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United States Senate

COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

October 21, 2020

VIA ELECTRONIC TRANSMISSION

The Honorable Alex M. Azar II
Secretary
The Department of Health & Human Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

We write today to inquire about the Department's oversight of the organ procurement and transplantation system in the United States.

The Centers for Medicare and Medicaid Services (CMS) is responsible for certifying the operation of regional organ procurement and transplant centers. Under federal law, CMS is charged with conducting reviews ("surveys") of Organ Procurement Organizations (OPOs) and certifying them every four years based on whether they meet the Conditions for Coverage, including outcome and process measures. The Department's own data suggests that thousands of lifesaving organs go unrecovered every year,¹ and investigative reporting has highlighted significant lapses in quality control and patient safety, including a report last month about a patient who died after the organ procurement organization (OPO) responsible for the transplant incorrectly identified the donor's blood type.² CMS recently proposed changes to the way it measures the performance of the 58 regional OPOs.³

¹ Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization, 84 Fed. Reg. 70628 (proposed December 17, 2019) (42 C.F.R. Part 486).

² Mary Katherine Wildeman, "He Died When He Got the Wrong Lungs. It Wasn't the Only Organ Error in SC that Day." THE POST AND COURIER (Sept. 11, 2020), available at https://www.postandcourier.com/health/he-died-when-he-got-the-wrong-lungs-it-wasnt-the-only-organ-error-in/article_c6a6e386-e704-11ea-91ce-2783df6c6f2d.html.

³ 84 Fed Reg. 70628, *supra* note 1.

CMS's role in overseeing the OPOs is complemented by the Health Resources and Service Administration (HRSA), which oversees the Organ Procurement and Transplantation Network (OPTN), currently operated by a HRSA contractor—the United Network for Organ Sharing (UNOS). In February 2020, the Finance Committee initiated an investigation into the conduct of the nation's organ donation and procurement system, and initially sought information from UNOS about the financial and operational performance of the OPOs within its network—the same OPOs certified by CMS.⁴

Our concerns regarding the Department's role in overseeing our nation's organ procurement organizations (OPOs) stem from Inspector General audits/reports,⁵ whistleblower accounts,⁶ investigative reporting, and research.⁷ Additionally, our internal analysis has shed light on the gaps in the federal government's oversight, resulting in fraud, waste, and abuse of our nation's Medicare program and American taxpayer dollars.

The Committee seeks to make informed policy recommendations about any necessary reforms to ensure patient safety, and that our nation's oversight systems are functioning properly, unencumbered by conflicts of interests. We therefore request that HHS provide responses to the following questions by November 2, 2020:

1. Please provide:
 - a. All surveys and certifications performed by CMS of all OPOs for the past 10 years.
 - b. All complaints about OPOs and/or the OPTN contractor (currently UNOS) made to CMS over the past 10 years.

⁴ See "Finance Committee Members Probe U.S. Organ Transplant System" S. COMM. ON FINANCE (Feb. 12, 2020), available at <https://www.finance.senate.gov/chairmans-news/finance-committee-members-probe-us-organ-transplant-system>.

⁵ U.S. DEP'T OF HEALTH & HUMAN SERV., OFFICE OF INSPECTOR GEN. [Hereinafter "OIG"], A-09-08-00033, "Review of OneLegacy's Reported Fiscal Year 2006 Organ Acquisition Overhead Costs and Administrative and General Costs" (Jan. 2010), available at <https://oig.hhs.gov/oas/reports/region9/90800033.pdf>. See also OIG, A-09-09-00087, "Review of California Transplant Donor Network's Reported Fiscal Year 2007 Organ Acquisition Overhead Costs and Administrative and General Costs" (Oct. 2010), available at <https://oig.hhs.gov/oas/reports/region9/90900087.pdf>.

⁶ Alex Ferrer, "Whistleblower threatened with being cremated alive after exposing mortuary kickback scheme," CBS NEWS (June 14, 2019) (reporting that after blowing the whistle to expose how taxpayers were being "ripped off," the whistleblower was "blackballed" from the entire industry, his boss threatened to "kill his family, and told him that he would be "cremated alive."), available at <https://www.cbsnews.com/news/whistleblower-threatened-with-being-cremated-alive-after-exposing-mortuary-kickback-scheme/>.

⁷ See "The Costly Effects of an Outdated Organ Donation System," BLOOM WORKS (Oct. 2020), (specifying that in terms of potential organ recipients, people of color "are less likely to get on the [national organ transplant] waitlist and less likely to find a match once they're on there.") (The Committee is looking into the racial disparities in the organ donation system, as highlighted by this recent report.).

- c. All complaints about OPOs and/or the OPTN contractor made to HRSA over the past 10 years.
 - d. An explanation of respective CMS and HRSA oversight functions, how they coordinate on complaints/oversight cases, and how many full-time employee equivalents at each agency are responsible for these functions.
2. Organ acquisition costs (also known as standard acquisition costs or “SAC fees”) can vary by more than 100% for the same organ across OPOs, and transplant centers and Medicare are ultimately responsible for these costs.
- a. What efforts is HHS taking to standardize OPO practices and reporting of such costs to rein in wasteful spending, and to understand the correlation between increasing SAC fees from OPOs and transplant center organ discard rates?
 - b. On what basis does CMS determine what costs (by amount as well as type) are reasonable for OPOs to charge as part of their standard acquisition charges?
 - c. It has been reported to us that the OPTN charges a fee for every patient placed on organ donation list as an “OPTN Registration Fee.” At the same time, it is our understanding that UNOS is also charging a “UNOS Registration Fee.” If true, payers, such as Medicare, and patients are being double-billed.⁸ Please verify if this is the case and explain how HHS pays for potential organ recipients to be added to the organ transplant waiting list.
3. UNOS has stated to the Committee that it does not evaluate any financial operations or performance of the OPOs within its network.⁹
- a. Please describe the methodology and frequency by which CMS monitors and audits financial operations of the OPOs to ensure that only allowable and appropriate costs are charged to HHS.
 - b. Please describe HHS policy with regard to oversight of OPO executive and board member compensation.
 - c. Please identify which of the 58 OPOs compensate their board members (beyond reasonable expenses for board-related activities and travel/lodging), including via contracts or other relationships with external organizations with which the board member maintains a relationship, the exact amount of compensation received by those board members, and whether HHS pays for these costs through its Medicare reimbursement for OPO services.

⁸ See “The Costly Effects of an Outdated Organ Donation System,” BLOOM WORKS (Oct. 2020), available at https://bloom-works.github.io/organ-donation-reform/assets/PDF/ODR-Money_Map_Final.pdf.

⁹ See UNOS Response to Chairman Grassley, Ranking Member Wyden, Senator Young, and Senator Cardin (Feb. 28, 2020) (Attachment A).

4. New research into OPO reimbursement models concluded that “OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.”¹⁰ Additionally, previous investigative reporting has highlighted that “80% of [OPOs] were harvesting tissues and sending them in exchange for fees to tissue processors and distributors, many of which are for-profit companies.”¹¹ Given this, please:
 - a. Describe how HHS ensures that OPOs operating tissue banks do not allow these functions and financial incentives to conflict with organ collection, including personal financial interests by OPO executives.
 - b. Provide a list of all OPOs currently operating and/or maintaining a financial interest in a tissue bank, as well as any OPO executives and/or board members who have personal financial interests in related tissue banks and/or tissue processing?
 - c. Describe all measures HHS has in place to ensure that tissue recovery is not prioritized over organ recovery, and that conflicts are resolved whenever they arise.
5. Please provide all documentation regarding coordination between HRSA, CMS and the OPTN contractor (currently UNOS) related to the following three cases involving lapses in patient safety:
 - i. The OPO, Sharing Hope South Carolina (sending the wrong lungs, leading to the recipient’s death);
 - ii. The OPO, Life Alliance Organ Recovery Agency (failing to identify an infection in a uterus it recovered for transplant, leading to a near-fatal outcome for the recipient); and
 - iii. The OPO, Donor Network of Arizona (wrongfully recovering corneas from a donor who was not registered and whose family did not provide consent).
6. Since the OPTN was created in 1984, UNOS remains the only contractor to bid for the contract with HHS.¹² Additionally, UNOS’s presumed ownership of its IT,

¹⁰ See Report on OPO Finances, THE BRIDGESPAN GROUP (forthcoming, Oct. 2020).

¹¹ Melody Petersen and David Willman, “How Organ and Tissue Donation Companies Worked Their Way into the County Morgue,” L.A. TIMES (Oct. 13, 2019), available at <https://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html>.

¹² GOV’T ACCOUNTABILITY OFFICE, File B-416248 (July 18, 2018), available at <https://www.gao.gov/assets/700/693614.pdf>.

despite having been funded with taxpayer dollars, has been perceived as an incumbency advantage. Given guidance from the Federal Acquisitions Regulation System to ensure “full and open competition”—please provide:

- a. All internal deliberations pertaining to HRSA’s determination in the 2018 OPTN contract that any bidder must have “three years of experience managing transplant projects of similar complexity.”¹³
 - b. Details regarding whether HHS ever been prevented from inspecting the OPTN IT system by the contractor, UNOS, or prevented from learning more about the operation of the IT systems?
 - c. All information pertaining to how HHS is pushing for the modernization of the OPTN IT systems?
7. A 2010 audit by the HHS Office of the Inspector General determined that OPO lobbying expenses are “unallowable” because they are “not related to patient care.”¹⁴ However, a recent investigative report highlighted that OPOs both directly and indirectly (via their trade association), have dramatically increased their lobbying expenditures in 2019 and 2020.¹⁵ Given this, what efforts is HHS taking to ensure that taxpayer dollars are not used for lobbying purposes by OPOs?

In closing, thank you for your attention to this very important matter. Responses to all questions should be provided no later than October 30, 2020. We look forward to your response. If you have any questions, please contact Rachael Soloway of Chairman Grassley’s staff and Melissa Dickerson of Ranking Member Wyden’s staff at (202) 224-4515.

Sincerely,

¹³ See Organ Procurement and Transplantation Network; HHS250201900001C (Nov. 18, 2018).

¹⁴ U.S. DEP’T OF HEALTH & HUMAN SERV., OFFICE OF INSPECTOR GEN., A-09-08-00033, *Review of OneLegacy’s Reported Fiscal Year 2006 Organ Acquisition Overhead Costs and Administrative and General Costs* (Jan. 2010), available at <https://oig.hhs.gov/oas/reports/region9/90800033.pdf>.

¹⁵ Adam Zagorin, “Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative While Pocketing Pandemic Relief Loans,” PROJECT ON GOVERNMENT OVERSIGHT (POGO) (Oct. 5, 2020), available at <https://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/>.

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