

United States Senate

WASHINGTON, DC 20510

March 26, 2025

VIA ELECTRONIC TRANSMISSION

Stephanie Carlton
Acting Administrator
Centers for Medicare and Medicaid Services

Dear Acting Administrator Carlton:

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 OPOs and the transplant centers, CMS also has a considerable responsibility for ensuring that these organizations do not engage in behaviors that undermine the system of equitable distribution of lifesaving organs.¹⁰ However, the Times found that at least some OPOs and transplant centers bypassed patients to reduce their work burden, increase their profits, and manipulate their performance measures without any apparent rebuke from CMS's former leadership.¹¹ In a particularly egregious example, the Times highlighted the story of LifeGift, a Texas-based OPO, that skipped difficult-to-match 15-year-old Marcus Edsall-Parr, who had been waiting for a transplant for almost his entire life, and gave the kidney to an open offer at an Illinois hospital rather than transporting the kidney from Illinois to Michigan.¹² According to the Times, Edsall-Parr's doctors filed a complaint about the incident, but have yet to receive a response.¹³ As the Times reported, Marcus's case is not an exception to the rule, but an example of an issue that has steadily increased in prevalence. 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.

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, (According to the Times, OPOs "are paid a set fee by receiving hospitals, regardless of what costs they incur. Speeding up allocation saves money on staffing." Additionally, OPOs are evaluated based on their ability to place organs and thus they are incentivized to reach out to transplant centers that they know are more likely to place the organ. Further, transplant centers are evaluated on patient outcomes and thus they are incentivized to skip over their sicker patients.).

¹² *Id.* (According to the Times, there was still time to transport the organ to Michigan, given the organ had been outside the donor's body for just 10 hours.).

¹³ *Id.*

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:

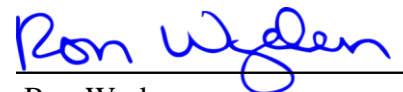
1. When did CMS first become aware of the increase in the number of cases where patients on the waiting list had been bypassed? What actions did CMS take? Provide all records.¹⁴
2. Provide details on CMS's processes for surveying OPOs and transplant centers to ensure proper operation of the donation system. Include all guidance or other directives CMS has provided to state survey agencies to facilitate these reviews.
3. Provide the list of OPOs and transplant centers surveyed from 2019-2025, including whether the survey was routine or in response to a complaint. In your response, provide the survey's findings.
4. Provide the annual bypass rate and organ discard rate for each OPO from 2019-2025.
5. Provide all complaints that CMS received regarding organ transplant list bypasses from 2019-2025. Provide all records and subsequent findings of the investigations into those complaints.
6. Did CMS communicate with HRSA regarding individual OPOs bypassing patients in need of an organ? If so, provide all records including a list of OPOs and the date HRSA notified CMS. If not, why not?
7. Provide all communications with the OPTN, OPTN committees, UNOS, and OPOs relating to individual OPOs bypassing patients in need of an organ.

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

¹⁴ "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).