

Title: “Securing the U.S. Organ Procurement and Transplantation Network Act”

Top Line: The “Securing the U.S. Organ Procurement and Transplantation Network Act” will improve the National Organ Transplantation Act of 1984 (NOTA) and provide the U.S. Department of Health and Human Services (HHS) with clear authority to expand competition for contracts related to the operation of the Organ Procurement and Transplantation Network (OPTN) - breaking up the monopoly the United Network for Organ Sharing (UNOS) has held since 1984. On April 10, 2023, Representatives Larry Bucshon (R-IN-8) and Robin Kelly (D-IL-2) introduced H.R. 2544, an identical bill in the House. The House bill is based on Senate Finance and Senate Health, Education, Labor and Pensions (HELP) Committees’ recommendations sent to the House Energy & Commerce Committee in late 2022. This legislation is the result of extensive oversight by the Senate Finance Committee beginning in 2020.

Background and Current Law: The National Organ Transplant Act (NOTA) of 1984 established the Organ Procurement and Transplantation Network (OPTN) to manage the U.S. organ donation system, including setting policy, maintaining critical organ matching technology, and ensuring compliance of OPTN members. The OPTN is the critical, national system whose responsibilities include matching deceased donor organs with the more than 105,000 patients waiting for an organ transplant. In the 40 years since Congress passed NOTA, the Health Resources and Services Administration (HRSA) has only awarded the contract to a single entity: the United Network for Organ Sharing (UNOS).

In 2020, the Senate Finance Committee began a bipartisan investigation into UNOS’s failures. On August 3, 2022, the Senate Finance Committee held a bipartisan hearing titled, “A System in Need of Repair: Addressing the Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network.” As part of this hearing, Senators Wyden and Grassley released a 66-page memo detailing the findings of their nearly two-year investigation. The report exposes underperforming organ procurement organizations (OPOs), mismanagement and lack of oversight by UNOS, antiquated information technology, patient and safety risks, and the improper use of Medicare funds. The report concluded “From the top down, the U.S. transplant network is not working, putting Americans’ lives at risk.”¹ It recommended removing barriers to competition for OPTN functions, including breaking up the monopoly contract. Similar calls have been made by House Committee on Oversight and Reform Subcommittee on Economic and Consumer Policy,² the House Appropriations Committee,³ and the United States Digital Service.⁴

The investigation also discovered that NOTA only permits the Department of Health and Human Services (HHS) to contract with a “non-profit entity with expertise in organ procurement and

¹ [https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20REL%20EASE\)%20on%20website.pdf](https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20REL%20EASE)%20on%20website.pdf).

² <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>

³ <https://docs.house.gov/meetings/AP/AP00/20210715/113908/HMKP-117-AP00-20210715-SD003.pdf> at pgs. 63, 64.

⁴ <https://www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/>

transplantation.” As drafted, NOTA has been interpreted to prevent HHS from soliciting multiple bids from public and private entities that can better manage and operate the OPTN contract. By opening the contract to competition, Congress can improve safety and efficiency for transplant patients.

In March 2023, the President’s Fiscal Year 2024 Budget included legislative proposals to “modernize statutory tools” related to the OPTN, and HRSA announced the OPTN Modernization Initiative, explicitly stating its intent to award multiple OPTN contracts, increase competition, and ensure equity and accountability.⁵ These reforms have been welcomed by several patient groups.⁶

Proposed Law: The proposed legislation would remove barriers in OPTN contracting and give HRSA statutory authority to improve management of the organ transplantation system in the U.S. The current OPTN contract is set to expire September 30, 2023, making the proposed changes urgent and timely for HRSA to make meaningful reforms.

The legislation would:

- Make technical amendments to NOTA;
- Remove barriers in OPTN contracting to broaden eligibility and types of awards HRSA can make to ensure the entire OPTN does not have to be operated by one entity;
- Improve HHS management of OPTN contracts by providing flexibility on the structure and funding of OPTN contracts, by removing the \$7 million funding cap (per CBO review the language does not affect spending or revenue);
- Require a GAO report on user fees to help Congress better understand how the OPTN is currently financed; and
- Provide HRSA the flexibility necessary to conduct a thoughtful, full and open competition process for the OPTN contract for the first time since the OPTN was established in 1986.

⁵ <https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf> at 37; <https://www.hrsa.gov/about/news/press-releases/organ-procurement-transplantation-network-modernization-initiative>.

⁶ <https://twitter.com/ASNAdvocacy/status/1648772396315299840?s=20>; American Society of Transplantation, <https://www.myast.org/ast-statement-hrsa%E2%80%99s-optn-modernization-initiative#>; American Society of Nephrology, <https://www.kidneynews.org/display/post/current-0/optn-modernization-initiative.xml>; Global Liver Institute, <https://globalliver.org/global-liver-institute-applauds-hrsas-announcement/>; National Kidney Foundation, <https://www.kidney.org/newsletter/advocacy/hrsa-s-plan-to-modernize-transplant-system>.