## CHUCK GRASSLEY, IOWA, CHAIRMAN

MIKE CRAPO, IDAHO PAT ROBERTS, KANSAS MICHAEL B, ENZI, WYOMING JOHN CORNYN, TEXAS JOHN THUNE, SOUTH DAKOTA RICHARD BURR, NORTH CAROLINA ROB PORTMAN, OHIO PATRICK J. TOOMEY, PENNSYLVANIA TIM SCOTT, SOUTH CAROLINA BILL CASSIDY, LOUISIANA JAMES LANKFORD, OKLAHOMA STEVE DAINES, MONTANA TODD YOUNG, INDIANA BEN SASSE, NEBRASKA RON WYDEN, OREGON DEBBIE STABENOW, MICHIGAN MARIA CANTWELL, WASHINGTON ROBERT MENENDEZ, NEW JERSEY THOMAS R, CARPER, DELAWARE BENJAMIN L CARDIN, MARYLAND SHERROD BROWN, OHIO MICHAEL F, BENNET, COLDRADO ROBERT P, CASEY, JR., PENNSYLVANIA MARK R, WARNER, VIRGINIA SHELDON WHITEHOUSE, RHODE ISLAND MAGGIE HASSAN, NEW HAMPSHIRE CATHERINE CORTEZ WASTO, NEVADA



COMMITTEE ON FINANCE WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

February 10, 2020

## VIA ELECTRONIC TRANSMISSION

Mr. Brian Shepard Chief Executive Officer United Network for Organ Sharing 700 North 4th Street Richmond, VA 23219

Dear Mr. Shepard:

We write today about concerning allegations of oversight gaps with respect to our nation's Organ Procurement and Transplantation Network (OPTN), the United Network for Organ Sharing (UNOS), and the network of 58 organ procurement organizations (OPOs) that UNOS monitors. Recent reports of lapses in patient safety, misuse of taxpayer dollars, and tens of thousands of organs going unrecovered or not transplanted lead us to question the adequacy of UNOS' oversight of these OPOs.

According to CMS, 20 Americans die each day because an organ transplant remains out of reach.<sup>1</sup> The number of patients awaiting organ transplantation has 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).<sup>2</sup> President Trump last year issued an Executive Order calling for "modernizing the organ recovery and transplantation systems," by establishing "more transparent, reliable, and enforceable objective metrics for evaluating an OPO's

availability-organ-supply.html. <sup>2</sup> HEALTH RESOURCES AND SERVICES ADMINISTRATION, [Hereinafter "HRSA"], Organ Donation Continues, at graph titled, "The Organ Shortage Continues" (last accessed on Feb. 10, 2020), *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.

<sup>&</sup>lt;sup>1</sup> 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-

performance.<sup>3</sup> In addition, in December 2019, the Centers for Medicare and Medicaid Services (CMS) at the Department of Health and Human Services (HHS) published a proposed rule, finding that 37 of the nation's 58 OPOs would fail to meet one or both of the two performance metrics that CMS proposed.<sup>4</sup>

According to HHS, OPOs are failing to recover or transplant thousands of eligible organs. In some cases, OPOs may be choosing not to pursue procurement of organs from single-organ donors, given that they are evaluated on the number of organs procured per donor.<sup>5</sup> A recent study cited by CMS found that there are 28,000 available organs from deceased donors annually, which are not procured for transplantation.<sup>6</sup> Additionally, there are thousands of organs that are recovered but not transplanted. Between 2013 and 2018, the proportion of kidneys recovered for transplant but not transplanted increased by 4.7 percent, and in 2018, almost one-fifth of kidneys recovered were not transplanted.<sup>7</sup>

This month, an investigation from Kaiser Health News, which touched on the amount of organs never transplanted, found that "a startling number of lifesaving organs are lost or delayed while being shipped on commercial flights, the delays often rendering them unusable" because UNOS tracks organs with "a primitive system of phone calls and paper manifests, with no GPS or other electronic tracking required."<sup>8</sup> This builds on previous reports detailing a human heart left on a commercial flight,<sup>9</sup> a pancreas left on an airport counter, and a kidney shipped to the wrong airport,<sup>10</sup> with the most recent investigative reporting finding that "there's little data to show how often these transportation problems occur [and] no federal agency... requires monitoring of

<sup>6</sup> Id. at 4, FN 2, 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 OPOs recovered less than half of the actual/potential donor organs, and 16 OPOs recovered less than one-third of such organs[.]"), *available at* <u>https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organdonation-in-america-12-2018.pdf</u>. See also D. Goldberg et. al., "Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States," AM. J. OF TRANSPLANT. Vol. 17, Issue 12 (July 20, 2017), *available at* <u>https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.14391</u>.

<u>t42cq\_EfbEUS7U73xKK\_wj4SU5H894MJGW3MmRzSAE2VsOeGvw6j7yPbEtPxr5o&\_hsmi=83118162</u>. <sup>9</sup> Chris Boyette & Nicole Chavez, "A human heart for donation was left behind by mistake on a Southwest flight,"

<sup>&</sup>lt;sup>3</sup> Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 10, 2019) (calling for the use of "evaluation metrics to establish more transparent, reliable, and standardized metrics for evaluating an OPO's performance").

<sup>&</sup>lt;sup>4</sup> U.S. DEP'T OF HEALTH & HUMAN SERV., CTRS. FOR MEDICARE & MEDICAID SERV., Proposed Rule, [Hereinafter referred to as "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. Part 486), *available at* https://www.hhs.gov/sites/default/files/cms-3380-p-ofr.pdf.

<sup>&</sup>lt;sup>5</sup> See CMS Proposed Rule at 4.

<sup>&</sup>lt;sup>7</sup> See "OPTN/SRTR 2018 Annual Data Report: Introduction," AM. J. OF TRANSPLANT. Vol. 20, Issue 1 (January 2, 2020), available at https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.15671.

<sup>&</sup>lt;sup>8</sup> JoNel Aleccia, "How Lifesaving Organs For Transplant Go Missing In Transit," KAISER HEALTH NEWS (Feb. 10, 2020), available at <a href="https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-">https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-</a>

transit/?utm\_campaign=KHN%3A%20First%20Edition&utm\_source=hs\_email&utm\_medium=email&utm\_content =83118162&\_hsenc=p2ANqtz-9tEt7W2kGciDcnT3QXYKmLIHyBUskfIFDNgYj9f--JDPPhA6t-

CNN (Dec. 14, 2018), available at https://www.cnn.com/2018/12/14/us/southwest-human-heart-plane-seattletrnd/index.html.

<sup>&</sup>lt;sup>10</sup> Emily Harris, "Lost in Transplantation," REVEAL NEWS & PRX (Feb. 8, 2020), *available at* <u>https://www.revealnews.org/episodes/lost-in-transplantation/</u>.

transportation for transplant organs.<sup>11</sup> Since UNOS is responsible for enforcing OPO safety standards, "it is difficult to determine how often problems occur because UNOS's records are hidden from scrutiny by the public or Congress.<sup>12</sup>

Serious patient safety issues have also been reported. For example, in March 2016, an OPO reportedly neglected to disclose an infection in a uterus that the OPO had recovered for transplant, which led to a near-fatal outcome for the organ recipient.<sup>13</sup> At the time of this incident, the OPO had already lost its good standing status, "indicating a serious lapse in patient safety or quality of care, according to UNOS."<sup>14</sup> UNOS later restored the OPO's status to good standing, and "refused to make public" or share with Congress any corrective actions taken by the OPO.<sup>15</sup>

The HHS Office of the Inspector General (OIG), Federal Bureau of Investigation, and others have identified inappropriate use of Medicare funds by OPOs, along with other illegal financial arrangements. According to the HHS Office of Inspector General (OIG), one OPO reported unallowable and unsupported expenditures on activities such as entertainment, meals, lobbying, and donations and gifts, resulting in \$500,000 in overpayments from the Medicare program,<sup>16</sup> and another OPO for \$300,000 in overpayments from the Medicare program.<sup>17</sup> Federal investigators uncovered an illegal kickback scheme between another OPO and a local funeral home.<sup>18</sup> Prior to blowing the whistle on his employer's illegal activities, an employee at this OPO endured physical abuse<sup>19</sup> and received death threats from his employer, court documents

<sup>&</sup>lt;sup>11</sup> See JoNel Aleccia, *supra* note 8 (finding that our nation does not have "an end-to-end unified transportation system," and instead, we have "a cobbled-together system of OPOs and couriers and private aircraft and commercial aircraft.")

<sup>&</sup>lt;sup>12</sup> Kimberly Kindy & Lenny Bernstein, "A human heart was left on a plane, revealing how organs move around the country," WASH. POST (Dec. 14, 2018), *available at* <u>https://www.washingtonpost.com/national/health-science/a-human-heart-was-left-on-a-plane-revealing-how-organs-move-around-the-country/2018/12/14/3aabe696-ffb7-11e8-862a-b6a6f3ce8199 story.html.</u>

<sup>&</sup>lt;sup>13</sup> Lenny Bernstein, "Behind the failure of the first U.S. uterine transplant," WASH. POST (Feb. 13, 2019), *available at* <u>https://www.washingtonpost.com/national/health-science/behind-the-failure-of-the-first-us-uterine-transplant/2019/02/13/6345f018-07c0-11e9-85b6-41c0fe0c5b8f story.html.</u>

<sup>&</sup>lt;sup>14</sup> Id. [internal quotation marks omitted].

<sup>&</sup>lt;sup>15</sup> Id.

<sup>&</sup>lt;sup>16</sup> 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*.

<sup>&</sup>lt;sup>17</sup> 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.

<sup>&</sup>lt;sup>18</sup> 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-

https://archives.fbi.gov/archives/birmingham/press-releases/2012/former-alabama-organ-center-executivesentenced-for-fraud.

<sup>&</sup>lt;sup>19</sup> 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* <u>https://www.cbsnews.com/news/whistleblower-threatened-with-being-cremated-alive-after-exposing-mortuary-kickback-scheme/.</u>

indicate.<sup>20</sup> Both of these organizations are still certified as qualified OPOs for the purposes of Medicare and Medicaid reimbursement.

Media reports and OIG audits point to a serious lack of accountability,<sup>21</sup> transparency,<sup>22</sup> and objective donor standards<sup>23</sup> that have allowed underperforming OPOs to continue operating.<sup>24</sup> More can—and must—be done to ensure that OPO performance improves. Because OPOs operate as regional monopolies, rigorous oversight is critical to ensure that all 58 OPOs are faithfully executing their mission of organ recovery.<sup>25</sup> And because the OPTN is tasked with monitoring all 58 OPOs,<sup>26</sup> we seek to better understand how UNOS either missed these issues or neglected to remediate them.<sup>27</sup> We therefore request that UNOS provide responses to the following questions by March 1, 2020:

- 1. How does UNOS fulfill the requirements of 42 C.F.R. § 121.10(b),<sup>28</sup> which tasks the OPTN Contractor with monitoring and overseeing all 58 OPOs? Specifically:
  - a. How does UNOS currently fulfill its requirement for ongoing monitoring and periodic reviews of OPOs for underperformance and what triggers or performance measures are used by UNOS to define OPO underperformance?

https://www.al.com/news/birmingham/2018/03/birmingham whistleblower award.html.

https://www.kidney.org/news/position-statement-reform-organ-procurement-organization-opo-metrics.

<sup>26</sup> 42 C.F.R. § 121.10(b).

<sup>&</sup>lt;sup>20</sup> Erin Edgemon, "Birmingham whistleblower awarded \$14.7 million in organ center probe," BIRMINGHAM REAL-TIME NEWS (last updated on Mar. 6, 2019), *available at* 

<sup>&</sup>lt;sup>21</sup> See CMS, Proposed Rule, *supra* note 4 at 57-60 (stating that 37 OPOs are out of compliance and underperforming with respect to at least one of two proposed metrics). *Cf.* The Bridgespan Group, *supra* note 6 (finding that "43 OPOs recovered less than half of the actual/potential donor organs, and 16 OPOs recovered less than one-third of such organs.").

<sup>&</sup>lt;sup>22</sup> 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.

<sup>&</sup>lt;sup>23</sup> Nat'l Kidney Foundation, *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* 

<sup>&</sup>lt;sup>24</sup> See e.g., 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) (noting that data cannot be used to hold OPOs accountable because "The data that OPOs submit to CMS in connection with the outcome measures is self-reported and unaudited...[and] 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.

<sup>&</sup>lt;sup>25</sup> See The Bridgespan Group, *supra* note 6 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.").

<sup>&</sup>lt;sup>27</sup> 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]." Senator Grassley referred to the flawed structure as "the fox guarding the chicken house."), *available at* <u>https://www.latimes.com/archives/la-xpm-2006-oct-22-me-transplant22-story.html.</u> <sup>28</sup> 42 C.F.R. § 486.324 (2006) [as amended at 77 FR 29031 (2012)].

- What, if any, efforts has UNOS undertaken to ensure the accuracy and i. consistency of OPO outcome measure data?
- Does UNOS ever audit self-reported data submitted by OPOs in relation to the ii. measures under 42 C.F.R. § 486.318(a) and (b)? If so, please detail how frequently such audits occur and what action is taken in response to an OPO that is found to have submitted inaccurate data.
- iii. Has UNOS provided guidance to OPOs on the definition of "eligible deaths" for purposes of reporting the number of organs recovered per eligible death?
- b. What, if any, steps has UNOS taken in response to media reports about staffing shortages at selected OPOs?<sup>29</sup>
- c. What, if any, steps has UNOS taken in response to findings in HHS OIG audits that multiple OPOs charged Medicare for unallowable expenditures?
- d. To what extent does the UNOS Membership & Professional Standards Committee (MPSC) conduct financial audits to ensure that all reported expenses in an OPO's Medicare Cost Reports are reasonable and focused on the OPO's mission of organ recovery? If the MPSC does not conduct any such audits, please explain why not.
- e. Is there an independent, third-party entity responsible for auditing each of the 58 OPOs to ensure that all costs are "reasonable," "necessary," "proper," and "allowable?"30 If so, please explain, including but not limited to the frequency with which such audits are conducted. If not, please explain why UNOS has not required any independent audits of OPOs.
- 2. Over the last 10 years, how many OPOs have been identified by the Scientific Registry of Transplant Recipients (SRTR) as statistically significantly underperforming over any reporting period?
- 3. For each of these OPOs identified as statistically significantly underperforming by the SRTR, please provide a list of all instances of OPO underperformance in the last 10 years (as defined by statistical significance between the observed value and the expected value for the metrics reported on by the SRTR). For each instance, please describe:
  - a. The OPO in question; whether the instance was formally presented to the MPSC and the corresponding date; the review process; the composition of the relevant

<sup>&</sup>lt;sup>29</sup> See 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-recovertransplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7 story.html.

<sup>&</sup>lt;sup>30</sup> 42 C.F.R. § 413.24(a), (b), and (c)(3)).

MPSC subcommittee(s) that reviewed each case, including any conflicts of interest for each MPSC member; the findings of such process; the recommended course of action, including whether a corrective action plan was implemented; and whether the respective OPO's standing status was changed as a result of the instance.

- 4. What steps has UNOS taken to address delays and other issues of organ transportation,<sup>31</sup> including to understand the impact of these issues on patient safety?
  - a. Please provide all documentation related to every instance, within the last 10 years, in which an organ was lost, delayed, damaged, or otherwise mishandled in transit, including the cause of the incident, the manner in which the incident was disclosed to the recipient and the family of the deceased donor, and all information related to the clinical impact these incidents have on recipients.
  - b. For each instance, please also indicate whether the organ was allocated by the UNOS Organ Center or the corresponding OPO.
- 5. Please provide data on the number of organs eligible for transplant that were recovered for transplant but not transplanted in the last 10 years, including the types of organs, the designated service areas (DSAs), and OPOs.
  - a. Please include all data related to the reasons why recovered organs were discarded.
- 6. In light of HHS OIG and Government Accountability Office (GAO) findings,<sup>32</sup> as well as public reporting about various OPO improprieties (some of which resulted in prison sentences for OPO executives,<sup>33</sup> misuse of taxpayer dollars,<sup>34</sup> life-threatening patient safety issues,<sup>35</sup> and troubling tissue recovery practices<sup>36</sup>), please provide:
  - a. A list of any OPOs that have been accorded probationary status or named a "Member Not in Good Standing," including dates on which each such OPO's status changed.
  - b. All materials related to the OPTN's fact-finding process with respect to any OPO that has ever been put on probation or listed as a "Member Not in Good Standing" by the OPTN, including all materials, reports, memos, audits, and correspondence relating to this process.

<sup>&</sup>lt;sup>31</sup> See JoNel Aleccia, *supra* note 8 (finding that "matters involving the transportation methods used by OPOs are arranged directly between OPOs and transplant centers," [which are both overseen by UNOS].).

<sup>&</sup>lt;sup>32</sup> GOV'T ACCOUNTABILITY OFFICE [Hereinafter GAO], GAO-08-412, Organ Transplant Programs, Federal Agencies Have Acted to Improve Oversight, but Implementation Issues Remain (Apr. 2008), available at https://www.gao.gov/new.items/d08412.pdf. See also OIG, A-09-08-00033, supra note 16.

<sup>&</sup>lt;sup>33</sup> See FBI, Former Alabama Organ Center Associate Director Sentenced for Fraud, supra note 18.

<sup>&</sup>lt;sup>34</sup> See OIG, A-09-08-00033, supra note 16. See also OIG, A-09-09-00087, supra note 17.

<sup>&</sup>lt;sup>35</sup> See Lenny Bernstein, supra note 13.

<sup>&</sup>lt;sup>36</sup> Melody Petersen, "In the rush to harvest body parts, death investigations have been upended," L.A. TIMES (Oct. 13, 2019), *available at* <u>https://www.latimes.com/business/story/2019-10-13/body-parts-harvesting-hinders-coroner-autopsies</u>.

- c. All complaints made regarding (or violations alleged against) OPOs that have been reported to UNOS, including those considered to be protected under peer review, both including cases referred and not referred to the MPSC, including all UNOS correspondence and corrective action plans, meeting minutes, and any other written records from MPSC deliberations related to those incidents.
- d. The names (and corresponding professional affiliations) of each individual that has ever served as chairperson of (1) the MPSC, and/or (2) the OPO subcommittee. (Please also provide a list of all members of the relevant MPSC subcommittee(s), and anyone else involved in the decision-making process regarding whether or not to investigate each complaint at the time of the referral or non-referral.)
- e. A description of the MPSC's overall structure (as well as its subcommittee structure), including how the oversight and investigatory responsibilities are apportioned between and among the various committees and subcommittees, as well as the process by which complaints are directed to various subcommittees or committees of MPSC.
- 7. Given that multiple OPOs recover tissue and some operate tissue banks,<sup>37</sup> on what mechanisms does UNOS rely to minimize conflicts of interest, and what measures does UNOS take to protect against OPOs prioritizing tissue recovery over organ recovery due to financial incentives?
  - a. Under what circumstances might financial incentives to recover tissue create a conflict of interest for an OPO?<sup>38</sup> In the event that such a conflict arises, how does UNOS ensure that it is resolved?
  - b. Please provide a list of each OPO currently operating a tissue bank. For OPOs that do not operate a tissue bank, please list any tissue-related companies with which they are affiliated.
  - c. To what extent and how are the nature of OPO relationships with tissue companies disclosed to donor families as well as the general public?<sup>39</sup>

<sup>&</sup>lt;sup>37</sup> 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, "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* <u>https://www.stltoday.com/business/local/mid-america-transplant-services-and-its-officials-move-intofor/article\_f37bb65b-f000-5bf7-bc00-097b2f6341f5.html</u>.

<sup>&</sup>lt;sup>38</sup> *Id.* (finding that the OPO serving 84 counties in eastern Missouri, Southern Illinois and northeastern Arkansas 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."). *Cf.* FBI, *Former Alabama Organ Center Associate Director Sentenced for Fraud, supra* note 18. *See also* 42 C.F.R. § 486.324, § 486.326 (2006).

<sup>&</sup>lt;sup>39</sup> Kate Wilson, "Abusing the 'Gift' of Tissue Donation," INT'L CONSORTIUM OF INVESTIGATIVE JOURNALISTS (July 18, 2012) (noting that "70 percent of donor families said they'd object to a loved one's tissue going to a for-profit

- d. Which OPO leaders, if any, have personal financial interests in tissue banks and/or tissue processing?
- 8. For each of the 58 OPOs, please provide the amount of compensation received by its chief executive officer (CEO) and its chief operating officer (COO) from the OPO or affiliated organization(s) (e.g., the OPO's foundation).
  - a. For each such CEO and COO, provide a breakdown of the compensation received from the OPO and/or affiliated organization(s) based on annual salary, bonuses, or other forms of compensation.
  - b. For each such CEO and COO, please disclose any business, entity, customer, supplier, contractor, or partner with which the OPO had a contract or financial relationship (e.g., tissue processors, cornea banks, funeral homes, OPO foundations, histocompatibility labs,<sup>40</sup> aviation companies, etc.), including but not limited to salary, consulting fees, sales commissions, or equity interests, and list the exact breakdown of compensation the CEO or COO receives.
  - c. How are these financial relationships disclosed to Federal entities and the public?
- 9. Given that some OPOs provide financial compensation for their board members (beyond reasonable expenses for board-related activities and travel/lodging),<sup>41</sup> please provide a list of which of the 58 OPOs compensate their board members, including via contracts or other relationships with external organizations with which the board member maintains a relationship, and the exact amount of compensation received by those board members.
- 10. Which OPOs, or organizations affiliated with OPOs (e.g., TxJet) own, operate, or otherwise maintain a private plane? If multiple OPOs, jointly own, operate, or otherwise maintain a private plane, or a parent organization owning multiple OPOs (e.g., DCI Donor Services) owns, operates, or otherwise maintains a private plane, or if an OPO leases any of their planes to another OPO, transplant center, or other organization, please explain.
  - a. How does UNOS ensure that these private planes are not used for flights that are not directly related to recovering or transplanting an organ?

<sup>41</sup> See "OneLegacy 990 Form," PROPUBLICA (last accessed on Feb. 10, 2020), available at https://projects.propublica.org/nonprofits/organizations/953138799; cf. "OneLegacy Foundation 990 Form," PROPUBLICA (last accessed on Feb. 10, 2020), available at https://projects.propublica.org/nonprofits/organizations/452936915.

business. Yet fewer than one in five said they'd been told that the harvested tissues could go to a for-profit company."), *available at* <u>https://www.icij.org/investigations/tissue/abusing-gift-tissue-donation/</u>.

<sup>&</sup>lt;sup>40</sup> OIG, A-09-16-02010, National Institute of Transplantation, an Independent Histocompatibility Laboratory, Did Not Fully Comply With Medicare's Cost-Reporting Requirements, (Sept. 2018), available at https://oig.hhs.gov/oas/reports/region9/91602010.pdf.

- b. For each flight, please indicate whether there is a corresponding UNOS ID number. For any flight, or any leg of a flight, that does not have a corresponding UNOS ID number, please state the purpose for each leg of the flight—such as "maintenance," or "OPO employees fly to conference," or "personal travel for the CEO of the OPO."
- c. If a private plane is used for unrelated purposes, such as to attend conferences, fundraisers, or for an OPO employee's personal travel, please provide documentation showing to what entity each leg of the flight was billed.

In closing, thank you for your attention to this very important matter. Responses to all questions should be provided no later than March 1, 2020. We look forward to your response. If you have any questions, please contact Rachael Soloway of Chairman Grassley's staff at (202) 224-1124 or David Berick of Ranking Member Wyden's staff at (202) 224-4515.

Sincerely,

Cluck &

Charles E. Grassley Chairman Committee on Finance

Todd Young Member Committee on Finance

Ron Wyden

Ron Wyden Ranking Member Committee on Finance

Benjamin L. Cardin Member Committee on Finance