

United States Senate

WASHINGTON, DC 20510

March 26, 2025

VIA ELECTRONIC TRANSMISSION

Thomas J. Engels
Administrator
Health Resources and Services Administration

Dear Administrator Engels:

On October 19, 2005, Senator Grassley, as then-Chairman of the Senate Finance Committee, launched his first investigation into the organ donation system.¹ Since then, for nearly two decades, we have engaged in bipartisan oversight of our nation's organ transplant system, the entities that compose this system, and the government offices tasked with ensuring patient safety and increasing accountability. Members of the Senate Finance Committee have consistently raised concerns about the Organ Procurement and Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS), which has been the sole contractor of the OPTN for the last 40-plus years.² Additionally, in 2023, a bipartisan group of Senators sent letters to various organ procurement organizations (OPOs), raising concerns about conflicts of interest and the procurement of unnecessary pancreata to game performance metrics.³ Further, we have previously raised concerns to the Health Resources and Services Administration (HRSA) and the Centers for Medicare & Medicaid Services (CMS) regarding their failures to properly oversee the OPTN and the OPOs.⁴ As a result of this long-standing, bipartisan oversight, Congress passed the Securing the U.S. OPTN Act in 2023, which resulted in the first

¹ Press Release, *Chairman Grassley follows up on violation of rules governing organ transplants, asks questions of federal watchdogs*, U.S. Sen. Comm. on Finance (Oct. 19, 2005), <https://www.finance.senate.gov/chairmans-news/chairman-grassley-follows-up-on-violation-of-rules-governing-organ-transplants-asks-questions-of-federal-watchdogs>.

² Press Release, *Finance Committee Members Probe U.S. Organ Transplant System*, Off. of Sen. Charles E. Grassley (Feb. 12, 2020), <https://www.grassley.senate.gov/news/news-releases/finance-committee-members-probe-us-organ-transplant-system>.

³ Press Release, *Wyden, Grassley, Cardin, Young Raise Alarm Over Dramatic Increase in Pancreata Procurement*, U.S. Sen. Comm. on Finance (Mar. 21, 2023), <https://www.finance.senate.gov/chairmans-news/wyden-grassley-cardin-young-raise-alarm-over-dramatic-increase-in-pancreata-procurement->; Press Release, *Grassley and Fellow Finance Committee Colleagues Investigate Organ Donation System for Potential Self-Dealing and Financial Conflicts of Interest*, Off. of Sen. Charles E. Grassley (Sept. 8, 2023), <https://www.grassley.senate.gov/news/news-releases/grassley-and-fellow-finance-committee-colleagues-investigate-organ-donation-system-for-potential-self-dealing-and-financial-conflicts-of-interest>.

⁴ Letter from Senator Ron Wyden, Senator Charles E. Grassley, Senator Benjamin L. Cardin, and Senator Todd Young to Administrator Chiquita Brooks-LaSure, Centers for Medicare & Medicaid Services (Sep. 5, 2023), https://www.grassley.senate.gov/imo/media/doc/wyden_grassley_cardin_young_to_cms_-_hhs_oig_opo_audit_report.pdf; Letter from Senator Ron Wyden, Senator Charles E. Grassley, Senator Todd Young, Senator Elizabeth Warren, and Senator Jerry Moran to Administrator Carole Johnson, Health Resources and Services Administration (May 2, 2024), https://www.grassley.senate.gov/imo/media/doc/wyden_grassley_et_al_to_hrsa_-_rfp.pdf; Press Release, *Wyden, Grassley, Cardin and Young Call on CMS to Strengthen Protections Against Excessive and Unnecessary Recoveries of Pancreata from Organ Donors*, U.S. Sen. Comm. on Finance (June 6, 2024), <https://www.finance.senate.gov/chairmans-news/wyden-grassley-cardin-and-young-call-on-cms-to-strengthen-protections-against-excessive-and-unnecessary-recoveries-of-pancreata-from-organ-donors>.

competitive bidding process for OPTN contracts in the program's nearly half-a-century history and gave HRSA additional statutory authorities to improve management of this system.⁵

It's with this history in mind that we write today to raise concerns about reports of organs being allocated out of sequence. On February 26 and 27, 2025, The New York Times released two articles titled, "Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored," and "Sick and Skipped Over: How We Investigated the Organ Transplant System."⁶ According to the reports, "last year, officials bypassed patients on organ waiting lists in nearly 20 percent of transplants from deceased donors. Those organs often went to patients who were not as sick, or had not been waiting as long."⁷ In 2016, that number was closer to two percent.⁸ The Times also found that "over the past five years, more than 1,200 people died after they got close to the top of a waiting list but were skipped."⁹

As the federal agency responsible for overseeing the OPTN, HRSA has a considerable responsibility in ensuring that this system is supporting the equitable distribution of organs as well as minimizing organ wastage, but it is clear that HRSA has not provided adequate oversight of the OPTN.¹⁰ According to the Times, since at least 2022, HRSA has been aware that more people on the waiting list are being skipped.¹¹ Despite this awareness, HRSA has taken minimal action to address these organ allocation shortfalls.¹² Specifically, HRSA sent the OPTN three critical comment letters, which requested the OPTN complete certain actions by March 31, 2025, after the agency found "potential[] widespread non-compliance with regulatory requirements of organ allocation."¹³ UNOS, the current OPTN contractor, reportedly determined that it was acceptable for the OPOs to skip over patients in 99.5% of cases, usually for the reason that the

⁵ Press Release, *Grassley, Colleagues Welcome Historic Reform to U.S. Organ Donation System as Bipartisan Bill is Signed into Law*, Off. of Sen. Charles E. Grassley (Sep. 22, 2023), <https://www.grassley.senate.gov/news/news-releases/grassley-colleagues-welcome-historic-reform-to-us-organ-donation-system-as-bipartisan-bill-is-signed-into-law>.

⁶ Brian Rosenthal, Mark Hansen, and Jeremy White, *Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored*, The New York Times (Feb. 26, 2025), <https://www.nytimes.com/interactive/2025/02/26/us/organ-transplants-waiting-list-skipped-patients.html>; Brian Rosenthal, *Sick and Skipped Over: How We Investigated the Organ Transplant System*, The New York Times (Feb. 27, 2025), <https://www.nytimes.com/2025/02/27/insider/how-times-investigated-the-organ-transplant-system.html>.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ Lee Fleisher, Jean Moody-Williams, and Jonathan Blum, *The Transplant Eco-System: The Role of Data in CMS Oversight of The Organ Procurement Organization*, Centers for Medicare & Medicaid Services (Apr. 28, 2023), <https://www.cms.gov/blog/transplant-eco-system-role-data-cms-oversight-organ-procurement-organizations>.

¹¹ New York Times, *supra* note 6.

¹² *Id.*; Organ Procurement & Transplantation Network, *OPTN critical comments*, at Allocation out of sequence, <https://optn.transplant.hrsa.gov/policies-bylaws/optn-critical-comments/>. (HRSA sent letters to the OPTN on August 30, 2024, November 27, 2024, and February 21, 2025.).

¹³ Organ Procurement & Transplantation Network, *supra* note 12 ("Consistent with the Secretary's authority and HRSA's oversight role, this letter directs the OPTN to complete the following actions by March 31, 2025: (A) Provide a detailed remediation plan to improve OPTN allocation policy requirements and policy definitions; (B) Propose a detailed, prospective OPTN compliance plan to ensure OPTN members come into compliance with the regulatory wastage provision and otherwise comply with statutory and regulatory requirements for the allocation of organs; (C) Create transparency into the submission, approval, and performance of protocols under the OPTN expedited placement variance to ensure government oversight, increase patient awareness and public transparency of variances, and increase patient access to transplants; (D) Propose a tool to provide public transparency into how frequently patients are excluded from access to organs for which they have been matched as a consequence of A.O.S.").

organ was at risk of going to waste.¹⁴ However, the Times found that the increase in line-skipping has not corresponded with a decrease in wasted organs. In fact, despite UNOS's assertions, the Times found the organ discard rate to be on the rise.¹⁵ This exceptionally high level of dismissals contravenes the primary goal of patient safety while failing to decrease the issue of discarded organs. Continued reports of unethical behavior within the organ donation system will undermine the willingness of Americans to give others the gift of life. Strengthening public trust in our nation's organ donation system is a matter of life and death.

In accordance with our long-standing oversight of the organ donation system, we are requesting answers to the following questions by no later than April 9, 2025:

1. When did HRSA first become aware of the increase in the number of cases where patients on the waiting list had been bypassed? What actions did HRSA take? Provide all records.¹⁶
2. Provide the unredacted copies of the critical comment letters that HRSA sent to the OPTN and UNOS on August 30, 2024, November 27, 2024, and February 21, 2025. Provide all responses in an unredacted format.
3. Provide all records and communications HRSA used for predication to investigate the allegations in the August 30, 2024, November 27, 2024, and February 21, 2025, critical comment letters.
4. Provide all communications with the OPTN, OPTN committees, and UNOS, relating to individual OPOs bypassing patients in need of an organ.
5. What role does HRSA play in UNOS and the peer review committee's process for reviewing cases of bypassed patients? Under what circumstances, if any, would HRSA overturn the decision of the bypass review committees? Provide all policies and procedures for conducting these reviews.
6. Provide all records of OPTN reviews of bypassing patients in need of an organ from 2019-2025, including the processes and results of reviews conducted by the OPTN Membership and Professional Standards Committee, which is charged to review all instances of out of sequence allocation.

¹⁴ *Id.* (According to the Times, in the rare occasion when the committee has acted, the committee has only gone as far as "sending 'notices of noncompliance,' the mildest action it can take.").

¹⁵ *Id.* (According to graphics from the Times, the organ discard rate was about 22% in 2024, while the rate was about 16% in 2018.).

¹⁶ "Records" include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (e-mails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

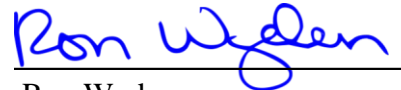
7. Provide all complaints that HRSA received regarding organ transplant list bypasses from 2019-2025. Provide all records and subsequent findings of the investigations into those complaints.
8. Did HRSA communicate with CMS regarding individual OPOs bypassing patients in need of an organ? If so, provide all records including a list of OPOs and the date CMS notified HRSA. If not, why not?
9. Has the OPTN completed any of the actions that HRSA directed the OPTN to complete in its February 21, 2025, letter? Provide all records.

Thank you for your prompt review and response. If you have any questions for Senator Grassley, please contact Tucker Akin with the Judiciary Committee staff at (202) 224-5225. If you have any questions for Senator Wyden, please contact Shade Streeter with the Finance Committee staff at (202) 573-0569.

Sincerely,



Charles E. Grassley
Chairman
Committee on the Judiciary



Ron Wyden
Ranking Member
Committee on Finance