BRETT GUTHRIE, KENTUCKY
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED NINETEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-3641
Minority (202) 225-2927

November 17, 2025

Mehmet Oz, M.D., MBA
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Oz:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce (Committee) is continuing its oversight of the U.S. organ transplant system, which includes the Organ Procurement and Transplantation Network (OPTN), its contractors, and the Organ Procurement Organizations (OPO). On Thursday, September 18, 2025, the Department of Health and Human Services (HHS) announced major efforts to improve safety, transparency, and efficiency within the organ procurement and transplantation system, as well as the unprecedented action of decertifying an OPO for the first time in U.S. history.[1] According to the announcement, the decision was made "after an investigation uncovered years of unsafe practices, poor training, chronic underperformance, understaffing, and paperwork errors."[2] As the Committee continues its investigation of our nation's organ procurement and transplantation system, the Committee seeks further information regarding the Centers for Medicare and Medicaid Services' (CMS) responsibility and efforts to ensure that patient safety remains a top priority.

CMS plays a critical role in quality assurance within the organ procurement and transplantation system by establishing and enforcing patient safety and health requirements. Transplant hospitals and OPOs must adhere to these requirements, known as conditions of participation (CoPs) and Conditions for Coverage (CfCs), to receive Medicare and Medicaid reimbursement.[3] Further, CMS is also responsible for evaluating and recertifying OPOs based on certain outcome measures established by the agency.[4] CMS then ranks OPOs into three performance tiers based on an OPO's performance on the measure relative to other OPOs around

[1] Press Release, U.S. Dep't of Health and Human Services, *HHS to Close University of Miami's Failing Organ Agency* (Sept. 18, 2025), *available at* https://www.hhs.gov/press-room/hhs-decertifies-miami-organ-agency-reforms-transplant-system.html.
[2] *Id*.
[3] MARCO A. VILLAGRANA, CONG. RESEARCH SERV., R48426, ORGAN PROCUREMENT AND TRANSPLANTATION: ADMINISTRATION, OVERSIGHT, AND POLICY ISSUES, 18 (Feb. 14, 2025).
[4] *Id.*

the country.[5] As such, CMS has a unique perspective into the challenges facing OPOs across the country and areas potentially in need of reform to ensure that patient safety remains the highest priority at every step in the process.

The Committee commends efforts by CMS to uphold the highest standards of care for all donor service areas (DSA). There have been numerous reports of potential patient safety incidents occurring in other parts of the country.[6] On July 22, 2025, the Committee's Subcommittee on Oversight and Investigations held a hearing to discuss the findings of Health Resources and Services Administration's (HRSA) investigative report, and subsequent corrective action plan, following whistleblower allegations of patient safety concerns at Kentucky Organ Donor Affiliates (KYDA),[7] the OPO serving Kentucky. The corrective action plan notes that "[s]ince the review of KYDA was initiated, HRSA has received reports of similar patterns of high risk [donation after circulatory death] procurement practices at other OPOs."[8] The CMS announcement on September 18, 2025, raises further questions about the prevalence of these incidents, as well as how CMS plans to proceed.

To further assist with the Committee's investigation, and to better understand CMS' role in ensuring patient safety throughout the system, we request a briefing no later than December 1, 2025, that addresses the following questions:

1. Please describe the investigative process that led to the decertification of Life Alliance Organ Recovery Agency (LAORA).

    a. Did CMS consult with any other federal entities leading up to this decision, and if so, what was the nature of these discussions?

    b. How will CMS continue to conduct oversight to ensure that the DSA will continue to adequately meet the needs of the community before the bidding process for this DSA takes place?

        i. Please describe the specific oversight actions that CMS intends to incorporate, such as site visits, inspections, interviews, or other actions.

---

[5] *Id*.
[6] *See, e.g.*, Brian M. Rosenthal and Julie Tate, *A Push for More Organ Transplants Is Putting Donors at Risk*, THE N.Y. TIMES, *available at* https://www.nytimes.com/2025/07/20/us/organ-transplants-donors-alive.html; *Mississippi organ donor lawsuit chilling tale of aggressive harvesting*, THE OXFORD EAGLE, *available at* https://oxfordeagle.com/2023/11/02/mississippi-organ-donor-lawsuit-chilling-tale-of-aggressive-harvesting/; Will Potter, *Comatose woman woke up moments before organ harvesting surgery...but docs 'told to operate anyway,'* MSN, *available at* https://www.msn.com/en-xl/news/other/comatose-woman-woke-up-moments-before-organ-harvesting-surgery-but-docs-told-to-operate-anyway/ar-AA1JYrdN.
[7] *Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System: Hearing Before H. Comm. on Energy & Commerce*, 119th Cong. 1.
[8] 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).

ii. Will this level of oversight be enhanced from what would otherwise be conducted at an OPO?

2. In addition to LAORA, is CMS considering the decertification of any other OPO?

    a. What are the current factors used when making the decision to decertify an OPO?

    b. What other corrective actions does CMS currently have available to incentivize improved performance by an OPO?

3. Beginning in 2026, CMS will evaluate OPOs based on organ donation rate and transplantation rate for the OPO to be recertified.[9] Will these evaluation metrics provide adequate incentives for OPOs to continuously improve their quality, not only by transplantation outcomes, but adherence to patient safety protocols?

    a. Are additional changes needed to the existing system to improve performance outcomes on measures including, but not limited to, donation and transplantation rates, as well as adherence to patient safety protocols?

    b. How could modifications to CMS' authority regarding the certification or recertification of OPOs improve the current system?[10]

        i. Are there changes that could be made to prevent consolidation if an OPO has been found to be underperforming?

4. Over the past calendar year, how many patient safety complaints or reports of unsafe organ procurement and transplantation practices have been received by CMS? How many of these complaints are currently being investigated?

    a. What percentage of these complaints are received directly, and how many are based on referrals by other oversight components of the organ procurement and transplantation system?

    b. How does CMS process, prioritize, evaluate, and address these complaints?

    c. Has CMS identified any patterns or trends appearing in the types of patient safety complaints received and the specific DSAs where these complaints originate from?

    d. How will CMS ensure that whistleblowers are protected when bringing forward complaints of potential issues concerning patient safety?

---

[9] Centers for Medicare and Medicaid Services, *Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations*, 85 Fed. Reg. 77898 (Dec. 2, 2020) (final rule).
[10] Social Security Act § 1138(b); Public Health Service Act § 371(b).

5. Please provide specifics on how CMS collaborates with HRSA to coordinate actions related to oversight of the organ procurement and transplantation system. For example, how frequently do CMS and HRSA interact or communicate, and through what specific means (i.e., conference calls, meetings, emails, etc.)?

6. How does CMS intend to make any of the information, data, or findings related to these investigations available to the public?

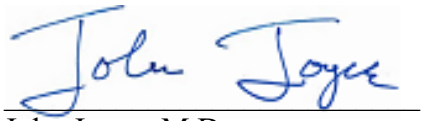
7. How will the newly established role of OPO Patient Safety Officer work, or interact, with CMS to improve outcomes for patients who are being considered as candidates for potential organ donation?

8. What further actions does CMS intend to pursue to ensure that public trust within the organ procurement and transplantation system is restored?

We appreciate your prompt attention to this matter. If you have any questions regarding this request, please contact the Committee Majority staff at (202) 225-3641.

Sincerely,

Brett Guthrie
Chairman
Committee on Energy and Commerce



John Joyce, M.D.
Chairman
Subcommittee on Oversight and Investigations