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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

September 12, 2025

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20852

Dear Administrator Engels:

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).

The Committee appreciates the Health Resources and Services Administration's (HRSA) willingness to testify at a recent hearing on July 22, 2025, before the Subcommittee on Oversight and Investigations on HRSA's recent investigative report, and subsequent corrective action plan, following whistleblower allegations of patient safety concerns at Kentucky Organ Donor Affiliates (KYDA),[1] the OPO serving the state of Kentucky. The corrective action plan raises questions about the possibility that there may be more systemic issues, noting 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."[2] Moreover, HRSA's testimony[3] and other public reports[4] suggest that these patterns are not limited to the instances

[1] *Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System: Hearing Before H. Comm. on Energy & Commerce*, 119th Cong. 1.
[2] 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).
[3] *Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System: Hearing Before H. Comm. on Energy & Commerce*, 119th Cong. 1 (statement by Dr. Raymond Lynch, Chief, Organ Transplant Branch, Health Resources and Services Admin.).
[4] *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.

detailed in HRSA's report and may exist in other parts of the country. Given these concerns, the Committee requests a staff level briefing to better understand the scope of these issues.

HRSA's report presents troubling evidence of potential threats to patient safety. The initial whistleblower allegation, which was brought to light during a previous hearing before the Committee on September 11, 2024,[5] detailed how a patient was "inaccurately pronounced brain dead and was pursued as an organ donor"[6] through the donation after cardiac, or circulatory, death (DCD) process at KYDA.[7] After investigating this particular case (known as the "index case"), and others similar in nature, the report revealed that of 351 cases analyzed, "103 cases (29.3%) had concerning features."[8] Some of these concerning features include issues related to patient family interactions,[9] medical assessments and healthcare team interactions,[10] recognition of high neurologic function,[11] and recognition and documentation of drugs in patient records.[12] The report notes the following:

> The prevalence of these patient-level failures in KYDA's practices suggests organizational dysfunction and poor quality and safety assurance culture at KYDA. Cases strongly similar to the 2021 index case were found to have occurred as recently as December 2024. **Cumulatively, evidence available to HRSA suggests there may be ongoing risk of harm to patients in KYDA's donation service area (DSA). Anecdotal evidence in contemporary popular media reporting suggests broader harm to the transplant system, as public faith in organ procurement suffers and individuals remove themselves from donor registries.**[13]

During the Subcommittee hearing on July 22, 2025, HRSA was questioned about the potential failure to adhere to existing protocols in the index case and was asked: "is it a broader systemic issue or is it limited to KYDA?"[14] HRSA responded, stating, "[u]nfortunately, it is not limited to KYDA. During the course of this investigation we received concerns that were in areas served by other OPOs."[15]

Further, the Committee is aware of additional reports of potential patient safety incidents occurring in other parts of the country.[16] HRSA's testimony coupled with these reports led to

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[5] *A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation: Hearing Before H. Comm. on Energy & Commerce*, 118th Cong. 2.
[6] Report from Division of Transplantation, Health Resources and Services Admin., to Suma Nair, PhD, MS, RD, Associate Admin., HSB, 2 (Mar. 24, 2025).
[7] *Id*. at 5.
[8] *Id*. at 11.
[9] *Id*. at 12.
[10] *Id*. at 13.
[11] *Id*. at 15.
[12] *Id*. at 18.
[13] *Id*. at 4.
[14] *Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System: Hearing Before H. Comm. on Energy & Commerce*, 119th Cong. 1 (question by Erin Houchin, Member of Congress).
[15] *Supra* at 3.
[16] *Supra* at 4.

growing concerns about whether these issues are occurring at other OPOs, and if so, to what extent. To further assist with the Committee's investigation, we request a briefing no later than September 26, 2025, that addresses the following questions:

1. What progress has been made by the OPTN Board of Directors in complying with HRSA's Corrective Action Plan?

2. HRSA's written testimony acknowledges that "HRSA has now established a new process where patient safety complaints come directly to HRSA to triage to the appropriate entities for further investigation,"[17] allowing for increased data collection for patient safety incidents. When did HRSA establish this new process, and what is the total number of complaints that HRSA received since establishing this process?

    a. What entities (e.g., OPOs, hospitals, transplant centers, organ recovery centers (ORCs), histocompatibility laboratories, etc.) are at issue in the concerns that have been reported to HRSA, and what is the nature of the complaints that were reported?

    b. What is the current status of HRSA's review of all complaints it has received?

    c. What is the total number and breakdown of complaints currently being evaluated for each entity and region of the country?

    d. Has HRSA identified any patterns or trends appearing in these investigations?

        i. If so, are there any patterns or trends occurring across multiple entities?

        ii. Does HRSA's process of complaint intake effectively show patterns or trends at a particular OPTN member organization or in a particular region that may warrant additional investigation by HRSA or another entity?

    e. Does HRSA plan to make any of this information, data, or findings available to the public?

3. Given the unprecedented nature of the KYDA investigation, does HRSA plan and have the capability to initiate other wide-ranging reviews, where appropriate, in response to a patient safety complaint that may suggest a systemic problem?

    a. What is the normal intake process for the complaints received by HRSA?

    b. Does HRSA evaluate complaints received through other means, or not directly through HRSA's new process for evaluating patient safety complaints?

[17] *Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System: Hearing Before H. Comm. on Energy & Commerce*, 119th Cong. 1 (written testimony by Dr. Raymond Lynch, Chief, Organ Transplant Branch, Health Resources and Services Admin.).

i. If so, please describe the other means through which HRSA receives the complaints and how many complaints it has received through these other means?

c. Has the agency initiated any HRSA-led reviews or investigations of other OPOs like the one conducted for KYDA? If so, please explain.

4. What are HRSA's short- and long-term plans or strategies for investigating all patient safety incidents and complaints across the country?

5. Have any of the concerns that have been reported to HRSA been referred to law enforcement? If so, which ones and to which law enforcement entity were they referred?

6. Has HRSA ever recommended to the Center for Medicare & Medicaid Services (CMS) that an OPO be decertified due to results of an investigation into complaints concerning patient safety?

    a. If so, which OPOs and why? If not, why not?

    b. How and when does HRSA communicate OPO investigation findings to CMS?

7. Has HRSA received any reports regarding retaliation against those who have expressed concerns about patient safety issues? If so, please explain.

8. Has HRSA been receiving full cooperation from the OPTN, its contractors, OPOs, and all other relevant entities during these reviews or investigations?

    a. Will HRSA direct the OPTN Board of Directors to conduct their own investigations for some or all patient safety complaints reviews and investigations?

9. For complaints currently being investigated by HRSA, are there any other government or non-government entities assisting HRSA or conducting separate investigations of these complaints?

    a. If so, who, and what is their role in these investigations?

10. How does HRSA plan to utilize the findings of these investigations to improve safety, efficacy, transparency, and trust within the organ procurement and transplantation system in the U.S.?

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 and the Minority staff at (202) 225-2927.

Sincerely,

Brett Guthrie
Chairman
Committee on Energy and Commerce

Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce

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

Yvette Clarke
Ranking Member
Subcommittee on Oversight and Investigations