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December 18, 2019

VIA ELECTRONIC TRANSMISSION

Ms. Joanne M. Chiedi
Acting Inspector General
Office of Inspector General
U.S. Department of Health & Human Services
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Acting Inspector General Chiedi:

We write today to request that your office conduct a comprehensive examination of the adequacy of the organ procurement and transplantation system in the United States.

Yesterday, the U.S. Department of Health and Human Services (HHS) took a step in the right direction by initiating a rulemaking addressing the lack of available organs for the 113,000 Americans sitting in limbo on the national waitlist.¹ This rule, proposed by HHS, through its Centers for Medicare and Medicaid Services (CMS),² is the Department's first response to President Trump's 2019 Executive Order, which called for reforms to Organ Procurement Organization (OPO) rules to "enhance the procurement and utilization of organs available through deceased donation." The Executive Order also called for the use of "evaluation metrics to establish more transparent, reliable, and standardized metrics for evaluating an OPO's performance."³ While we await the implementation of these important regulatory changes by HHS and CMS, 20 Americans die each day, according to CMS Administrator Verma, because a potentially life-saving

¹ See Press Release, U.S. Dep't of Health & Human Serv., "Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply" (Dec. 17, 2019), available at <https://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html>.

² U.S. DEP'T OF HEALTH & HUMAN SERV., CTMS. FOR MEDICARE & MEDICAID SERV. [Hereinafter "CMS"], Proposed Rule, *Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization* (proposed on Dec. 17, 2019) (to be codified at 42 C.F.R. pt. 486), available at <https://www.hhs.gov/sites/default/files/cms-3380-p-ofr.pdf>.

³ Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 10, 2019).

organ transplant remains out of reach.⁴ If, as research suggests, thousands of eligible organs are not being transplanted due to a serious lack of accountability,⁵ transparency, and objective donor standards,⁶ then more must be done.

Six years have elapsed since the Office of Inspector General (OIG) issued a report unearthing unallowable Medicare reimbursement claims and highlighting other oversight deficiencies in the organ procurement and transplantation system.⁷ That 2013 report indicates that selected OPOs improperly billed the Medicare program for alcohol and entertainment expenses as well as lobbying-related expenditures. Earlier OIG reports also discuss expenditures by OPOs on public education, which in some cases have included football game tickets, sponsorship of a golf tournament, a retirement party, a New Year's Eve celebration, a parade float, professional musical entertainment, and blocks of hotel rooms amounting to over \$70,000 for a single event.

During this same six-year period, the number of patients awaiting organ transplantation has increasingly outpaced the supply of donated organs; and every ten minutes, another person is added to the national waitlist, according to the Health Resources and Services Administration (HRSA).⁸ This shortfall exists despite the recent growth in the number of organ donations,⁹ which researchers attribute not to improved organ procurement by OPOs, but primarily to the increase in

⁴ See Press Release, *supra* note 1.

⁵ Yale School of Mgmt., "Three Questions: Prof. Vahideh Manshadi on Improving Kidney Donation" YALE INSIGHTS (July 18, 2019) (stating that "there are approximately 28,000 additional available organs each year from deceased donors that do not get procured or transplanted due to breakdowns in the current system."), available at <https://insights.som.yale.edu/insights/three-questions-prof-vahideh-manshadi-on-improving-kidney-donation>.

⁶ Nat'l Kidney Foundation (NKF), *Position Statement on Reform of Organ Procurement Organization Metrics*, (July 7, 2019) (noting that a "dual accountability metric is important to ensure that as many organs as possible, including less than perfect organs, are recovered and successfully transplanted."), available at <https://www.kidney.org/news/position-statement-reform-organ-procurement-organization-opo-metrics>.

⁷ U.S. DEP'T OF HEALTH & HUMAN SERV., OFFICE OF INSPECTOR GEN. [Hereinafter "OIG"], A-09-12-02085, *Medicare Could Have Saved Millions if Organ Procurement Organizations Had Correctly Reported Procurement of Double Lungs as Two Organs* (Dec. 2013), available at <https://oig.hhs.gov/oas/reports/region9/91202085.pdf>.

⁸ HEALTH RESOURCES AND SERVICES ADMINISTRATION, [Hereinafter "HRSA"], *Organ Donation Continues*, at graph titled, "The Organ Shortage Continues" (last accessed on Dec. 18, 2019), available at <https://www.organdonor.gov/statistics-stories/statistics.html#glance>. See also Gwendolyn Proctor, *HRSA Examined: The Healthcare Systems Bureau*, HRSA (Apr. 2019), available at <https://www.hrsa.gov/sites/default/files/hrsa/grants/manage/technicalassistance/hsb-2019.pdf>.

⁹ David Goldberg, M.D. & Raymond Lynch, M.D., *Improvements in Organ Donation: Riding the Coattails of a National Tragedy*, Nat'l Center for Biotechnology Information, U.S. Nat'l Library of Med. (Nov. 2019) (stating in its Abstract that "While there have been improvements in performance at some OPOs, based on these data it is indisputable that nationally the increased number of donors is almost wholly attributable to the drug epidemic, and reflects the byproduct of a national tragedy, rather than an improved system to be celebrated."), available at <https://www.ncbi.nlm.nih.gov/pubmed/31742783>. See also Mandeep R. Mehra, M.D., et al., "The Drug-Intoxication Epidemic and Solid-Organ Transplantation," 378 N ENGL J. MED. 1943-45 (May 2018) ("We were surprised to learn that almost all of the increased transplant activity in the United States within the last five years is a result of the drug overdose crisis."), available at <https://www.nejm.org/doi/10.1056/NEJMc1802706>.

opioid-related deaths nationwide.¹⁰ Meanwhile, investigative reports and whistleblower accounts of inefficiencies point to a need for more rigorous oversight by Congress and the OIG.¹¹

These are not new concerns: the need for greater accountability and transparency in the entire organ procurement and transplantation system has been discussed for over a dozen years. For example, in 2005, the effectiveness and independence of the Organ Procurement and Transplantation Network (OPTN)/Unified Network for Organ Sharing (UNOS), which oversees all 58 OPOs, was called into question.¹² Little has changed over the last 15 years,¹³ which is why it is so important that the OIG and Congress conduct additional oversight of the entire system. We can no longer stand by idly while the fox guards the hen house.¹⁴ Therefore, we request the OIG provide responses to the following questions:

1. To what extent has the OIG audited or investigated activities by the 58 nonprofit OPOs that procure organs from recently deceased donors and deliver them to certified transplant centers for critically ill patients in need of an organ transplant? Please identify which OPOs the OIG has audited or investigated since 2009, and provide the dates of each such audit or investigation, a summary of the OIG's findings, any recommendations issued, and the extent to which the OIG's recommendations have (or have not) been implemented.
2. In light of recent research, which suggests the vast majority of OPOs are underperforming, with organ recovery rates of less than 50%,¹⁵ has the OIG identified practices, such as

¹⁰ Nat'l Academies of Sciences Engineering Med., Comm. on Issues in Organ Donor Intervention Research, *Opportunities for Organ Donor Intervention Research, Saving Lives by Improving the Quality and Quantity of Organs for Transplantation*, NAT'L ACADEMIES PRESS (2017), available at https://www.ncbi.nlm.nih.gov/books/NBK458645/pdf/Bookshelf_NBK458645.pdf.

¹¹ Kimberly Kindy et al., "Lives Lost, Organs Wasted," WASH. POST (Dec. 20, 2018), available at <https://www.washingtonpost.com/graphics/2018/national/organ-transplant-shortages/>;

¹² 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>.

¹³ See Press Release, Todd Young, U.S. Senator, "Young Introduces Legislation to Bring Greater Accountability to Organ Donation System" (July 9, 2019) ("[I]t's clear that the best way to save lives is to bring greater transparency, oversight, and accountability to the organizations responsible for getting organs from the donors to the patients who need them."), available at <https://www.young.senate.gov/newsroom/press-releases/young-introduces-legislation-to-bring-greater-accountability-to-organ-donation-system>.

¹⁴ Charles Ornstein & Tracy Weber, "Transplant Monitor Lax in Oversight," LA TIMES (Oct. 22, 2006) (noting UNOS' flawed structure as a regulator and membership organization, run by professionals on the boards of UNOS, and a transplant center [or OPO], which Senator Grassley replied, "It's kind of like the fox guarding the chicken house."), available at <https://www.latimes.com/archives/la-xpm-2006-oct-22-me-transplant22-story.html>.

¹⁵ See CMS, Proposed Rule, *supra* note 2 at 57-60. *Cf.*, The Bridgespan Group, *Reforming Organ Donation in America, Saving 25,000 Lives Per year and \$13 Billion in Taxpayer Funds Over Five Years* (Jan. 2019) (finding that 43 OPOs were underperforming—with recovery rates below 50%, meaning these OPOs recovered less than half of the actual/potential donor organs, and 16 OPOs recovered less than one-third), available at <https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf>.

enhanced cost reporting, that could be imposed to identify reasons for poor performance or underperformance? If so, which OPOs should be subjected to enhanced reporting requirements?

3. To ensure that OPOs are focused on achieving their mission of organ recovery, regular fiscal oversight is necessary,¹⁶ but nearly a decade has elapsed since the OIG identified misuse of taxpayer dollars by OPOs in four reports spanning a two-year period. What other efforts has the OIG initiated in this area since 2012? Also, in light of recent investigative reports questioning OPO practices,¹⁷ is the OIG auditing (or planning to audit) or taking other actions to identify unallowable or unsupported expenses by the other 54 OPOs across the country? Please explain.
 - a. For example, has the OIG ever audited or investigated LiveOnNY,¹⁸ which has been flagged for decertification by CMS on multiple occasions since 2013,¹⁹ and yet, still had its contract renewed by CMS in 2019?²⁰ If so, what were the findings of the audit or investigation? Please explain.
 - b. Has OneLegacy reimbursed the Medicare program for its \$76,686 in unallowable expenditures on lobbying, deferred compensation, gifts, donations, dining, entertainment, and alcohol,²¹ or reimbursed the Medicare program for some or all

¹⁶ U.S. DEP'T OF HEALTH & HUMAN SERV., OIG, OEI-01-88-01331, *Addressing Increased Organ Acquisition Costs* (Sept. 1987), available at <https://oig.hhs.gov/oei/reports/oei-01-86-00108.pdf>. See also The Bridgespan Group, *supra* note 15 at 8 (finding that “Each of the 58 OPOs in the United States operates as an unchecked regional monopoly. Performance varies across the OPO network, with many persistent underperformers failing to improve over the last decade.”).

¹⁷ Melody Petersen & David Willman, “How organ and tissue donation companies worked their way into the county morgue,” *LA TIMES* (Oct. 13, 2019), available at <https://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html>. See also Andrew Conte & Luis Fábregas, “Investigation finds improper spending among organ procurers,” *infra* note 22.

¹⁸ Kimberly Kindy, “Underperforming in New York: Nonprofit struggles to recover transplantable organs,” *WASH. POST* (Dec. 20, 2018) (stating that “...complaints from hospital staff about LiveOnNY [the OPO] date to at least 2010, records show[,]...[and] [a]t Long Island Jewish Medical Center, staff complained it took 22 hours for LiveOnNY to arrive and evaluate a 42-year-old stroke victim approaching brain death.”), available at https://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html.

¹⁹ Letter from Helen M. Irvin, RN MBA, President & CEO of New York Organ Donor Network to OIRA Administrator Shelanski, Office of Management & Budget (Oct. 28, 2013) (stating that their own data [or any OPO's data] cannot be used to hold them accountable because “... the data that OPOs submit to CMS in connection with the outcome measures is self-reported and unaudited. Not surprisingly, errors have been found in the data on which CMS has relied as the basis for judging OPO performance.”), available at https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf.

²⁰ Kimberly Kindy & Lenny Bernstein, “Despite Low Performance, Organ Collection Group Gets New Federal Contract,” *WASH. POST* (Feb. 4, 2019), available at https://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html.

²¹ 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>.

of its \$85,645 in expenditures on the Rose Bowl and the Rose Parade?²² Because OneLegacy has appealed the OIG's reimbursement decision and its initial appeal hearing is scheduled to take place next month, please provide documentation of the OPO's public education costs, including, but not limited to its expenditures on the Rose Bowl and Rose Parade in calendar years 2007 through 2019.

- c. Has California Donor Network reimbursed the Medicare program for \$33,431 in unallowable expenditures, including nearly \$19,000 to host a retirement party as well as other entertainment, lobbying, and dining-related expenditures?²³ Additionally, has California Donor Network reimbursed the Medicare program for \$51,304 in unallowable and unsupported costs?
- d. Has LifeCenter Northwest reimbursed the Medicare program \$88,205, after deficiencies were identified by the OIG in the OPO's organ procurement reports and organ statistics?²⁴
- e. Has Donor Network of Arizona reimbursed the Medicare program \$8,455, after deficiencies were identified by the OIG in the OPO's organ procurement reports and organ statistics?²⁵
- f. What reforms have been adopted since the issuance of the OIG's four reports on OPOs to ensure that reported expenses in Medicare Cost Reports are reasonable and focused on the OPO's mission of organ recovery?
 - i. Please rank each OPO according to the amount of executive compensation received by its chief executive officer. For each such CEO, also provide detailed information on annual salary, bonuses, and additional sources of OPO-related compensation, such as compensation derived from OPO partner organizations (e.g., tissue processors, cornea banks, and funeral homes).²⁶

²² Andrew Conte & Luis Fábregas, "Investigation finds improper spending among organ procurers," ASS'N OF HEALTH CARE JOURNALISTS (Nov. 11, 2013), available at <https://healthjournalism.org/resources-articles-details.php?id=268#.XfleQuRYamQ>.

²³ 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>.

²⁴ OIG, A-09-11-02039, *LifeCenter Northwest Did Not Fully Comply With Medicare Requirements for Reporting Organ Statistics in its Fiscal Year 2009 Medicare Cost Report* (Nov. 2012), available at <https://oig.hhs.gov/oas/reports/region9/91102039.pdf>.

²⁵ OIG, A-09-11-02035, *Donor Network of Arizona Did Not Fully Comply With Medicare Requirements for Reporting Organ Statistics and Related Costs I its Fiscal Year 2009 Medicare Cost Report* (Mar. 2012), available at <https://oig.hhs.gov/oas/reports/region9/91102035.pdf>.

²⁶ U.S. FEDERAL BUREAU OF INVESTIGATION, *Former Alabama Organ Center Associate Director Sentenced for Fraud*, U.S. Attorney's Office, Northern District of Alabama, (June 13, 2012), available at <https://archives.fbi.gov/archives/birmingham/press-releases/2012/former-alabama-organ-center-executive-sentenced-for-fraud>.

4. Has the OIG audited or investigated any OPOs, such as Indiana Donor Network, that purchased airplanes for organ procurement purposes?²⁷
 - a. Has the OIG identified any OPOs that submitted reimbursement claims to cover the cost of flights that were not directly related to an OPO's charitable mission? If so, did the OPO reimburse the Medicare program for any unallowable expenditures? Please explain and provide documentation.
 - b. What measures are in place to provide sufficient transparency to ensure that these airplanes are not used for personal travel and then billed to taxpayers?
5. UNOS, the only entity to ever have the OPTN contract, is tasked with conducting audits and oversight of all 58 OPOs. Due to concerns, dating back to 1999,²⁸ that UNOS exercises a monopoly in this area, has the OIG ever audited or investigated UNOS? If so, when? If not, why not?
6. The OIG's 2013 report indicates that 44 of 58 OPOs incorrectly reported lung procurement statistics (resulting in unnecessary government expenditures of over \$8,000,000).²⁹ Has the OIG's recommendation that CMS resolve this issue by updating the Provider Reimbursement Manual (PRM) been implemented?³⁰
 - a. Please provide a list of the 44 OPOs that incorrectly reported lung procurement costs during fiscal year 2011.
 - b. Since 2013, has the OIG conducted additional oversight of the 44 OPOs that incorrectly reported lung procurement costs in Medicare Cost Reports? If so, what were the OIG's findings? If the OIG identified unallowable claims as a result of this additional oversight, to what extent was the Medicare program overbilled by each such OPO in each of the last eight fiscal years? Please provide documentation.
7. As noted by the OIG in a 2001 report, some OPOs that operate tissue banks are *not* accredited by the American Association of Tissue Banks (AATB),³¹ and may not have

²⁷ Kylie Veleta, "Indiana Flies High: Only State with Dedicated Organ Jet," INSIDE INDIANA BUSINESS (Oct. 30, 2017), available at <https://www.insideindianabusiness.com/story/36716152/indiana-flies-high-only-state-with-dedicated-organ-jet>.

²⁸ Brigid McMenamin, "The Organ King" FORBES (Nov. 1, 1999) ("[UNOS is] the federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly."), available at <https://www.forbes.com/forbes/1999/1101/6411164a.html#4c13d3ea659f>; see also Charles Ornstein, *supra* note 14.

²⁹ See OIG, A-09-12-02085, *supra* note 7 (finding that if the 44 OPOs evaluated by the OIG had reported procurement costs correctly, then the Medicare program would have saved approximately \$8,851,018 during FY2011).

³⁰ CMS, The Provider Reimbursement Manual – Part 1, Chapter 31, *Organ Donation and Transplant Reimbursement* (Nov. 4, 2019), available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929>.

³¹ OIG, OEI-01-00-00441, *Oversight of Tissue Banking* (Jan. 2001) (noting that as of 2001, the OIG identified 5 of the 58 AATB accredited tissue banks as for-profit entities, and 11 of these 58 tissue banks as OPOs.) (noting further that in addition to the 58 accredited tissue banks, that the OIG found another 90 tissue banks that were not AATB accredited.), available at <https://oig.hhs.gov/oei/reports/oei-01-00-00441.pdf>.

adequate mechanisms to avoid conflicts of interest. What financial incentives do OPOs have to prioritize tissue recovery over organ procurement, and under what circumstances do such financial incentives create a conflict of interest?³²

- a. How many OPOs currently operate tissue banks that are accredited by the AATB? Please provide a list of these OPOs and the date on which they completed the AATB's accreditation program.
 - b. How many OPOs operate tissue banks that are *not* accredited by the AATB? Please provide a list of these OPOs.
8. Are mechanisms in place to ensure that financial assets controlled by OPOs, including OPO endowments and OPO foundations, are used to advance the mission for which the OPO was granted non-profit status?
9. Internal Revenue Service 990 filings indicate that some OPOs have transferred financial assets to their private foundations.³³ Given this, has the OIG investigated whether OPO foundations then use these resources for purposes that the OIG had previously deemed impermissible for OPOs?

Thank you in advance for your response. Responses to questions 1 through 5 should be provided no later than January 2, 2020. Responses to questions 6 through 9 should be provided no later than January 16, 2020. If you have any questions about these requests, please contact Rachael Soloway of Chairman Grassley's Committee staff at (202) 224-1124 and Jaymi Light of Senator Young's staff at (202) 224-5623.

Sincerely,



Charles E. Grassley
Chairman
Committee on Finance



Todd Young
Member
Committee on Finance

³² Jim Doyle, "Mid-America Transplant Services and its officials move into for-profit ventures," ST. LOUIS POST-DISPATCH (Nov. 12, 2012) (noting that the OPO "acts increasingly like a for-profit enterprise, selling body parts for financial gain and harboring potential conflicts of interest—while exempted from most federal and state taxes. It invests millions of dollars in for-profit ventures and supplies human bone and tissue to firms in which it maintains an ownership stake and leadership role...[and the OPO's] tax filings do not disclose its financial ties to the for-profit firm [AlloSource]."), available at https://www.stltoday.com/business/local/mid-america-transplant-services-and-its-officials-move-into-for/article_f37bb65b-f000-5bf7-bc00-097b2f6341f5.html; cf., Melody Petersen, *supra* note 20.

³³ See Nonprofit Explorer (last accessed on Dec. 18, 2019), available at <https://projects.propublica.org/nonprofits/>; e.g., LiveOnNYFoundation, (last accessed on Dec. 18, 2019), available at <https://projects.propublica.org/nonprofits/organizations/475156525/201842769349300409/IRS990>.