

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY

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July 25, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Ave., S.W.
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Becerra and Administrator Brooks-LaSure:

The Committee on Oversight and Accountability is conducting oversight of regulations governing our nation's organ procurement organizations (OPOs). As you know, in 2020 the Centers for Medicare and Medicaid Services (CMS) issued a Final Rule titled, *Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations* (Final Rule). The Committee seeks your assistance in understanding why, four years later, CMS has still not issued necessary guidance regarding competition and decertification around the Final Rule.¹ CMS' inaction has created lack of clarity, increased uncertainty for Americans who need a transplant, and threatens to erode accountability for OPOs.

The Final Rule was intended to address widely recognized and longstanding failures of OPOs to effectively manage the collection of organs from donors to lower tragic and unnecessary loss of life.² Thousands of Americans die each year waiting for a transplant that does not arrive in time or are removed from waiting lists because they become too sick to accept a transplant.³ At the same time, many OPOs have already been identified by CMS as failing to

¹ 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) (CMS-3380-F) (codified at 42 C.F.R. § 486.301 (2020)).

² Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 10, 2019).

³ U.S. Dep't of Health & Human Servs., OPTN, Organ Procurement & Transplantation Network, National data.

meet performance thresholds and in the absence of guidance from CMS, OPOs have been filling this void by writing their own rules.

Reforming our nation's transplant system has long been a bipartisan issue.⁴ In 2021, I joined my colleagues in two bipartisan, bicameral letters requesting that the Biden Administration and CMS adopt and enforce the Trump Administration's Final Rule and hold OPOs accountable prior to the 2026 decertification process, when OPOs identified by objective data as failing will lose their government-backed contracts, allowing higher performing OPOs to step in and better serve patients.⁵ To date, the Administration and CMS have ignored the years-long bipartisan nature of this life and death issue, which I fear will tragically be measured in lives lost.

Under CMS' evaluation system, Tier 3 rated OPOs are "out of compliance with the established outcome measures, thus, not meeting the minimum standards to be an OPO" (Tier 1 OPOs are the highest rated).⁶ According to 2021 data from CMS, 24 of our nation's 56 OPOs, are failing, classified as Tier 3.⁷ It has been *five years* since the Trump Administration first charged CMS with reforming the opaque OPO performance metrics system.⁸ It is now July 25, 2024, halfway through the year in which OPOs will be evaluated on their data for decertification in 2026 under the Final Rule.⁹ And yet there is still not clear guidance for OPOs, instead many of these entities are continuing to call the shots and write their own rules.

In one example, CMS' abdication of its responsibilities to issue guidance is playing out in my home state of Kentucky. In February, Kentucky Organ Donor Affiliates, Inc., a Tier 3 OPO¹⁰ that, absent improvement in 2024, will be subject to decertification in 2026,¹¹ announced

⁴ Laura Arnold & John Arnold, *A simple bureaucratic organ donation fix will save thousands of lives*, STAT NEWS (July 24, 2019) ("The partisan debates raging across the U.S. are often framed as a battle for the nation's soul. The battle for our nation's organs, however, is a distinctly more bipartisan affair."); *See also* Securing the U.S. Organ Procurement and Transplantation Network Act, Pub. L. No. 118-14 § 137 Stat. 69 (2023).

⁵ Letter from Ron Wyden et al., Chairman, Sen. Fin. Comm., to Norris Cochran, Acting Sec'y, U.S. Dept. of Health & Human Servs. (Mar. 16, 2021); Letter from Ron Wyden et al., Chairman, Sen. Fin. Comm., to Xavier Becerra, Sec'y, U.S. Dept. of Health & Human Servs., and Chiquita Brooks-LaSure, Adm', Ctrs. for Medicare & Medicaid Servs. (July 19, 2021).

⁶ Ctrs. for Medicare & Medicaid Servs., *Blog, The Transplant Eco-System: The Role of Data in CMS Oversight of the Organ Procurement Organizations* (Apr. 28, 2023).

⁷ Ctrs. for Medicare & Medicaid Servs., *Organ Procurement Organizations, Ann. Pub. Aggregated Performance Rep.* (2023).

⁸ Exec. Order, *supra*, note 2.

⁹ Ctrs. for Medicare & Medicaid Servs., *Newsroom, Fact Sheets, Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020); *See also* 42 C.F.R. § 486.301 (2021).

¹⁰ Ctrs. for Medicare & Medicaid Servs., *supra*, note 7.

¹¹ Medicare and Medicaid Programs, *supra*, note 1, at 79.

its intention to merge this year with Cincinnati-based LifeCenter Organ Donor Network.¹² The new OPO, rebranded as Network for Hope (NFH), summarized the merger as follows: “[t]he combined organization will be the largest OPO in the region and 16th largest in the country....”¹³ Although both of these OPOs have faced bipartisan congressional scrutiny,¹⁴ CMS has remained silent regarding the implications of this merger for the 2026 decertification process. CMS’ failure to conduct oversight or provide guidance raises questions about the agency’s readiness to hold government funded monopolies accountable for falling short on performance metrics and appropriately using the taxpayer funds they receive.

In another example of failure to conduct oversight, CMS’ inaction has forced transplant hospitals to step in to fill the void. Two transplant hospitals have submitted hospital waiver requests to CMS to work with higher-performing OPOs outside of their designated service area (DSA).¹⁵ In November 2022, North Carolina Baptist Hospital submitted a waiver request to CMS that would allow the hospital to work with LifeShare Carolinas, a Tier 1 OPO, instead of HonorBridge, a Tier 3 OPO.¹⁶ A 2024 waiver request in Nevada¹⁷ has resulted in a lawsuit between two OPOs involving allegations of illegal conduct, including potential violations of state and federal anti-kickback statutes and misuse of COVID-19 related funding.¹⁸ These disputes and uncertainties could seemingly have been avoided by appropriate agency oversight and guidance.

To assist our investigation, we request an initial briefing as soon as possible, but not later than August 1, 2024. We expect the briefing to include a description of the steps CMS is taking to ensure the Final Rule is implemented without dilution or delay, including what CMS is doing to proactively issue guidance and conduct ongoing oversight so that OPOs, patients and donor families know how the next phase of the process will work.

¹² Tom Latek, *Kentucky, Cincinnati donor affiliates merging as Network for Hope*, KENTUCKY TODAY (May 16, 2024).

¹³ *Kentucky Organ Donor Affiliates and Life Center Organ Donor Network Sign Letter of Intent to Merge, Creating the 16th Largest Organ Procurement Organization in the United States*, Kentucky Organ Donor Affiliates, LifeCenter (Feb. 2, 2024).

¹⁴ Letter from Ron Wyden et al., Chairman, Sen. Fin. Comm., to Ms. Julie Bergin, CEO, Kentucky Organ Donor Affiliates (Mar. 20, 2023); Letter from Ron Wyden et al., to Mr. Barry Massa, Executive Director, LifeCenter Organ Donor Network (Sept. 5, 2023).

¹⁵ Medicare and Medicaid Programs, *Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area*, 87 Fed. Reg. 68160 (Nov. 14, 2022) (Notice with request for comment); Medicare and Medicaid Programs, *Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area*, 88 Fed. Reg. 19646 (May 3, 2023) (Notice with request for comment).

¹⁶ Medicare and Medicaid Programs, *Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area*, 87 Fed. Reg. 68160 (Nov. 14, 2022) (Notice with request for comment).

¹⁷ Medicare and Medicaid Programs, *Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area*, 88 FR 82381 (Nov. 24, 2023) (Notice with request for comment).

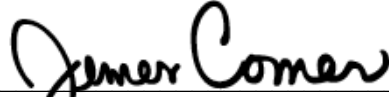
¹⁸ FIRST AMENDED CIVIL COMPLAINT DEMAND FOR JURTY TRIAL, *4, *22, *35, *Donor Network West v. Nevada Donor Network, Inc.*, No.: 3:23-cv-00632-ART-CSD (D.Nev.).

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The Committee on Oversight and Accountability is the principal oversight committee of the U.S. House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X.

Thank you in advance for your cooperation with this inquiry.

Sincerely,

A handwritten signature in black ink that reads "James Comer". The signature is written in a cursive style with a large, prominent "J" and "C".

James Comer
Chairman
Committee on Oversight and Accountability

cc: The Honorable Jamie Raskin, Ranking Member
Committee on Oversight and Accountability