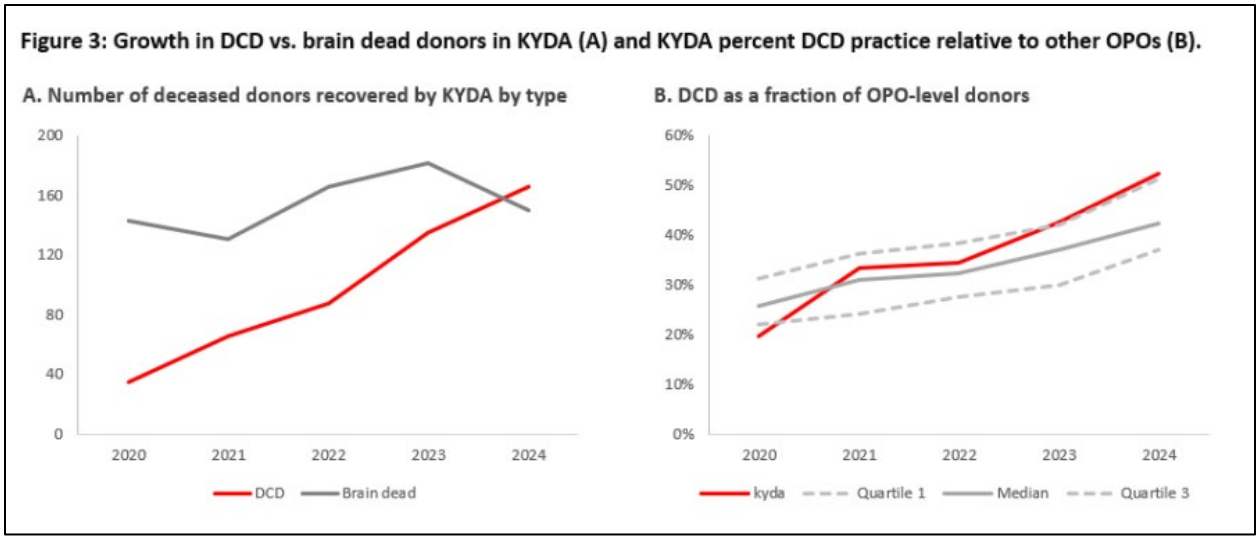

Figure 5: "Growth in DCD vs. brain dead donors in KYDA (A) and KYDA percent DCD practice relative to other OPOs (B)."[78]

D. Prior Committee Activity

During the 118th Congress, the Committee on Energy and Commerce passed the *Securing the U.S. Organ Procurement and Transplantation Network Act* to both modernize OPTN and allow HRSA to institute a competitive contracting process to find the best contractors for various OPTN functions.[79] This legislation was signed into law on September 22, 2023.[80]

In addition to this legislation, the Subcommittee on Oversight and Investigations launched an investigation into the organ procurement and transplantation system. On March 20, 2024, the Committee sent a letter to UNOS requesting information related concerns surrounding data security and operability, patient safety and equity, and conflicts of interest.[81] The Committee also sent a letter to HRSA on March 20, 2024, requesting information related to implementation of the *Securing the U.S. Organ Procurement and Transplantation Network Act* as well as other concerns related to effective oversight and management.[82]

On September 11, 2024, the Subcommittee on Oversight and Investigations held a hearing focusing on the implementation of reforms at OPTN, including the need for stronger oversight and accountability as well as ongoing patient safety concerns.[83] Witnesses on the panel highlighted examples of inefficiencies, conflicts of interest, and instances of retaliation against

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[78] *Supra* note 30, at 10.
[79] Securing the U.S. Organ Procurement and Transplantation Network Act of 2023, Pub. L 118-14 (amending 42 USC § 274).
[80] *Id*.
[81] Letter from Cathy McMorris Rodgers, Chair, H. Comm. on Energy and Commerce, *et. al*., to Maureen McBride, Chief Executive Officer, United Network for Organ Sharing (Mar. 20, 2024).
[82] Letter from Cathy McMorris Rodgers, Chair, H. Comm. on Energy and Commerce, *et. al*., to Carole Johnson, Administrator, Health Resources and Services Admin. (Mar. 20, 2024).
[83] *A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation: Hearing Before the H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations*, 118th Cong. 2 (Sept. 11, 2024).

employees seeking to report misconduct.[84] During this hearing, questions were raised related to allegations of mismanagement and patient safety concerns after patients began exhibiting signs of increased neurologic function after being previously deemed suitable as an organ donation candidate.[85] Several of these allegations, particularly those related to patient safety,[86] were later substantiated through the findings contained in HRSA's March 2025 report.[87]

IV. KEY QUESTIONS

The hearing may include discussion around the following key questions:

- What are the findings and lessons learned from HRSA's review and report?
- What changes are necessary to address patient safety concerns and restore public trust in the nation's organ procurement and transplant system?
- How might the culture and reporting mechanisms be improved to allow for increased data collection of organ procurement and transplantation procedures, reporting of safety concerns, and eliminating the fear of retaliation?
- What are the challenges to reducing conflicts of interest within the existing system?
- How can HRSA work collaboratively with the OPTN to improve management and efficacy within the existing system?
- Are sufficient protocols currently in place for DCD procedures that ensure patient safety? If so, are those protocols being followed across all OPOs? If not, what protocols should be refined to ensure patient safety?
- Should Congress consider potential changes to the federal government's role in overseeing organ procurement and transplantation?

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Majority Committee staff at (202) 225-3641.

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[84] *Id*.
[85] *Id*.
[86] *A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation: Hearing Before the H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations*, 118th Cong. 2 (Sept. 11, 2024) (questions by Morgan Griffith, Chairman, Subcommittee on Oversight and Investigations).
[87] *Supra* note 30, at 20.