



MEMORANDUM

To: Members and Staff, Subcommittee on Oversight and Investigations

From: Majority Committee Staff

Re: A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation.

The Subcommittee on Oversight and Investigations will hold a hearing on Wednesday, September 11, 2024, at 10:30 a.m. (ET). The hearing will take place in 2322 Rayburn House Office Building. The title of the hearing is “A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation.”

I. WITNESSES

- **Greg Segal**, Founder & CEO, Organize
- **Dr. Robert Cannon**, M.D., Associate Professor of Surgery, University of Alabama at Birmingham, Surgical Director for Liver Transplant
- **Dr. Seth Karp**, M.D., Surgeon-in-Chief, Vanderbilt University Medical Center
- **Dr. Jesse Roach**, Senior Vice President of Government Relations, National Kidney Foundation

II. OVERVIEW

This hearing will conduct oversight on the implementation of the *Securing the U.S. Organ Procurement and Transplantation Network Act* (the Act), which was enacted one year ago to modernize and improve the nation’s organ procurement and transplantation system.¹ The discussion will cover the current status of the law’s implementation, ongoing patient safety concerns, and efforts to strengthen oversight and accountability within the Organ Procurement and Transplantation Network (OPTN).

The Act is currently being implemented by the Health Resources and Services Administration (HRSA). One key provision of the Act is the requirement that the OPTN Board of Directors be independent and separate from the contractor managing the network. The Act also aims to address longstanding conflicts of interest and improve transparency and accountability within the OPTN. Both HRSA and the President of the OPTN, Dr. Richard Formica, were invited to testify before the Committee on the progress of the Act’s implementation but declined, citing short notice (HRSA was notified of the hearing on Friday, August 30th and Dr. Formica was informed of the hearing on Sunday, September 1st).

¹ H.R. 2544, 118th Cong. (2023). Available at <https://www.congress.gov/bill/118th-congress/house-bill/2544>.

III. BACKGROUND

Since the OPTN's inception, the contract has been awarded to a single contractor: the United Network for Organ Sharing (UNOS).² After decades of a sole contract, issued by HRSA, Congress unanimously passed the *Securing the U.S. Organ Procurement and Transplantation Network Act* and the Act was signed into law on September 22, 2023.³

The objective of the Act is to address significant concerns with the donation and transplantation system. For the first time since the enactment of the OPTN, the OPTN contract is open for competitive bidding. For years the OPTN has experienced challenges with systemic mismanagement, resulting in a system that is not serving patients properly.⁴ The Committee is committed to supporting and overseeing the implementation of the Act, intended to give HRSA increased ability to address these concerns, particularly as HRSA receives responses to new solicitations for OPTN contracts that UNOS has solely managed for nearly 40 years.⁵

According to HRSA, 17 people die each day waiting for an organ transplant.⁶ A recent HRSA-funded study found that while Americans die each day waiting for organ transplants, as few as one in five potential donor organs are recovered.⁷ Furthermore, gaps in oversight – such as the reliance on self-reported data from OPOs – has historically allowed these organizations to mask poor performance and mismanagement, preventing the decertification of failing OPOs.⁸ Although the Act aims to improve the efficacy of the OPTN, challenges remain in ensuring that organ recovery rates improve and that all transplant centers follow best practices to maximize patient safety. Delays in reforming certain policies have also been noted, and the Committee seeks to monitor HRSA's efforts closely.

Systemic inefficiencies in the organ procurement process have long been identified as a critical problem with preventable errors, such as lost or mishandled organs, contributing to as many

² About OPTN, Organ Procurement & Transplantation Network, <https://optn.transplant.hrsa.gov/about/> (last visited Sept. 9, 2024).

³ The White House, Bill Signed: H.R. 2544, The White House (Sept. 22, 2023), <https://www.whitehouse.gov/briefing-room/legislation/2023/09/22/bill-signed-h-r-2544/>.

⁴ The White House, Bill Signed: H.R. 2544, The White House (Sept. 22, 2023), <https://www.whitehouse.gov/briefing-room/legislation/2023/09/22/bill-signed-h-r-2544/>; Lenny Bernstein, Transplant Program Failures Lead to Deaths and Injuries, Senate Report Finds, Wash. Post (Aug. 3, 2022), <https://www.washingtonpost.com/health/2022/08/03/transplant-deaths-mistakes-senate-finance/>; Inequity in Organ Donation: The Costly Effects of an Outdated Organ Donation System, <https://costlyeffects.organdonationreform.org/Inequity/> (last visited Sept. 9, 2024).

⁵ Letter from Cathy McMorris Rodgers, Chair, House Comm. on Energy & Com., to Dr. Maureen McBride, Chief Exec. Officer, United Network for Organ Sharing (Mar. 20, 2024), https://d1dth6e84htgma.cloudfront.net/03_20_24_Letter_to_UNOS_re_OPTN_faa4a80755.pdf.

⁶ Organ Donation Statistics, OrganDonor.gov, <https://www.organdonor.gov/learn/organ-donation-statistics> (last visited Sept. 9, 2024).

⁷ HRSA, OPTN Deceased Donor Potential Study (DDPS) (2015), https://optn.transplant.hrsa.gov/media/1161/ddps_03-2015.pdf.

⁸ Press Release, CMS Finalizes Policy That Will Increase the Number of Available Life-Saving Organs by Holding Organ Procurement Organizations Accountable, Centers for Medicare & Medicaid Services (Mar. 30, 2021), <https://www.cms.gov/newsroom/press-releases/cms-finalizes-policy-will-increase-number-available-lifesavings-organs-holding-organ-procurement>.

as 28,000 organs failing to be transplanted annually.⁹ These failures have posed serious risks to patient outcomes, underscoring the urgent need for enhanced accountability and performance standards within the organ procurement system.

HRSA recently announced the separation of the OPTN Board of Directors from the OPTN contractor, a significant step in the OPTN Modernization Initiative.¹⁰ As of August 29, HRSA awarded the OPTN Board Support contract to The American Institutes for Research (AIR), a national nonprofit organization, to support the newly incorporated OPTN Board of Directors. AIR will be responsible for eliminating conflicts of interest and ensuring that data, evidence, and the voices of clinical leaders, scientific experts, patients, and donor families drive the Board's decisions.¹¹ AIR will also establish a transitional nominating committee and conduct a special election to create a fully independent Board.¹² Additionally, AIR will review and recommend updates to the OPTN bylaws and conflict of interest policies to support the new Board in its oversight and management responsibilities.¹³ These changes represent a key component of the bipartisan *Securing the U.S. Organ Procurement and Transplantation Network Act*.

In the year since the passage of the *Securing the U.S. Organ Procurement and Transplantation Network Act*, meaningful steps have been taken to modernize and improve the OPTN. However, the ongoing challenges, including patient safety concerns and conflicts of interest, highlight the need for sustained oversight. This hearing will provide an essential forum to assess the progress made and to ensure that the reforms underway lead to a more effective and equitable OPTN system that better serves patients and their families.

IV. OBJECTIVES

- Hear from stakeholders regarding implementation of the *Securing the U.S. Organ Procurement and Transplantation Network Act*.
- Inquire about ongoing patient-safety concerns.
- Examine efforts to strengthen oversight, improve accountability, and address conflicts of interest within the OPTN.

V. STAFF CONTACT

If you have questions regarding this hearing, please contact Lauren Kennedy with the majority committee staff at Lauren.Kennedy@mail.house.gov or 202-225-3641.

⁹ The Bridgespan Group, *Reforming Organ Donation in America*, at 1 (Jan. 2019), <https://www.bridgespan.org/getmedia/b936ac70-4449-4f8e-a6b7-d5618b9eade2/reforming-organ-donation-in-america-01-2019.pdf>; Samuel Hammond, *How to Stop Losing 17,500 Kidneys*, *Statecraft* (Aug. 16, 2023), <https://www.statecraft.pub/p/how-to-stop-losing-17500-kidneys>.

¹⁰ *Organ Procurement and Transplantation Network Modernization*, Health Resources & Services Administration, <https://www.hrsa.gov/optn-modernization> (last visited Sept. 9, 2024).

¹¹ *Id.*

¹² Press Release, American Institutes for Research to Support Efforts to Strengthen U.S. System of Organ Donation, American Institutes for Research (Aug. 23, 2023), <https://air.org/news/press-release/american-institutes-research-support-efforts-strengthen-us-system-organ-donation>.

¹³ *Id.*