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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

JOSHUA SHEINKMAN, STAFF DIRECTOR
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September 5, 2023

VIA ELECTRONIC TRANSMISSION

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

Dear Administrator Brooks-LaSure:

We write today regarding the Department of Health and Human Services (HHS), Office of Inspector General's (OIG) recently released audit report titled *Medicare Paid Independent Organ Procurement Organizations Over Half a Million Dollars for Professional and Public Education Overhead Costs That Did Not Meet Medicare Requirements*, which found that an estimated \$664,295 of taxpayer money was misspent on unallowable professional and public education overhead costs, including for entertainment, meals, lobbying, and gifts.¹ The audit report's findings and recommendations reinforce prior OIG audit reports,² as well as the Senate

¹ U.S. DEP'T OF HEALTH & HUMAN SERV., OFFICE OF INSPECTOR GEN., A-09-21-03020, *Medicare Paid Independent Organ Procurement Organizations Over Half a Million Dollars for Professional and Public Education Overhead Costs that Did Not Meet Medicare Requirements*, (Aug. 2023), at 1, 7, 25, available at <https://oig.hhs.gov/oas/reports/region9/92103020.asp>.

² Review of OneLegacy's Reported Fiscal Year 2006 Organ Acquisition Overhead Costs and Administrative and General Costs, (A-09-08-00033), issued Jan. 21, 2010, <https://oig.hhs.gov/oas/reports/region9/90800033.pdf>; Review of California Transplant Donor Network's Reported Fiscal Year 2007 Organ Acquisition Overhead Costs and Administrative and General Costs, (A-09-09-00087), issued Oct. 1, 2010, <https://oig.hhs.gov/oas/reports/region9/90900087.pdf>; Medicare Could Have Saved Millions If Organ Procurement Organizations Had Correctly Reported Procurement of Double Lungs as Two Organs, (A-09-12-02085), issued Dec. 31, 2013, <https://oig.hhs.gov/oas/reports/region9/91202085.pdf>; LifeCenter Northwest Did Not Fully Comply With Medicare Requirements For Reporting Organ Statistics In Its Fiscal Year 2009 Medicare Cost Report, (A-09-11-02039), issued Nov. 15, 2012, <https://oig.hhs.gov/oas/reports/region9/91102039.pdf>; and Donor Network of Arizona Did Not Fully Comply With Medicare Requirements For Reporting Organ Statistics and Related Costs In Its Fiscal

Committee on Finance’s investigation into the nation’s transplant system, which concluded, “from the top down, the U.S. transplant network is not working, putting Americans’ lives at risk.”³

We have written extensively about the need for greater accountability and transparency across the organ procurement and transplantation system.⁴ This includes asking questions about organ procurement organizations’ (OPOs) Medicare abuses and other oversight deficiencies as well as requesting that the HHS OIG conduct comprehensive audits of these failures.⁵ When launching our bipartisan investigation into the U.S Organ Procurement and Transplantation Network (OPTN), we identified serious concerns about the misuse of taxpayer dollars, writing that, “numerous inspector general audits and news reports...highlighted questionable financial practices of some organ procurement organizations.”⁶ In an October 2020 letter, we again reiterated our concerns about the lack of oversight of the organ procurement system in the United States, stating, “...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.”⁷

As the Senate Committee on Finance continues its investigation into the nation’s organ procurement system, we are concerned that these abuses and misuse of taxpayer dollars may result from CMS’s failure to properly oversee OPO finances. We are also troubled by the audit’s

Year 2009 Medicare Cost Report, (A-09-11-02035), issued March 13, 2012, available at <https://oig.hhs.gov/oas/reports/region9/91102035.pdf>.

³ Letter from U.S. Senate Comm. on Finance to SFC Majority/Minority Health LA’s, *Hearing - A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network*, (Aug. 3 2020), available at <https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Memo.pdf>.

⁴ See Press Release, Chuck Grassley, U.S. Senator & Chairman, U.S. Senate Committee on Finance, *Chairman Grassley follows up on violation of rules governing organ transplants, asks questions of federal watchdogs*, (Oct. 19, 2005) (noting that as Chairman of the U.S. Senate Committee on Finance, with jurisdiction over the Medicare and Medicaid programs, the Committee has “a responsibility to the more than 80 million Americans [in 2005, which is approximately 130 million Americans in 2019, according to CMS] who receive health care coverage, including organ transplants under those programs.”), available at <https://www.finance.senate.gov/chairmans-news/chairman-grassley-follows-up-on-violation-of-rules-governing-organ-transplants-asks-questions-of-federal-watchdogs>.

⁵ Letter from U.S. Senate Comm. on Finance to Joanne M. Chiedi, Acting Inspector General, Office of the Inspector Gen., U.S. Dep’t of Health and Human Serv., (Dec. 18, 2019), available at [https://www.finance.senate.gov/imo/media/doc/CEG.Young%20to%20HHSOIG%20\(OPO%20Oversight\)%20Dec.18.2019.pdf](https://www.finance.senate.gov/imo/media/doc/CEG.Young%20to%20HHSOIG%20(OPO%20Oversight)%20Dec.18.2019.pdf).

⁶ *Finance Committee Members Probe U.S. Organ Transplant System*, U.S. SENATE COMM. ON FINANCE, (Feb. 12, 2020), (the letter’s requests for information about the organ procurement and transplant process and various OPOs include: legally required periodic performance reviews of OPOs; audits of OPOs that suggest the governments Medicare program was billed for unallowable expenditures), available at <https://www.finance.senate.gov/chairmans-news/finance-committee-members-probe-us-organ-transplant-system>.

⁷ Letter from U.S. Senate Comm. on Finance to Secretary Alex M. Azar II, U.S. Dep’t of Health and Human Serv., (Oct. 23, 2020), available at <https://www.finance.senate.gov/imo/media/doc/FinalSIGNED%20-%20Grassley%20Wyden%20to%20HHS%2023Oct2020.pdf>

narrow scope, which focused solely on professional and public education overhead costs,⁸ representing only a small percentage of overall OPO costs.⁹

According to the audit, “the OPOs reported unallowable costs because (1) they did not understand how CMS requirements applied to them and (2) their staff made administrative errors or were not aware that costs did not meet Medicare requirements.”¹⁰

OPOs are funded on a cost-reimbursement basis. Medicare reimburses 100 percent of reasonable costs for allowable services related to renal organ procurement and transplant centers reimburse OPOs for non-renal organ procurement.¹¹ Additionally, as researchers have noted, “OPOs are geographic monopolies and subject only to limited financial disclosure requirements, leaving the transplant center with limited visibility into OPO costs and little negotiating power.”¹² Therefore, this cost-reimbursement system means that “OPOs can pass through all expenses to payors with little accountability and limited incentive to allocate resources efficiently,” absent adequate CMS oversight and accountability.¹³

This ongoing lack of oversight has enabled OPOs to circumvent Medicare reimbursement requirements, resulting in misspent taxpayer dollars, including on sports tickets and other

⁸ U.S. DEP’T OF HEALTH & HUMAN SERV., OFFICE OF INSPECTOR GEN., A-09-21-03020, *Medicare Paid Independent Organ Procurement Organizations Over Half a Million Dollars for Professional and Public Education Overhead Costs that Did Not Meet Medicare Requirements*, (Aug. 2023), available at <https://oig.hhs.gov/oas/reports/region9/92103020.asp>.

⁹ *Id.* at 3 (noting that “an independent OPO’s Medicare cost report includes direct costs, administrative and general costs, and overhead costs associated with procuring organs.”); *Medicare Provider Reimbursement Manual*, CENTERS FOR MEDICARE AND MEDICAID SERVICES, (Accessed Aug. 21, 2023), available at <https://www.cms.gov/files/document/r10p233i.pdf>.

¹⁰ U.S. DEP’T OF HEALTH & HUMAN SERV., OFFICE OF INSPECTOR GEN., A-09-21-03020, *Medicare Paid Independent Organ Procurement Organizations Over Half a Million Dollars for Professional and Public Education Overhead Costs that Did Not Meet Medicare Requirements*, (Aug. 2023), (some OPOs stated that definitions of unallowable cost in the Federal Regulations and CMS Manual are not applicable to them, two OPOs stated that they were not aware that the costs did not meet Medicare requirements, and another OPO claimed that they were not aware that money paid to a hospital and healthcare association was used for lobbying activities.) at 12, available at <https://oig.hhs.gov/oas/reports/region9/92103020.asp>.

¹¹ 42 C.F.R. § 413.200(d); Provider Reimbursement Manual (PRM) 15-1 Ch. 31 §3108(B), available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929>; 42 C.F.R. § 413.200(e), available at <https://www.govinfo.gov/content/pkg/CFR-2010-title42-vol2/pdf/CFR-2010-title42-vol2-sec413-200.pdf>; and Paul Rosenberg et. al., *Transforming Organ Donation in America, Appendix A*, THE BRIDGESPAN GROUP, (Dec. 2020), available at <https://www.bridgespan.org/getmedia/4905f7a5-41d7-4240-bd31-0017ec500029/Bridgespan-OPO-Report-FINAL-Appendix-A.pdf>.

¹² Paul Rosenberg et. al., *Transforming Organ Donation in America, Appendix A*, THE BRIDGESPAN GROUP, (Dec. 2020), available at <https://www.bridgespan.org/getmedia/4905f7a5-41d7-4240-bd31-0017ec500029/Bridgespan-OPO-Report-FINAL-Appendix-A.pdf>.

¹³ *Id.*

executive perks disguised as ‘education and awareness.’¹⁴ Clearly these expenditures do not meaningfully contribute to organ recovery and they raise additional questions about the legitimacy of OPO spending since 24 of the nation’s 56 OPOs are failing (i.e., classified as Tier 3).¹⁵ Given that financial reimbursement structures drive behavior, we urge CMS to act quickly and decisively to implement the audit report’s recommendations¹⁶ and exercise robust oversight of OPO finances.¹⁷

The OIG audit report also identified gaps in the current financial reimbursement structure that contribute to financial mismanagement, outside the limited scope of its audit. Specifically, the audit report outlined systemic failures with the existing OPO cost-reimbursement structure which incentivize waste, fraud, and abuse of taxpayer dollars.¹⁸ The report found that “opportunities and incentives exist for OPOs to: (1) inflate their [standard acquisition costs] SACs for nonkidney organs, (2) misallocate overhead costs between reimbursable and nonreimbursable costs, and (3) not work actively to recover all available organs.”¹⁹ The OIG commented, “[t]hese concerns not only negatively affect the Medicare trust fund but also negatively affect people in need of organ transplants.”²⁰

We have supported regulatory reforms to hold OPOs accountable through the 2021 OPO rule.²¹ In parallel, however, given the sustained historical failures of the OPO system — which have cost tens of thousands of American lives — we believe financial reimbursement reforms are also

¹⁴ OIG Audit Report at 12 (one OPO stated that costs incurred for tickets to a baseball game were allowable and related to patient care and another OPO stated that meals provided at meetings on organ donation were related to patient care and allowable), available at <https://oig.hhs.gov/oas/reports/region9/92103020.asp>.

¹⁵ *Organ Procurement Organizations Annual Public Aggregated Performance Report 2023*, CMS, (2023), available at <https://www.cms.gov/files/document/opo-annual-public-performance-report-2023.pdf>.

¹⁶ OIG Audit Report at 13 (HHS OIG made the following two recommendations to CMS and CMS concurred: 1) instruct Palmetto GBA to recover \$72,208 in unallowable Medicare payments by adjusting the applicable OPOs’ cost report to correct the \$148,750 of unallowable professional and public education overhead costs reported and 2) update applicable Medicare requirements to clarify which types of professional and public education overhead costs are unallowable, which could have saved Medicare an estimated \$664,295 for professional and public education overhead costs during our audit period.).

¹⁷ OIG Audit Report at 8 and 9 (one OPO reported unallowable costs of \$1,550 for a donation that sponsored a State Coroner’s Association Symposium. These funds covered the cost of attendance, which included a cocktail reception at which alcohol was served, lunch and dinner at a museum, and raffle prizes. Additional unallowable entertainment expenses included \$1,000 for a photo booth and \$2,211 for tickets to various sporting events and to a winter parade).

¹⁸ OIG Audit Report at 13 and 14.

¹⁹ OIG Audit Report (the report also notes that “because OPOs establish their own SACs for nonkidney organs and Palmetto does not review these SACs, there is an incentive for independent OPOs to include costs that are not reasonable and necessary as part of their nonkidney SACs.”), available at <https://oig.hhs.gov/oas/reports/region9/92103020.pdf>.

²⁰ *Id.*

²¹ Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. 77898 (proposed Dec. 2, 2020) (to be codified at 42 C.F.R. pt. 486).

needed. Research has revealed “the OPO full-reimbursement model has been insufficient to drive its intended goal of ensuring OPOs pursue all donation opportunities.”²²

Given the urgent need to protect patients, taxpayers, and the Medicare Trust Fund from potential waste, fraud, and abuse, we request written answers to the following questions no later than September 19, 2023, and a briefing from your agency no later than one week following receipt of your answers.²³

1. CMS instructed Palmetto GBA to recoup \$72,206 in unallowable Medicare payments, as identified in the HHS OIG’s audit report. What steps have you taken to ensure that Palmetto GBA recoups that taxpayer money? If none, please explain why not.
2. What specific steps has CMS taken to update its OPO reimbursement regulations to new models that incentivize higher OPO performance?²⁴ If none, please explain why not.
3. When will CMS issue updated guidance about Medicare reimbursement policies and procedures that OPOs must follow?
4. Given the OIG’s findings that “opportunities and incentives exist for OPOs to inflate their SACs for non-kidney organs,”²⁵ what specific steps has CMS taken to make OPO finances more transparent, including those related to the itemized costs included in SAC fees? If none, please explain why not.
5. Since OPOs have financial incentives to shift their costs to kidneys compared to nonrenal organs, what specific steps has CMS taken to address this Medicare payment abuse? If none, please explain why not.

²² Paul Rosenberg et al., *Transforming Organ Donation in America*; Appendix A, THE BRIDGESPAN GROUP, (Dec. 2020) at 4, available at <https://www.bridgespan.org/getmedia/4905f7a5-41d7-4240-bd31-0017ec500029/Bridgespan-OPO-Report-FINAL-Appendix-A.pdf>.

²³ While some information that the Committee seeks may be stored within OPOs, transplant centers, the OPTN and/or its current contractor UNOS, hospitals, or other industry stakeholders, we note HHS’s broad authority to access OPO and transplant program records (42 CFR 121.11(a)(2)(ii)) which states: “**Access to facilities and records.** OPOs and transplant hospitals shall permit the Secretary and the Comptroller General, or their designees, to inspect facilities and records pertaining to any aspect of services performed related to organ donation and transplantation.”

²⁴ CMS has existing authority to change the current regulation governing payments to OPOs (42 CFR 413.200) or via its waiver authority under Section 1115A of the Social Security Act to design and launch a demonstration project via the Center for Medicare & Medicaid Innovation.

²⁵ U.S. DEP’T OF HEALTH & HUMAN SERV., OFFICE OF INSPECTOR GEN., A-09-21-03020, *Medicare Paid Independent Organ Procurement Organizations Over Half a Million Dollars for Professional and Public Education Overhead Costs that Did Not Meet Medicare Requirements*, (Aug. 2023), available at <https://oig.hhs.gov/oas/reports/region9/92103020.asp>.

- a. What steps has CMS taken to audit OPOs with the highest reported kidney discard rates to assess whether this practice incentivized those discards? If none, please explain why not.

6. The OIG noted that it “did not perform an overall assessment of CMS’s internal control structure.”²⁶ Based on the existence of Medicare waste, fraud, and abuse, we are concerned that CMS has not exercised necessary oversight to ensure OPO compliance with CMS regulations and guidance. Accordingly, provide the committee all plans to conduct more extensive audits of all OPO costs, including unallowable costs, recoupment of misspent taxpayer dollars, and oversight of professional and public education overhead costs.

7. What specific steps has CMS taken to move away from cost reimbursement for OPOs, including the promulgation of new regulations and leveraging its waiver authority under Section 1115A of the Social Security Act to design and launch a demonstration project via the Centers for Medicare & Medicaid Innovation to test alternative methods of reimbursement? If none, please explain why not.

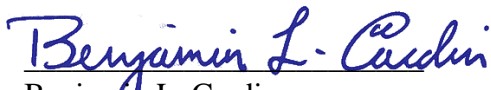
Sincerely,



Ron Wyden
Chairman
Committee on Finance



Charles E. Grassley
Member
Committee on Finance



Benjamin L. Cardin
Member
Committee on Finance



Todd Young
Member
Committee on Finance

²⁶ *Id.* at 15.