

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051  
MINORITY (202) 225-5074  
<http://oversight.house.gov>

December 23, 2020

Ms. Jill Grandas  
Executive Director  
DCI Donor Services, Inc.  
1600 Hayes Street, Suite 300  
Nashville, TN 37203

Dear Ms. Grandas:

The Subcommittee on Economic and Consumer Policy seeks documents and information about DCI Donor Services, Inc.'s management and business activities. Mismanagement, waste, and abuse have been widely reported in the organ-transplantation industry. Financial conflicts of interest between not-for-profit organizations and for-profit tissue processing companies have been documented. Much-needed transparency and accountability reforms have been opposed by lobbyists working on behalf of Organ Procurement Organizations (OPOs).

**Shocking Mismanagement Reported in Organ Procurement**

Nationally, there are 58 OPOs. According to one white paper, each of these OPOs "operates as an unchecked regional monopoly," and performance levels across OPOs are highly variable.<sup>1</sup> There is an "astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system," which is "allowing hundreds of thousands of potential organ donations to fall through the cracks."<sup>2</sup> One research analysis estimated there may be up to 28,000 available organs from deceased donors annually that are not ultimately transplanted into patients who need them, which equates to around 25,000 lives that are not saved even when

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<sup>1</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>2</sup> Editorial Board, *She Beat Cancer. Now, She's in Another Fight for Her Life*, *New York Times* (Aug. 20, 2019) (online at [www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html](http://www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html)).

organ donors are located.<sup>3</sup> The burden of OPO failures is disproportionately borne by patients of color, making OPO reform an urgent health care equity issue.<sup>4</sup>

This waste results from various problems afflicting OPOs and the United Network for Organ Sharing (UNOS), which operates as the national Organ Procurement Transplantation Network (OPTN). There are reports of gross mismanagement, such as the failure to hire enough staff to respond to all donation cases.<sup>5</sup> UNOS is plagued by reports of serious lapses in quality control, such as allowing a “startling number” of transplantable organs to be lost, damaged, or delayed in transit—including mistakenly being left on airplanes—to the extent that they become degraded and must be discarded or otherwise result in worse outcomes for patients.<sup>6</sup> There are also reports of financial impropriety.<sup>7</sup>

Meanwhile, OPOs have reportedly misrepresented their efficiency at finding and collecting potential transplantable organs.<sup>8</sup> OPOs have self-reported their performance measures, and expert analysis has shown that the vast majority of OPOs significantly exaggerate their organ procurement rates, and their recovery rates are significantly lower than reported.<sup>9</sup> This has led prominent healthcare analysts and scientists, such as Dr. DJ Patil, the former Chief Data Scientist of the United States, to refer to current data from OPOs as “functionally useless.”<sup>10</sup> The Association of Organ Procurement Organizations (AOPO) has even claimed that

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<sup>5</sup> *Underperforming in New York: Nonprofit Struggles to Recover Transplantable Organs*, Washington Post (Dec. 20, 2018) (online at [www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7\\_story.html](http://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html)).

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<sup>10</sup> Laura and John Arnold, *A Simple Bureaucratic Organ Donation Fix Will Save Thousands of Lives*, STAT, (July 23, 2019) (online at [www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/](http://www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/)).

“self-reported” data could not be used to decertify an OPO because “accuracy and consistency of data cannot be assured.”<sup>11</sup>

This litany of reports is an indictment against the industry and demonstrates the need for reform.

### **Health Authorities Attempt to Reform the Organ Procurement System**

On July 10, 2019, President Trump signed an executive order titled “Advancing American Kidney Health,” to “establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.”<sup>12</sup> On December 17, 2019, HHS announced a proposed rule from the Centers for Medicare and Medicaid Services (CMS) to improve OPO performance metrics and accountability.<sup>13</sup> On November 20, 2020, CMS finalized a rule to enforce new objective measures for donation and transplantation, update those benchmarks based on national OPO performance, allow for some competition for OPOs with middling performance, and require more frequent recertification reviews.<sup>14</sup>

In explaining the need for its rule, HHS found that OPOs may be choosing not to pursue procurement of organs from single-organ donors because the OPOs want an increased organs-per-donor metric. This means that life-saving organs are not collected. As HHS itself projected, compliance with the new OPO performance measures would lead to 5,600 to 7,300 additional organ transplants per year.<sup>15</sup>

Tens of thousands of patients are currently being underserved by poor-performing OPOs, and 33 Americans die every day for lack of an organ transplant. For these reasons, we look forward to working with you and the incoming Administration to accelerate enforcement of the final rule and begin decertifying failing OPOs as soon as possible.<sup>16</sup>

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<sup>11</sup> *Despite Low Performance, Organ Collection Group Gets New Federal Contract*, Washington Post (Feb. 10, 2019) (online at [www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc\\_story.html](http://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html)).

<sup>12</sup> Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 10, 2019).

<sup>13</sup> Department of Health and Human Services, *Press Release: Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply* (online at [www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html](http://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html)).

<sup>14</sup> Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020) (online at [www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos](http://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos)).

<sup>15</sup> *Id.*

<sup>16</sup> Editorial Board, *Many Die Waiting for Organs*. (Aug. 1, 2020) (online at [www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f\\_story.html](http://www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f_story.html)).

## **AOPO and OPOs Lobbied Against Proposed Reforms**

In response to this rule, AOPO has seemingly “ratcheted up dramatically” its lobbying expenditures to oppose the Executive Order and HHS’s proposed rule. One OPO executive stated at an official UNOS meeting that it was “fortunate” that federal agencies were dealing with the coronavirus, because that would allow OPOs to mount a “real congressional action campaign” to oppose new reforms. While AOPO, its members, and affiliated organizations spent a total of only about \$160,000 per year on lobbying in 2017 and 2018 combined, their spending nearly tripled in 2019 to \$452,000. In the first half of 2020, lobbying expenditures had already reached \$450,000. AOPO reportedly told its members that it would change its nonprofit status from 501(c)(3) to (c)(6) to allow for freer spending on lobbying.<sup>17</sup> OPOs in Los Angeles, Chicago, New England, Philadelphia, Houston, Seattle, Minnesota, and Nashville began lobbying last year under a new coalition, the Organ Donation Advocacy Group.<sup>18</sup>

While AOPO and the OPO industry have been lobbying against life-saving reforms, they have also engaged in lobbying efforts to receive federal funding intended to support frontline healthcare workers and struggling small businesses during the coronavirus pandemic. Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress established the \$175 billion Provider Relief Fund to support frontline health care providers.<sup>19</sup> AOPO requested from HHS that OPOs be given some of these discretionary funds, contending that “the Congressional intent of the Act is to provide an influx of funds to the healthcare industry, which the federally regulated OPOs service.”<sup>20</sup> An investigative report found that while AOPO and OPOs “battle Trump’s plan, some in the industry have been approved for what may total more than \$100 million” in Paycheck Protection Program (PPP) loans intended for struggling small businesses, “even though, in some cases, organ procurement industry borrowers involved in the lobbying are sitting on large financial assets, expensive real estate, or other reserves, in one case valued at more than \$112 million.”<sup>21</sup>

## **OPO Industry Conflicts of Interest and Misuse of Funds**

We are also concerned about possible conflicts of interests in the OPO industry that may detract from the OPOs’ core mission of recovering organs for transplant. Recent investigative reporting has exposed suspicious relationships between OPOs and other segments of the health sector unrelated to organ transplantation, such as the multi-billion dollar tissue business, medical

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<sup>17</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>18</sup> Open Secrets, *Client Profile: Organ Donation Advocacy Group* (online at [www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038](http://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038)).

<sup>19</sup> Pub. L. No: 116-136, §15011.

<sup>20</sup> Letter from Kelly Ranum, President, Association of Organ Procurement Organizations, to The Honorable Alex M. Azar II, Secretary, Department of Health and Human Services (Apr. 30, 2020).

<sup>21</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

examiners, and coroners.<sup>22</sup> A new report finds that “OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.”<sup>23</sup>

Your OPO itself has raised some concerns. DCI Donor Services has many potential conflicts of interest, since in addition to operating three OPOs (Tennessee Donor Services, New Mexico Donor Services, and Sierra Donor Services), DCI operates over 207 dialysis centers, a tissue bank, and an eye bank.<sup>24</sup>

To assist the Subcommittee in its review of this matter, please provide the following information for DCI Donor Services and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
3. All documents related to compliance with CMS’s proposed or final performance standards, including analyses of past and projected future performance and plans to comply with standards;
4. All policies and procedures related to:
  - a. conflicts of interest;
  - b. Standard Acquisition Cost (SAC) fees for all organs, including their calculation and approval;
  - c. activities unrelated to organ transplantation, such as business with tissue banks, tissue processors, laboratories, coroners, and funeral homes (including documents related to whether the OPO runs its own tissue bank, tissue processor, laboratory, or other business operation unrelated to organ transplantation);
  - d. tissue processing, including avoiding conflicts with organ-recovery priorities and disclosures to donors about possible conflicts of interest, as well as all consent forms presented to donor families related to organ and tissue donation; and
  - e. organs that are lost, delayed, damaged, or otherwise mishandled in transit, including all policies in place to ensure the successful tracking and

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<sup>22</sup> *How Organ and Tissue Donation Companies Worked Their Way into the County Morgue*, Los Angeles Times (Oct. 13, 2019) (online at [www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html](http://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html)).

<sup>23</sup> The Bridgespan Group, *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations* (Nov. 2020) (online at [www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf](http://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf)).

<sup>24</sup> DCI Donor Services, *Our History* (online at <https://dcids.org/history/>) (accessed Dec. 4, 2020).

transportation of organs; and

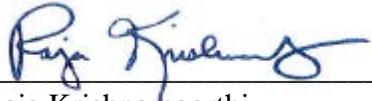
5. All documents related to any contract, grant, consulting agreement, or other relationship between the OPO and any other entity, including tissue processors, laboratories, coroners, or funeral homes, and a list of all transfers of funds under such arrangements and the transfer's purpose;
6. All documents related to meetings of the board of directors, including agendas, meeting minutes, and presentation slide decks, since January 1, 2014;
7. A list of all governing board members and officers, and for each board member or officer:
  - a. title(s);
  - b. length of service;
  - c. compensation from the OPO for the past four years;
  - d. compensation from any related foundation for the past four years;
  - e. compensation from any OPO-affiliated entity for the past four years;
  - f. income from other entities that have a contractual relationship with the OPO or any related foundation or other affiliated entity, for the past four years;
  - g. all terms of board membership or employment, at any time, at UNOS/OPTN, AOPO, or another OPO, OPO foundation, or OPO-affiliated entity;
  - h. all other employment for the past four years; and
  - i. a list of any family members of an OPO executive or board member employed by any OPO, OPO foundation, OPO-affiliated entity, or any other entity with which your OPO maintains a business relationship, including their position, compensation, and a description of how the relationship was disclosed; and
8. All employment contracts in which bonus or compensation is tied to volume-based incentives for organ, tissue, or any other medical products of human origin;
9. All documents related to reviews by the OPTN, UNOS and/or the UNOS Membership and Professional Standards Committee (MPSC), including all meeting transcripts and summaries, all corrective action plans generated, all follow-up reviews regarding corrective plans, all consultant agreements and referrals, and whether the OPO was ever considered a Member Not in Good Standing (with corresponding dates);
10. All documents related to the calculation of the Standard Acquisition Cost (SAC) fees for all organs for years 2015 – 2019, broken down by each organ category, including:

- a. an itemized breakdown of how OPO costs were apportioned to determine the SAC; and
  - b. costs attributable to each organ type for multi-organ recoveries; and
11. For any jet or other form of private aviation that the OPO, through itself or any subsidiary or affiliate, owns, rents, or otherwise uses or controls, please provide:
  - a. a full list of flights or legs of flights taken since January 1, 2014, indicating for which flights or legs of flights there was no associated UNOS ID#;
  - b. the passenger log for each such flight or leg of a flight;
  - c. the purpose of each such flight or leg of a flight; and
  - d. documentation showing to what entity each flight or leg of a flight was billed; and
12. All documents 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;
13. All emails and other communications between officers, employees, or board members of your OPO and UNOS/OPTN, AOPO, and/or other lobbyists or lobbying group(s) regarding HHS's proposed rule of December 17, 2019, or final rule from November 20, 2020, including any contemplated or planned outreach to HHS, CMS, HRSA and/or any of HRSA's contractors, and/or Congressional offices (personal and Committee staff); and
14. All documents related to any decision to apply for, receive, and keep or return PPP loans or other coronavirus-related loans or grants, including, board minutes, loan application documents, and receipt of transfer.

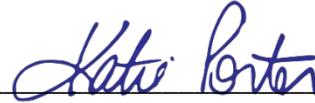
The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request.

If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy



Katie Porter  
Member of Congress

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

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December 23, 2020

Ms. Kellie Hanner  
President and Chief Executive Officer  
Indiana Donor Network  
3760 Guion Road  
Indianapolis, IN 46222

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This litany of reports is an indictment against the industry and demonstrates the need for reform.

### **Health Authorities Attempt to Reform the Organ Procurement System**

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### **AOPO and OPOs Lobbied Against Proposed Reforms**

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### **OPO Industry Conflicts of Interest and Misuse of Funds**

We are also concerned about possible conflicts of interests in the OPO industry that may detract from the OPOs’ core mission of recovering organs for transplant. Recent investigative reporting has exposed suspicious relationships between OPOs and other segments of the health sector unrelated to organ transplantation, such as the multi-billion dollar tissue business, medical examiners, and coroners.<sup>22</sup> A new report finds that “OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.”<sup>23</sup>

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<sup>18</sup> Open Secrets, *Client Profile: Organ Donation Advocacy Group* (online at [www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038](http://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038)).

<sup>19</sup> Pub. L. No: 116-136, §15011.

<sup>20</sup> Letter from Kelly Ranum, President, Association of Organ Procurement Organizations, to The Honorable Alex M. Azar II, Secretary, Department of Health and Human Services (Apr. 30, 2020).

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<sup>22</sup> *How Organ and Tissue Donation Companies Worked Their Way into the County Morgue*, Los Angeles Times (Oct. 13, 2019) (online at [www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html](http://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html)).

<sup>23</sup> The Bridgespan Group, *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations* (Nov. 2020) (online at

Your OPO itself has raised some concerns. Indiana Donor Network operates as a subsidiary a private airline called TxJet, with three airplanes, and claims that, “as a nonprofit, a small percentage of TxJet operations is allowed to be used for non-organ transplant flights.”<sup>24</sup> For 2019, TxJet reported net revenues of over \$2.8 million and net assets of over \$7 million.<sup>25</sup>

To assist the Subcommittee in its review of this matter, please provide the following information for Indiana Donor Network and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
3. All documents related to compliance with CMS’s proposed or final performance standards, including analyses of past and projected future performance and plans to comply with standards;
4. All policies and procedures related to:
  - a. conflicts of interest;
  - b. Standard Acquisition Cost (SAC) fees for all organs, including their calculation and approval;
  - c. activities unrelated to organ transplantation, such as business with tissue banks, tissue processors, laboratories, coroners, and funeral homes (including documents related to whether the OPO runs its own tissue bank, tissue processor, laboratory, or other business operation unrelated to organ transplantation);
  - d. tissue processing, including avoiding conflicts with organ-recovery priorities and disclosures to donors about possible conflicts of interest, as well as all consent forms presented to donor families related to organ and tissue donation; and
  - e. organs that are lost, delayed, damaged, or otherwise mishandled in transit, including all policies in place to ensure the successful tracking and transportation of organs; and
5. All documents related to any contract, grant, consulting agreement, or other relationship between the OPO and any other entity, including tissue processors, laboratories, coroners, or funeral homes, and a list of all transfers of funds under such arrangements and the transfer’s purpose;

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[www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf](http://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf).

<sup>24</sup> Tx Jet, *Frequently Asked Questions* (online at <https://txjet.org/faq/>).

<sup>25</sup> IRS Form 990 for TxJet, Tax Year 2019 (online at [www.causeiq.com/organizations/view\\_990/463166639/f9d15565dd4857956dea7956f5d16767](http://www.causeiq.com/organizations/view_990/463166639/f9d15565dd4857956dea7956f5d16767)).

6. All documents related to meetings of the board of directors, including agendas, meeting minutes, and presentation slide decks, since January 1, 2014;
7. A list of all governing board members and officers, and for each board member or officer:
  - a. title(s);
  - b. length of service;
  - c. compensation from the OPO for the past four years;
  - d. compensation from any related foundation for the past four years;
  - e. compensation from any OPO-affiliated entity for the past four years;
  - f. income from other entities that have a contractual relationship with the OPO or any related foundation or other affiliated entity, for the past four years;
  - g. all terms of board membership or employment, at any time, at UNOS/OPTN, AOPO, or another OPO, OPO foundation, or OPO-affiliated entity;
  - h. all other employment for the past four years; and
  - i. a list of any family members of an OPO executive or board member employed by any OPO, OPO foundation, OPO-affiliated entity, or any other entity with which your OPO maintains a business relationship, including their position, compensation, and a description of how the relationship was disclosed; and
8. All employment contracts in which bonus or compensation is tied to volume-based incentives for organ, tissue, or any other medical products of human origin;
9. All documents related to reviews by the OPTN, UNOS and/or the UNOS Membership and Professional Standards Committee (MPSC), including all meeting transcripts and summaries, all corrective action plans generated, all follow-up reviews regarding corrective plans, all consultant agreements and referrals, and whether the OPO was ever considered a Member Not in Good Standing (with corresponding dates);
10. All documents related to the calculation of the Standard Acquisition Cost (SAC) fees for all organs for years 2015 – 2019, broken down by each organ category, including:
  - a. an itemized breakdown of how OPO costs were apportioned to determine the SAC; and
  - b. costs attributable to each organ type for multi-organ recoveries; and
11. For any jet or other form of private aviation that the OPO, through itself or any subsidiary or affiliate, owns, rents, or otherwise uses or controls, please provide:

- a. a full list of flights or legs of flights taken since January 1, 2014, indicating for which flights or legs of flights there was no associated UNOS ID#;
  - b. the passenger log for each such flight or leg of a flight;
  - c. the purpose of each such flight or leg of a flight; and
  - d. documentation showing to what entity each flight or leg of a flight was billed; and
12. All documents 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;
  13. All emails and other communications between officers, employees, or board members of your OPO and UNOS/OPTN, AOPO, and/or other lobbyists or lobbying group(s) regarding HHS's proposed rule of December 17, 2019, or final rule from November 20, 2020, including any contemplated or planned outreach to HHS, CMS, HRSA and/or any of HRSA's contractors, and/or Congressional offices (personal and Committee staff); and
  14. All documents related to any decision to apply for, receive, and keep or return PPP loans or other coronavirus-related loans or grants, including, board minutes, loan application documents, and receipt of transfer.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request.

If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy



Katie Porter  
Member of Congress

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051

MINORITY (202) 225-5074

<http://oversight.house.gov>

December 23, 2020

Ms. Julie Bergin  
President and Chief Executive Officer  
Kentucky Organ Donor Affiliates  
10160 Linn Station Road  
Louisville, KY 40223

Dear Ms. Bergin:

The Subcommittee on Economic and Consumer Policy seeks documents and information about Kentucky Organ Donor Affiliates' management and business activities. Mismanagement, waste, and abuse have been widely reported in the organ-transplantation industry. Financial conflicts of interest between not-for-profit organizations and for-profit tissue processing companies have been documented. Much-needed transparency and accountability reforms have been opposed by lobbyists working on behalf of Organ Procurement Organizations (OPOs).

**Shocking Mismanagement Reported in Organ Procurement**

Nationally, there are 58 OPOs. According to one white paper, each of these OPOs "operates as an unchecked regional monopoly," and performance levels across OPOs are highly variable.<sup>1</sup> There is an "astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system," which is "allowing hundreds of thousands of potential organ donations to fall through the cracks."<sup>2</sup> One research analysis estimated there may be up to 28,000 available organs from deceased donors annually that are not ultimately transplanted into patients who need them, which equates to around 25,000 lives that are not saved even when

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<sup>1</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>2</sup> Editorial Board, *She Beat Cancer. Now, She's in Another Fight for Her Life.*, New York Times (Aug. 20, 2019) (online at [www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html](http://www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html)).

organ donors are located.<sup>3</sup> The burden of OPO failures is disproportionately borne by patients of color, making OPO reform an urgent health care equity issue.<sup>4</sup>

This waste results from various problems afflicting OPOs and the United Network for Organ Sharing (UNOS), which operates as the national Organ Procurement Transplantation Network (OPTN). There are reports of gross mismanagement, such as the failure to hire enough staff to respond to all donation cases.<sup>5</sup> UNOS is plagued by reports of serious lapses in quality control, such as allowing a “startling number” of transplantable organs to be lost, damaged, or delayed in transit—including mistakenly being left on airplanes—to the extent that they become degraded and must be discarded or otherwise result in worse outcomes for patients.<sup>6</sup> There are also reports of financial impropriety.<sup>7</sup>

Meanwhile, OPOs have reportedly misrepresented their efficiency at finding and collecting potential transplantable organs.<sup>8</sup> OPOs have self-reported their performance measures, and expert analysis has shown that the vast majority of OPOs significantly exaggerate their organ procurement rates, and their recovery rates are significantly lower than reported.<sup>9</sup> This has led prominent healthcare analysts and scientists, such as Dr. DJ Patil, the former Chief Data Scientist of the United States, to refer to current data from OPOs as “functionally useless.”<sup>10</sup> The Association of Organ Procurement Organizations (AOPO) has even claimed that “self-reported” data could not be used to decertify an OPO because “accuracy and consistency of data cannot be assured.”<sup>11</sup>

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<sup>3</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>4</sup> Bloom Works, *The Costly Effects of an Outdated Organ Donation System: Inequity in Organ Donation* (online at <https://bloomworks.digital/organdonationreform/Inequity>).

<sup>5</sup> *Underperforming in New York: Nonprofit Struggles to Recover Transplantable Organs*, Washington Post (Dec. 20, 2018) (online at [www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7\\_story.html](http://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html)).

<sup>6</sup> *How Lifesaving Organs for Transplant Go Missing in Transit*, Kaiser Health News (Feb. 10, 2020) (online at <https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/>).

<sup>7</sup> *Taxpayers Help Pay for Organ Donor Groups’ Parties, Rose Parade Expenses*, Trib Live (Oct. 19, 2013) (online at <https://archive.triblive.com/local/pittsburgh-alleggheny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>).

<sup>8</sup> *Video Op-Ed: 11,000 American Patients Will Die This Year Waiting for Transplants*, New York Times (June 11, 2019) (online at [www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html](http://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html)).

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<sup>17</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>18</sup> Open Secrets, *Client Profile: Organ Donation Advocacy Group* (online at [www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038](http://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038)).

<sup>19</sup> Pub. L. No: 116-136, §15011.

<sup>20</sup> Letter from Kelly Ranum, President, Association of Organ Procurement Organizations, to The Honorable Alex M. Azar II, Secretary, Department of Health and Human Services (Apr. 30, 2020).

<sup>21</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>22</sup> *How Organ and Tissue Donation Companies Worked Their Way into the County Morgue*, Los Angeles Times (Oct. 13, 2019) (online at [www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html](http://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html)).

<sup>23</sup> The Bridgespan Group, *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations* (Nov. 2020) (online at

Your OPO itself has raised some concerns. Kentucky Organ Donor Affiliates falls into CMS's third tier of failing OPOs, third-to-last, and would need to recover over 180 additional organs a year to meet new standards.<sup>24</sup> We are also concerned about conflicts of interest between organ transplantation and the tissue business, since your Chief Clinical Officer is also on the Board of Governors for the American Association of Tissue Banks.<sup>25</sup>

To assist the Subcommittee in its review of this matter, please provide the following information for Kentucky Organ Donor Affiliates and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
3. All documents related to compliance with CMS's proposed or final performance standards, including analyses of past and projected future performance and plans to comply with standards;
4. All policies and procedures related to:
  - a. conflicts of interest;
  - b. Standard Acquisition Cost (SAC) fees for all organs, including their calculation and approval;
  - c. activities unrelated to organ transplantation, such as business with tissue banks, tissue processors, laboratories, coroners, and funeral homes (including documents related to whether the OPO runs its own tissue bank, tissue processor, laboratory, or other business operation unrelated to organ transplantation);
  - d. tissue processing, including avoiding conflicts with organ-recovery priorities and disclosures to donors about possible conflicts of interest, as well as all consent forms presented to donor families related to organ and tissue donation; and
  - e. organs that are lost, delayed, damaged, or otherwise mishandled in transit, including all policies in place to ensure the successful tracking and transportation of organs; and

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[www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf](http://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf)).

<sup>24</sup> Centers for Medicare and Medicaid Services, *Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule* (Nov. 20, 2020) (online at [www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf](http://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf)).

<sup>25</sup> American Association of Tissue Banks, *AATB Board of Governors* (online at [www.aatb.org/about-us/board-governors](http://www.aatb.org/about-us/board-governors)) (accessed Dec. 4, 2020).

5. All documents related to any contract, grant, consulting agreement, or other relationship between the OPO and any other entity, including tissue processors, laboratories, coroners, or funeral homes, and a list of all transfers of funds under such arrangements and the transfer's purpose;
6. All documents related to meetings of the board of directors, including agendas, meeting minutes, and presentation slide decks, since January 1, 2014;
7. A list of all governing board members and officers, and for each board member or officer:
  - a. title(s);
  - b. length of service;
  - c. compensation from the OPO for the past four years;
  - d. compensation from any related foundation for the past four years;
  - e. compensation from any OPO-affiliated entity for the past four years;
  - f. income from other entities that have a contractual relationship with the OPO or any related foundation or other affiliated entity, for the past four years;
  - g. all terms of board membership or employment, at any time, at UNOS/OPTN, AOPO, or another OPO, OPO foundation, or OPO-affiliated entity;
  - h. all other employment for the past four years; and
  - i. a list of any family members of an OPO executive or board member employed by any OPO, OPO foundation, OPO-affiliated entity, or any other entity with which your OPO maintains a business relationship, including their position, compensation, and a description of how the relationship was disclosed; and
8. All employment contracts in which bonus or compensation is tied to volume-based incentives for organ, tissue, or any other medical products of human origin;
9. All documents related to reviews by the OPTN, UNOS and/or the UNOS Membership and Professional Standards Committee (MPSC), including all meeting transcripts and summaries, all corrective action plans generated, all follow-up reviews regarding corrective plans, all consultant agreements and referrals, and whether the OPO was ever considered a Member Not in Good Standing (with corresponding dates);
10. All documents related to the calculation of the Standard Acquisition Cost (SAC) fees for all organs for years 2015 – 2019, broken down by each organ category, including:
  - a. an itemized breakdown of how OPO costs were apportioned to determine the SAC; and
  - b. costs attributable to each organ type for multi-organ recoveries;

11. For any jet or other form of private aviation that the OPO, through itself or any subsidiary or affiliate, owns, rents, or otherwise uses or controls, please provide:
  - a. a full list of flights or legs of flights taken since January 1, 2014, indicating for which flights or legs of flights there was no associated UNOS ID#;
  - b. the passenger log for each such flight or leg of a flight;
  - c. the purpose of each such flight or leg of a flight; and
  - d. documentation showing to what entity each flight or leg of a flight was billed; and
12. All documents 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;
13. All emails and other communications between officers, employees, or board members of your OPO and UNOS/OPTN, AOPO, and/or other lobbyists or lobbying group(s) regarding HHS's proposed rule of December 17, 2019, or final rule from November 20, 2020, including any contemplated or planned outreach to HHS, CMS, HRSA and/or any of HRSA's contractors, and/or Congressional offices (personal and Committee staff); and
14. All documents related to any decision to apply for, receive, and keep or return PPP loans or other coronavirus-related loans or grants, including, board minutes, loan application documents, and receipt of transfer.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy



Katie Porter  
Member of Congress

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051

MINORITY (202) 225-5074

<http://oversight.house.gov>

December 23, 2020

Mr. Christopher B. Meeks  
Executive Director  
Legacy of Hope  
516 20th Street South  
Birmingham, AL 35233

Dear Mr. Meeks:

The Subcommittee on Economic and Consumer Policy seeks documents and information about Legacy of Hope's management and business activities. Mismanagement, waste, and abuse have been widely reported in the organ-transplantation industry. Financial conflicts of interest between not-for-profit organizations and for-profit tissue processing companies have been documented. Much-needed transparency and accountability reforms have been opposed by lobbyists working on behalf of Organ Procurement Organizations (OPOs).

**Shocking Mismanagement Reported in Organ Procurement**

Nationally, there are 58 OPOs. According to one white paper, each of these OPOs "operates as an unchecked regional monopoly," and performance levels across OPOs are highly variable.<sup>1</sup> There is an "astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system," which is "allowing hundreds of thousands of potential organ donations to fall through the cracks."<sup>2</sup> One research analysis estimated there may be up to 28,000 available organs from deceased donors annually that are not ultimately transplanted into patients who need them, which equates to around 25,000 lives that are not saved even when

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<sup>1</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>2</sup> Editorial Board, *She Beat Cancer. Now, She's in Another Fight for Her Life.*, New York Times (Aug. 20, 2019) (online at [www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html](http://www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html)).

organ donors are located.<sup>3</sup> The burden of OPO failures is disproportionately borne by patients of color, making OPO reform an urgent health care equity issue.<sup>4</sup>

This waste results from various problems afflicting OPOs and the United Network for Organ Sharing (UNOS), which operates as the national Organ Procurement Transplantation Network (OPTN). There are reports of gross mismanagement, such as the failure to hire enough staff to respond to all donation cases.<sup>5</sup> UNOS is plagued by reports of serious lapses in quality control, such as allowing a “startling number” of transplantable organs to be lost, damaged, or delayed in transit—including mistakenly being left on airplanes—to the extent that they become degraded and must be discarded or otherwise result in worse outcomes for patients.<sup>6</sup> There are also reports of financial impropriety.<sup>7</sup>

Meanwhile, OPOs have reportedly misrepresented their efficiency at finding and collecting potential transplantable organs.<sup>8</sup> OPOs have self-reported their performance measures, and expert analysis has shown that the vast majority of OPOs significantly exaggerate their organ procurement rates, and their recovery rates are significantly lower than reported.<sup>9</sup> This has led prominent healthcare analysts and scientists, such as Dr. DJ Patil, the former Chief Data Scientist of the United States, to refer to current data from OPOs as “functionally useless.”<sup>10</sup> The Association of Organ Procurement Organizations (AOPO) has even claimed that “self-reported” data could not be used to decertify an OPO because “accuracy and consistency of data cannot be assured.”<sup>11</sup>

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<sup>3</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>4</sup> Bloom Works, *The Costly Effects of an Outdated Organ Donation System: Inequity in Organ Donation* (online at <https://bloomworks.digital/organdonationreform/Inequity>).

<sup>5</sup> *Underperforming in New York: Nonprofit Struggles to Recover Transplantable Organs*, Washington Post (Dec. 20, 2018) (online at [www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7\\_story.html](http://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html)).

<sup>6</sup> *How Lifesaving Organs for Transplant Go Missing in Transit*, Kaiser Health News (Feb. 10, 2020) (online at <https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/>).

<sup>7</sup> *Taxpayers Help Pay for Organ Donor Groups’ Parties, Rose Parade Expenses*, Trib Live (Oct. 19, 2013) (online at <https://archive.triblive.com/local/pittsburgh-alleggheny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>).

<sup>8</sup> *Video Op-Ed: 11,000 American Patients Will Die This Year Waiting for Transplants*, New York Times (June 11, 2019) (online at [www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html](http://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html)).

<sup>9</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>10</sup> Laura and John Arnold, *A Simple Bureaucratic Organ Donation Fix Will Save Thousands of Lives*, STAT, (July 23, 2019) (online at [www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/](http://www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/)).

<sup>11</sup> *Despite Low Performance, Organ Collection Group Gets New Federal Contract*, Washington Post (Feb. 10, 2019) (online at [www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc\\_story.html](http://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html)).

This litany of reports is an indictment against the industry and demonstrates the need for reform.

### **Health Authorities Attempt to Reform the Organ Procurement System**

On July 10, 2019, President Trump signed an executive order titled “Advancing American Kidney Health,” to “establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.”<sup>12</sup> On December 17, 2019, HHS announced a proposed rule from the Centers for Medicare and Medicaid Services (CMS) to improve OPO performance metrics and accountability.<sup>13</sup> On November 20, 2020, CMS finalized a rule to enforce new objective measures for donation and transplantation, update those benchmarks based on national OPO performance, allow for some competition for OPOs with middling performance, and require more frequent recertification reviews.<sup>14</sup>

In explaining the need for its rule, HHS found that OPOs may be choosing not to pursue procurement of organs from single-organ donors because the OPOs want an increased organs-per-donor metric. This means that life-saving organs are not collected. As HHS itself projected, compliance with the new OPO performance measures would lead to 5,600 to 7,300 additional organ transplants per year.<sup>15</sup>

Tens of thousands of patients are currently being underserved by poor-performing OPOs, and 33 Americans die every day for lack of an organ transplant. For these reasons, we look forward to working with you and the incoming Administration to accelerate enforcement of the final rule and begin decertifying failing OPOs as soon as possible.<sup>16</sup>

### **AOPO and OPOs Lobbied Against Proposed Reforms**

In response to this rule, AOPO has seemingly “ratcheted up dramatically” its lobbying expenditures to oppose the Executive Order and HHS’s proposed rule. One OPO executive stated at an official UNOS meeting that it was “fortunate” that federal agencies were dealing with the coronavirus, because that would allow OPOs to mount a “real congressional action campaign” to oppose new reforms. While AOPO, its members, and affiliated organizations

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<sup>12</sup> Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 10, 2019) (online at [www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/](http://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/)).

<sup>13</sup> Department of Health and Human Services, *Press Release: Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply* (online at [www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html](http://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html)).

<sup>14</sup> Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020) (online at [www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos](http://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos)).

<sup>15</sup> *Id.*

<sup>16</sup> Editorial Board, *Many Die Waiting for Organs*. (Aug. 1, 2020) (online at [www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f\\_story.html](http://www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f_story.html)).

spent a total of only about \$160,000 per year on lobbying in 2017 and 2018 combined, their spending nearly tripled in 2019 to \$452,000. In the first half of 2020, lobbying expenditures had already reached \$450,000. AOPO reportedly told its members that it would change its nonprofit status from 501(c)(3) to (c)(6) to allow for freer spending on lobbying.<sup>17</sup> OPOs in Los Angeles, Chicago, New England, Philadelphia, Houston, Seattle, Minnesota, and Nashville began lobbying last year under a new coalition, the Organ Donation Advocacy Group.<sup>18</sup>

While AOPO and the OPO industry have been lobbying against life-saving reforms, they have also engaged in lobbying efforts to receive federal funding intended to support frontline healthcare workers and struggling small businesses during the coronavirus pandemic. Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress established the \$175 billion Provider Relief Fund to support frontline health care providers.<sup>19</sup> AOPO requested from HHS that OPOs be given some of these discretionary funds, contending that “the Congressional intent of the Act is to provide an influx of funds to the healthcare industry, which the federally regulated OPOs service.”<sup>20</sup> An investigative report found that while AOPO and OPOs “battle Trump’s plan, some in the industry have been approved for what may total more than \$100 million” in Paycheck Protection Program (PPP) loans intended for struggling small businesses, “even though, in some cases, organ procurement industry borrowers involved in the lobbying are sitting on large financial assets, expensive real estate, or other reserves, in one case valued at more than \$112 million.”<sup>21</sup>

### **OPO Industry Conflicts of Interest and Misuse of Funds**

We are also concerned about possible conflicts of interests in the OPO industry that may detract from the OPOs’ core mission of recovering organs for transplant. Recent investigative reporting has exposed suspicious relationships between OPOs and other segments of the health sector unrelated to organ transplantation, such as the multi-billion dollar tissue business, medical examiners, and coroners.<sup>22</sup> A new report finds that “OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.”<sup>23</sup>

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<sup>17</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>18</sup> Open Secrets, *Client Profile: Organ Donation Advocacy Group* (online at [www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038](http://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038)).

<sup>19</sup> Pub. L. No: 116-136, §15011.

<sup>20</sup> Letter from Kelly Ranum, President, Association of Organ Procurement Organizations, to The Honorable Alex M. Azar II, Secretary, Department of Health and Human Services (Apr. 30, 2020).

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<sup>22</sup> *How Organ and Tissue Donation Companies Worked Their Way into the County Morgue*, Los Angeles Times (Oct. 13, 2019) (online at [www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html](http://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html)).

<sup>23</sup> The Bridgespan Group, *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations* (Nov. 2020) (online at

Your OPO itself has raised some concerns. A judge sentenced the former director of the Alabama Organ Center to 13 months in prison for his role in a scheme to take kickbacks from a funeral home that did business with the OPO. Over the course of four years, director Demosthenes Lalisian solicited and received kickbacks totaling \$242,344, and his deputy director received kickbacks totaling \$256,207, in exchange for promoting the funeral home and steering to it services paid for by the OPO's parent foundation.<sup>24</sup> The Alabama Organ Center was rebranded as Legacy of Hope, where it continues its legacy of poor performance, requiring nearly 100 additional organs a year to meet HHS's new standards.<sup>25</sup>

To assist the Subcommittee in its review of this matter, please provide the following information for Legacy of Hope and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
3. All documents related to compliance with CMS's proposed or final performance standards, including analyses of past and projected future performance and plans to comply with standards;
4. All policies and procedures related to:
  - a. conflicts of interest;
  - b. Standard Acquisition Cost (SAC) fees for all organs, including their calculation and approval;
  - c. activities unrelated to organ transplantation, such as business with tissue banks, tissue processors, laboratories, coroners, and funeral homes (including documents related to whether the OPO runs its own tissue bank, tissue processor, laboratory, or other business operation unrelated to organ transplantation);
  - d. tissue processing, including avoiding conflicts with organ-recovery priorities and disclosures to donors about possible conflicts of interest, as well as all consent forms presented to donor families related to organ and tissue donation; and

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[www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf](http://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf).

<sup>24</sup> U.S. Attorney's Office, Northern District of Alabama, *Press Release: Former Alabama Organ Center Executive Sentenced for Fraud* (May 16, 2012) (online at <https://archives.fbi.gov/archives/birmingham/press-releases/2012/former-alabama-organ-center-executive-sentenced-for-fraud>).

<sup>25</sup> Centers for Medicare and Medicaid Services, *Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule* (Nov. 20, 2020) (online at [www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf](http://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf)).

- e. organs that are lost, delayed, damaged, or otherwise mishandled in transit, including all policies in place to ensure the successful tracking and transportation of organs; and
5. All documents related to any contract, grant, consulting agreement, or other relationship between the OPO and any other entity, including tissue processors, laboratories, coroners, or funeral homes, and a list of all transfers of funds under such arrangements and the transfer's purpose;
6. All documents related to meetings of the board of directors, including agendas, meeting minutes, and presentation slide decks, since January 1, 2014;
7. A list of all governing board members and officers, and for each board member or officer:
  - a. title(s);
  - b. length of service;
  - c. compensation from the OPO for the past four years;
  - d. compensation from any related foundation for the past four years;
  - e. compensation from any OPO-affiliated entity for the past four years;
  - f. income from other entities that have a contractual relationship with the OPO or any related foundation or other affiliated entity, for the past four years;
  - g. all terms of board membership or employment, at any time, at UNOS/OPTN, AOPO, or another OPO, OPO foundation, or OPO-affiliated entity;
  - h. all other employment for the past four years; and
  - i. a list of any family members of an OPO executive or board member employed by any OPO, OPO foundation, OPO-affiliated entity, or any other entity with which your OPO maintains a business relationship, including their position, compensation, and a description of how the relationship was disclosed; and
8. All employment contracts in which bonus or compensation is tied to volume-based incentives for organ, tissue, or any other medical products of human origin;
9. All documents related to reviews by the OPTN, UNOS and/or the UNOS Membership and Professional Standards Committee (MPSC), including all meeting transcripts and summaries, all corrective action plans generated, all follow-up reviews regarding corrective plans, all consultant agreements and referrals, and whether the OPO was every considered a Member Not in Good Standing (with corresponding dates);
10. All documents related to the calculation of the Standard Acquisition Cost (SAC) fees for all organs for years 2015 – 2019, broken down by each organ category, including:

- a. an itemized breakdown of how OPO costs were apportioned to determine the SAC; and
  - b. costs attributable to each organ type for multi-organ recoveries; and
11. For any jet or other form of private aviation that the OPO, through itself or any subsidiary or affiliate, owns, rents, or otherwise uses or controls, please provide:
- a. a full list of flights or legs of flights taken since January 1, 2014, indicating for which flights or legs of flights there was no associated UNOS ID#;
  - b. the passenger log for each such flight or leg of a flight;
  - c. the purpose of each such flight or leg of a flight; and
  - d. documentation showing to what entity each flight or leg of a flight was billed; and
12. All documents 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;
13. All emails and other communications between officers, employees, or board members of your OPO and UNOS/OPTN, AOPO, and/or other lobbyists or lobbying group(s) regarding HHS's proposed rule of December 17, 2019, or final rule from November 20, 2020, including any contemplated or planned outreach to HHS, CMS, HRSA and/or any of HRSA's contractors, and/or Congressional offices (personal and Committee staff); and
14. All documents related to any decision to apply for, receive, and keep or return PPP loans or other coronavirus-related loans or grants, including, board minutes, loan application documents, and receipt of transfer.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy



Katie Porter  
Member of Congress

Mr. Christopher B. Meeks  
Page 8

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051

MINORITY (202) 225-5074

<http://oversight.house.gov>

December 23, 2020

Dr. Sam Salama  
Executive Director  
Life Alliance Organ Recovery Agency  
1951 N.W. 7th Avenue, Suite 220  
Miami, FL 33136

Dear Dr. Salama:

The Subcommittee on Economic and Consumer Policy seeks documents and information about Life Alliance Organ Recovery Agency's management and business activities. Mismanagement, waste, and abuse have been widely reported in the organ-transplantation industry. Financial conflicts of interest between not-for-profit organizations and for-profit tissue processing companies have been documented. Much-needed transparency and accountability reforms have been opposed by lobbyists working on behalf of Organ Procurement Organizations (OPOs).

### **Shocking Mismanagement Reported in Organ Procurement**

Nationally, there are 58 OPOs. According to one white paper, each of these OPOs "operates as an unchecked regional monopoly," and performance levels across OPOs are highly variable.<sup>1</sup> There is an "astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system," which is "allowing hundreds of thousands of potential organ donations to fall through the cracks."<sup>2</sup> One research analysis estimated there may be up to 28,000 available organs from deceased donors annually that are not ultimately transplanted into patients who need them, which equates to around 25,000 lives that are not saved even when

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<sup>1</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>2</sup> Editorial Board, *She Beat Cancer. Now, She's in Another Fight for Her Life.*, New York Times (Aug. 20, 2019) (online at [www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html](http://www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html)).

organ donors are located.<sup>3</sup> The burden of OPO failures is disproportionately borne by patients of color, making OPO reform an urgent health care equity issue.<sup>4</sup>

This waste results from various problems afflicting OPOs and the United Network for Organ Sharing (UNOS), which operates as the national Organ Procurement Transplantation Network (OPTN). There are reports of gross mismanagement, such as the failure to hire enough staff to respond to all donation cases.<sup>5</sup> UNOS is plagued by reports of serious lapses in quality control, such as allowing a “startling number” of transplantable organs to be lost, damaged, or delayed in transit—including mistakenly being left on airplanes—to the extent that they become degraded and must be discarded or otherwise result in worse outcomes for patients.<sup>6</sup> There are also reports of financial impropriety.<sup>7</sup>

Meanwhile, OPOs have reportedly misrepresented their efficiency at finding and collecting potential transplantable organs.<sup>8</sup> OPOs have self-reported their performance measures, and expert analysis has shown that the vast majority of OPOs significantly exaggerate their organ procurement rates, and their recovery rates are significantly lower than reported.<sup>9</sup> This has led prominent healthcare analysts and scientists, such as Dr. DJ Patil, the former Chief Data Scientist of the United States, to refer to current data from OPOs as “functionally useless.”<sup>10</sup> The Association of Organ Procurement Organizations (AOPO) has even claimed that “self-reported” data could not be used to decertify an OPO because “accuracy and consistency of data cannot be assured.”<sup>11</sup>

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<sup>3</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>4</sup> Bloom Works, *The Costly Effects of an Outdated Organ Donation System: Inequity in Organ Donation* (online at <https://bloomworks.digital/organdonationreform/Inequity>).

<sup>5</sup> *Underperforming in New York: Nonprofit Struggles to Recover Transplantable Organs*, Washington Post (Dec. 20, 2018) (online at [www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7\\_story.html](http://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html)).

<sup>6</sup> *How Lifesaving Organs for Transplant Go Missing in Transit*, Kaiser Health News (Feb. 10, 2020) (online at <https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/>).

<sup>7</sup> *Taxpayers Help Pay for Organ Donor Groups’ Parties, Rose Parade Expenses*, Trib Live (Oct. 19, 2013) (online at <https://archive.triblive.com/local/pittsburgh-alleggheny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>).

<sup>8</sup> *Video Op-Ed: 11,000 American Patients Will Die This Year Waiting for Transplants*, New York Times (June 11, 2019) (online at [www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html](http://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html)).

<sup>9</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>10</sup> Laura and John Arnold, *A Simple Bureaucratic Organ Donation Fix Will Save Thousands of Lives*, STAT, (July 23, 2019) (online at [www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/](http://www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/)).

<sup>11</sup> *Despite Low Performance, Organ Collection Group Gets New Federal Contract*, Washington Post (Feb. 10, 2019) (online at [www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc\\_story.html](http://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html)).

This litany of reports is an indictment against the industry and demonstrates the need for reform.

### **Health Authorities Attempt to Reform the Organ Procurement System**

On July 10, 2019, President Trump signed an executive order titled “Advancing American Kidney Health,” to “establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.”<sup>12</sup> On December 17, 2019, HHS announced a proposed rule from the Centers for Medicare and Medicaid Services (CMS) to improve OPO performance metrics and accountability.<sup>13</sup> On November 20, 2020, CMS finalized a rule to enforce new objective measures for donation and transplantation, update those benchmarks based on national OPO performance, allow for some competition for OPOs with middling performance, and require more frequent recertification reviews.<sup>14</sup>

In explaining the need for its rule, HHS found that OPOs may be choosing not to pursue procurement of organs from single-organ donors because the OPOs want an increased organs-per-donor metric. This means that life-saving organs are not collected. As HHS itself projected, compliance with the new OPO performance measures would lead to 5,600 to 7,300 additional organ transplants per year.<sup>15</sup>

Tens of thousands of patients are currently being underserved by poor-performing OPOs, and 33 Americans die every day for lack of an organ transplant. For these reasons, we look forward to working with you and the incoming Administration to accelerate enforcement of the final rule and begin decertifying failing OPOs as soon as possible.<sup>16</sup>

### **AOPO and OPOs Lobbied Against Proposed Reforms**

In response to this rule, AOPO has seemingly “ratcheted up dramatically” its lobbying expenditures to oppose the Executive Order and HHS’s proposed rule. One OPO executive stated at an official UNOS meeting that it was “fortunate” that federal agencies were dealing with the coronavirus, because that would allow OPOs to mount a “real congressional action

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<sup>12</sup> Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 10, 2019) (online at [www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/](http://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/)).

<sup>13</sup> Department of Health and Human Services, *Press Release: Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply* (online at [www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html](http://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html)).

<sup>14</sup> Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020) (online at [www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos](http://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos)).

<sup>15</sup> *Id.*

<sup>16</sup> Editorial Board, *Many Die Waiting for Organs*. (Aug. 1, 2020) (online at [www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f\\_story.html](http://www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f_story.html)).

campaign” to oppose new reforms. While AOPO, its members, and affiliated organizations spent a total of only about \$160,000 per year on lobbying in 2017 and 2018 combined, their spending nearly tripled in 2019 to \$452,000. In the first half of 2020, lobbying expenditures had already reached \$450,000. AOPO reportedly told its members that it would change its nonprofit status from 501(c)(3) to (c)(6) to allow for freer spending on lobbying.<sup>17</sup> OPOs in Los Angeles, Chicago, New England, Philadelphia, Houston, Seattle, Minnesota, and Nashville began lobbying last year under a new coalition, the Organ Donation Advocacy Group.<sup>18</sup>

While AOPO and the OPO industry have been lobbying against life-saving reforms, they have also engaged in lobbying efforts to receive federal funding intended to support frontline healthcare workers and struggling small businesses during the coronavirus pandemic. Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress established the \$175 billion Provider Relief Fund to support frontline health care providers.<sup>19</sup> AOPO requested from HHS that OPOs be given some of these discretionary funds, contending that “the Congressional intent of the Act is to provide an influx of funds to the healthcare industry, which the federally regulated OPOs service.”<sup>20</sup> An investigative report found that while AOPO and OPOs “battle Trump’s plan, some in the industry have been approved for what may total more than \$100 million” in Paycheck Protection Program (PPP) loans intended for struggling small businesses, “even though, in some cases, organ procurement industry borrowers involved in the lobbying are sitting on large financial assets, expensive real estate, or other reserves, in one case valued at more than \$112 million.”<sup>21</sup>

### **OPO Industry Conflicts of Interest and Misuse of Funds**

We are also concerned about possible conflicts of interests in the OPO industry that may detract from the OPOs’ core mission of recovering organs for transplant. Recent investigative reporting has exposed suspicious relationships between OPOs and other segments of the health sector unrelated to organ transplantation, such as the multi-billion dollar tissue business, medical examiners, and coroners.<sup>22</sup> A new report finds that “OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.”<sup>23</sup>

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<sup>17</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>18</sup> Open Secrets, *Client Profile: Organ Donation Advocacy Group* (online at [www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038](http://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038)).

<sup>19</sup> Pub. L. No: 116-136, §15011.

<sup>20</sup> Letter from Kelly Ranum, President, Association of Organ Procurement Organizations, to The Honorable Alex M. Azar II, Secretary, Department of Health and Human Services (Apr. 30, 2020).

<sup>21</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>22</sup> *How Organ and Tissue Donation Companies Worked Their Way into the County Morgue*, Los Angeles Times (Oct. 13, 2019) (online at [www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html](http://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html)).

<sup>23</sup> The Bridgespan Group, *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations* (Nov. 2020) (online at

Your OPO itself has raised some concerns. Life Alliance ranked second-to-last among all OPOs nationwide under HHS's new outcome measures and would need to recover over 200 additional organs every year in order to meet new standards.<sup>24</sup> Life Alliance reportedly sent a uterine to a transplant center without notifying it that the donor suffered from a bladder infection, causing the attempted uterine transplant, the first in the United States, to fail.<sup>25</sup> In 2014, a human pancreas was left sitting on a counter at Life Alliance for nearly two hours.<sup>26</sup> A former administrator was alleged to have physically assaulted a registered nurse and former medical director, the product of an apparently toxic work environment.<sup>27</sup>

To assist the Subcommittee in its review of this matter, please provide the following information for Life Alliance and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
3. All documents related to compliance with CMS's proposed or final performance standards, including analyses of past and projected future performance and plans to comply with standards;
4. All policies and procedures related to:
  - a. conflicts of interest;
  - b. Standard Acquisition Cost (SAC) fees for all organs, including their calculation and approval;
  - c. activities unrelated to organ transplantation, such as business with tissue banks, tissue processors, laboratories, coroners, and funeral homes (including documents related to whether the OPO runs its own tissue bank,

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[www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf](http://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf)).

<sup>24</sup> Centers for Medicare and Medicaid Services, *Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule* (Nov. 20, 2020) (online at [www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf](http://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf)).

<sup>25</sup> *Behind the Failure of the First U.S. Uterine Transplant*, Washington Post (Feb. 13, 2019) (online at [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](http://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)).

<sup>26</sup> *A Human Heart Was Left on a Plane, Revealing How Organs Move Around the Country*, Washington Post (Dec. 14, 2018) (online at [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](http://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)).

<sup>27</sup> *Doctor, Nurse: UM Administrator Assaulted Us*, Miami Herald (Jan. 24, 2015) (online at [www.miamiherald.com/news/local/community/miami-dade/article8081760.html](http://www.miamiherald.com/news/local/community/miami-dade/article8081760.html)).

- tissue processor, laboratory, or other business operation unrelated to organ transplantation);
  - d. tissue processing, including avoiding conflicts with organ-recovery priorities and disclosures to donors about possible conflicts of interest, as well as all consent forms presented to donor families related to organ and tissue donation; and
  - e. organs that are lost, delayed, damaged, or otherwise mishandled in transit, including all policies in place to ensure the successful tracking and transportation of organs;
5. All documents related to any contract, grant, consulting agreement, or other relationship between the OPO and any other entity, including tissue processors, laboratories, coroners, or funeral homes, and a list of all transfers of funds under such arrangements and the transfer's purpose;
6. All documents related to meetings of the board of directors, including agendas, meeting minutes, and presentation slide decks, since January 1, 2014;
7. A list of all governing board members and officers, and for each board member or officer:
- a. title(s);
  - b. length of service;
  - c. compensation from the OPO for the past four years;
  - d. compensation from any related foundation for the past four years;
  - e. compensation from any OPO-affiliated entity for the past four years;
  - f. income from other entities that have a contractual relationship with the OPO or any related foundation or other affiliated entity, for the past four years;
  - g. all terms of board membership or employment, at any time, at UNOS/OPTN, AOPO, or another OPO, OPO foundation, or OPO-affiliated entity;
  - h. all other employment for the past four years; and
  - i. a list of any family members of an OPO executive or board member employed by any OPO, OPO foundation, OPO-affiliated entity, or any other entity with which your OPO maintains a business relationship, including their position, compensation, and a description of how the relationship was disclosed; and
8. All employment contracts in which bonus or compensation is tied to volume-based incentives for organ, tissue, or any other medical products of human origin;
9. All documents related to reviews by the OPTN, UNOS and/or the UNOS Membership and Professional Standards Committee (MPSC), including all meeting transcripts and summaries, all corrective action plans generated, all follow-up reviews regarding corrective plans, all consultant agreements and referrals, and whether the OPO was ever considered a Member Not in Good

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10. All documents related to the calculation of the Standard Acquisition Cost (SAC) fees for all organs for years 2015 – 2019, broken down by each organ category, including:
  - a. an itemized breakdown of how OPO costs were apportioned to determine the SAC; and
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  - a. a full list of flights or legs of flights taken since January 1, 2014, indicating for which flights or legs of flights there was no associated UNOS ID#;
  - b. the passenger log for each such flight or leg of a flight;
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13. All emails and other communications between officers, employees, or board members of your OPO and UNOS/OPTN, AOPO, and/or other lobbyists or lobbying group(s) regarding HHS's proposed rule of December 17, 2019, or final rule from November 20, 2020, including any contemplated or planned outreach to HHS, CMS, HRSA and/or any of HRSA's contractors, and/or Congressional offices (personal and Committee staff); and
14. All documents related to any decision to apply for, receive, and keep or return PPP loans or other coronavirus-related loans or grants, including, board minutes, loan application documents, and receipt of transfer.

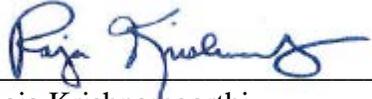
The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee’s request.

If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Dr. Sam Salama

Page 8

Sincerely,



Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy



Katie Porter  
Member of Congress

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

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December 23, 2020

Ms. Jean A. Davis  
President and Chief Executive Officer  
LifeLink Foundation  
9661 Delaney Creek Boulevard  
Tampa, FL 33619

Dear Ms. Davis:

The Subcommittee on Economic and Consumer Policy seeks documents and information about LifeLink Foundation's management and business activities. Mismanagement, waste, and abuse have been widely reported in the organ-transplantation industry. Financial conflicts of interest between not-for-profit organizations and for-profit tissue processing companies have been documented. Much-needed transparency and accountability reforms have been opposed by lobbyists working on behalf of Organ Procurement Organizations (OPOs).

**Shocking Mismanagement Reported in Organ Procurement**

Nationally, there are 58 OPOs. According to one white paper, each of these OPOs "operates as an unchecked regional monopoly," and performance levels across OPOs are highly variable.<sup>1</sup> There is an "astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system," which is "allowing hundreds of thousands of potential organ donations to fall through the cracks."<sup>2</sup> One research analysis estimated there may be up to 28,000 available organs from deceased donors annually that are not ultimately transplanted into patients who need them, which equates to around 25,000 lives that are not saved even when

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<sup>1</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

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organ donors are located.<sup>3</sup> The burden of OPO failures is disproportionately borne by patients of color, making OPO reform an urgent health care equity issue.<sup>4</sup>

This waste results from various problems afflicting OPOs and the United Network for Organ Sharing (UNOS), which operates as the national Organ Procurement Transplantation Network (OPTN). There are reports of gross mismanagement, such as the failure to hire enough staff to respond to all donation cases.<sup>5</sup> UNOS is plagued by reports of serious lapses in quality control, such as allowing a “startling number” of transplantable organs to be lost, damaged, or delayed in transit—including mistakenly being left on airplanes—to the extent that they become degraded and must be discarded or otherwise result in worse outcomes for patients.<sup>6</sup> There are also reports of financial impropriety.<sup>7</sup>

Meanwhile, OPOs have reportedly misrepresented their efficiency at finding and collecting potential transplantable organs.<sup>8</sup> OPOs have self-reported their performance measures, and expert analysis has shown that the vast majority of OPOs significantly exaggerate their organ procurement rates, and their recovery rates are significantly lower than reported.<sup>9</sup> This has led prominent healthcare analysts and scientists, such as Dr. DJ Patil, the former Chief Data Scientist of the United States, to refer to current data from OPOs as “functionally useless.”<sup>10</sup> The Association of Organ Procurement Organizations (AOPO) has even claimed that “self-reported” data could not be used to decertify an OPO because “accuracy and consistency of data cannot be assured.”<sup>11</sup>

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<sup>5</sup> *Underperforming in New York: Nonprofit Struggles to Recover Transplantable Organs*, Washington Post (Dec. 20, 2018) (online at [www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7\\_story.html](http://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html)).

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<sup>7</sup> *Taxpayers Help Pay for Organ Donor Groups’ Parties, Rose Parade Expenses*, Trib Live (Oct. 19, 2013) (online at <https://archive.triblive.com/local/pittsburgh-alleggheny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>).

<sup>8</sup> *Video Op-Ed: 11,000 American Patients Will Die This Year Waiting for Transplants*, New York Times (June 11, 2019) (online at [www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html](http://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html)).

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This litany of reports is an indictment against the industry and demonstrates the need for reform.

### **Health Authorities Attempt to Reform the Organ Procurement System**

On July 10, 2019, President Trump signed an executive order titled “Advancing American Kidney Health,” to “establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.”<sup>12</sup> On December 17, 2019, HHS announced a proposed rule from the Centers for Medicare and Medicaid Services (CMS) to improve OPO performance metrics and accountability.<sup>13</sup> On November 20, 2020, CMS finalized a rule to enforce new objective measures for donation and transplantation, update those benchmarks based on national OPO performance, allow for some competition for OPOs with middling performance, and require more frequent recertification reviews.<sup>14</sup>

In explaining the need for its rule, HHS found that OPOs may be choosing not to pursue procurement of organs from single-organ donors because the OPOs want an increased organs-per-donor metric. This means that life-saving organs are not collected. As HHS itself projected, compliance with the new OPO performance measures would lead to 5,600 to 7,300 additional organ transplants per year.<sup>15</sup>

Tens of thousands of patients are currently being underserved by poor-performing OPOs, and 33 Americans die every day for lack of an organ transplant. For these reasons, we look forward to working with you and the incoming Administration to accelerate enforcement of the final rule and begin decertifying failing OPOs as soon as possible.<sup>16</sup>

### **AOPO and OPOs Lobbied Against Proposed Reforms**

In response to this rule, AOPO has seemingly “ratcheted up dramatically” its lobbying expenditures to oppose the Executive Order and HHS’s proposed rule. One OPO executive stated at an official UNOS meeting that it was “fortunate” that federal agencies were dealing with the coronavirus, because that would allow OPOs to mount a “real congressional action

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<sup>12</sup> Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 10, 2019) (online at [www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/](http://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/)).

<sup>13</sup> Department of Health and Human Services, *Press Release: Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply* (online at [www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html](http://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html)).

<sup>14</sup> Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020) (online at [www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos](http://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos)).

<sup>15</sup> *Id.*

<sup>16</sup> Editorial Board, *Many Die Waiting for Organs*. (Aug. 1, 2020) (online at [www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f\\_story.html](http://www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f_story.html)).

campaign” to oppose new reforms. While AOPO, its members, and affiliated organizations spent a total of only about \$160,000 per year on lobbying in 2017 and 2018 combined, their spending nearly tripled in 2019 to \$452,000. In the first half of 2020, lobbying expenditures had already reached \$450,000. AOPO reportedly told its members that it would change its nonprofit status from 501(c)(3) to (c)(6) to allow for freer spending on lobbying.<sup>17</sup> OPOs in Los Angeles, Chicago, New England, Philadelphia, Houston, Seattle, Minnesota, and Nashville began lobbying last year under a new coalition, the Organ Donation Advocacy Group.<sup>18</sup>

While AOPO and the OPO industry have been lobbying against life-saving reforms, they have also engaged in lobbying efforts to receive federal funding intended to support frontline healthcare workers and struggling small businesses during the coronavirus pandemic. Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress established the \$175 billion Provider Relief Fund to support frontline health care providers.<sup>19</sup> AOPO requested from HHS that OPOs be given some of these discretionary funds, contending that “the Congressional intent of the Act is to provide an influx of funds to the healthcare industry, which the federally regulated OPOs service.”<sup>20</sup> An investigative report found that while AOPO and OPOs “battle Trump’s plan, some in the industry have been approved for what may total more than \$100 million” in Paycheck Protection Program (PPP) loans intended for struggling small businesses, “even though, in some cases, organ procurement industry borrowers involved in the lobbying are sitting on large financial assets, expensive real estate, or other reserves, in one case valued at more than \$112 million.”<sup>21</sup>

### **OPO Industry Conflicts of Interest and Misuse of Funds**

We are also concerned about possible conflicts of interests in the OPO industry that may detract from the OPOs’ core mission of recovering organs for transplant. Recent investigative reporting has exposed suspicious relationships between OPOs and other segments of the health sector unrelated to organ transplantation, such as the multi-billion dollar tissue business, medical examiners, and coroners.<sup>22</sup> A new report finds that “OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.”<sup>23</sup>

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<sup>17</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>18</sup> Open Secrets, *Client Profile: Organ Donation Advocacy Group* (online at [www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038](http://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038)).

<sup>19</sup> Pub. L. No: 116-136, §15011.

<sup>20</sup> Letter from Kelly Ranum, President, Association of Organ Procurement Organizations, to The Honorable Alex M. Azar II, Secretary, Department of Health and Human Services (Apr. 30, 2020).

<sup>21</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>22</sup> *How Organ and Tissue Donation Companies Worked Their Way into the County Morgue*, Los Angeles Times (Oct. 13, 2019) (online at [www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html](http://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html)).

<sup>23</sup> The Bridgespan Group, *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations* (Nov. 2020) (online at

Your OPO itself has raised some concerns. LifeLink operates three OPOs: LifeLink of Georgia, LifeLink of Florida, and LifeLink of Puerto Rico. It reported over \$11 million in net revenue in 2018, on top of over \$128 million in net assets. You as President and CEO were compensated over \$1.2 million, the Chairman of the Board was compensated over \$900,000, and other officers were handsomely compensated.<sup>24</sup>

To assist the Subcommittee in its review of this matter, please provide the following information for LifeLink Foundation and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
3. All documents related to compliance with CMS's proposed or final performance standards, including analyses of past and projected future performance and plans to comply with standards;
4. All policies and procedures related to:
  - a. conflicts of interest;
  - b. Standard Acquisition Cost (SAC) fees for all organs, including their calculation and approval;
  - c. activities unrelated to organ transplantation, such as business with tissue banks, tissue processors, laboratories, coroners, and funeral homes (including documents related to whether the OPO runs its own tissue bank, tissue processor, laboratory, or other business operation unrelated to organ transplantation);
  - d. tissue processing, including avoiding conflicts with organ-recovery priorities and disclosures to donors about possible conflicts of interest, as well as all consent forms presented to donor families related to organ and tissue donation; and
  - e. organs that are lost, delayed, damaged, or otherwise mishandled in transit, including all policies in place to ensure the successful tracking and transportation of organs; and
5. All documents related to any contract, grant, consulting agreement, or other relationship between the OPO and any other entity, including tissue processors, laboratories, coroners, or funeral homes, and a list of all transfers of funds under

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[www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf](http://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf)).

<sup>24</sup> LifeLink Foundation Inc., IRS Form 990, Return of Organization Exempt from Income Tax, FY 2018 (dated June 2, 2020) (online at [https://projects.propublica.org/nonprofits/display\\_990/592193032/09\\_2020\\_prefixes\\_59-62%2F592193032\\_201906\\_990\\_2020092417327932](https://projects.propublica.org/nonprofits/display_990/592193032/09_2020_prefixes_59-62%2F592193032_201906_990_2020092417327932)).

- such arrangements and the transfer's purpose;
6. All documents related to meetings of the board of directors, including agendas, meeting minutes, and presentation slide decks, since January 1, 2014;
  7. A list of all governing board members and officers, and for each board member or officer:
    - a. title(s);
    - b. length of service;
    - c. compensation from the OPO for the past four years;
    - d. compensation from any related foundation for the past four years;
    - e. compensation from any OPO-affiliated entity for the past four years;
    - f. income from other entities that have a contractual relationship with the OPO or any related foundation or other affiliated entity, for the past four years;
    - g. all terms of board membership or employment, at any time, at UNOS/OPTN, AOPO, or another OPO, OPO foundation, or OPO-affiliated entity;
    - h. all other employment for the past four years; and
    - i. a list of any family members of an OPO executive or board member employed by any OPO, OPO foundation, OPO-affiliated entity, or any other entity with which your OPO maintains a business relationship, including their position, compensation, and a description of how the relationship was disclosed;
  8. All employment contracts in which bonus or compensation is tied to volume-based incentives for organ, tissue, or any other medical products of human origin;
  9. All documents related to reviews by the OPTN, UNOS and/or the UNOS Membership and Professional Standards Committee (MPSC), including all meeting transcripts and summaries, all corrective action plans generated, all follow-up reviews regarding corrective plans, all consultant agreements and referrals, and whether the OPO was ever considered a Member Not in Good Standing (with corresponding dates);
  10. All documents related to the calculation of the Standard Acquisition Cost (SAC) fees for all organs for years 2015 – 2019, broken down by each organ category, including:
    - a. an itemized breakdown of how OPO costs were apportioned to determine the SAC; and
    - b. costs attributable to each organ type for multi-organ recoveries;
  11. For any jet or other form of private aviation that the OPO, through itself or any subsidiary or affiliate, owns, rents, or otherwise uses or controls, please provide:

- a. a full list of flights or legs of flights taken since January 1, 2014, indicating for which flights or legs of flights there was no associated UNOS ID#;
  - b. the passenger log for each such flight or leg of a flight;
  - c. the purpose of each such flight or leg of a flight; and
  - d. documentation showing to what entity each flight or leg of a flight was billed; and
12. All documents 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;
  13. All emails and other communications between officers, employees, or board members of your OPO and UNOS/OPTN, AOPO, and/or other lobbyists or lobbying group(s) regarding HHS's proposed rule of December 17, 2019, or final rule from November 20, 2020, including any contemplated or planned outreach to HHS, CMS, HRSA and/or any of HRSA's contractors, and/or Congressional offices (personal and Committee staff); and
  14. All documents related to any decision to apply for, receive, and keep or return PPP loans or other coronavirus-related loans or grants, including, board minutes, loan application documents, and receipt of transfer.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy



Katie Porter  
Member of Congress

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051

MINORITY (202) 225-5074

<http://oversight.house.gov>

December 23, 2020

Mr. Rony Thomas  
President and Chief Executive Officer  
LifeNet Health  
1864 Concert Drive  
Virginia Beach, VA 23453

Dear Mr. Thomas:

The Subcommittee on Economic and Consumer Policy seeks documents and information about LifeNet Health's management and business activities. Mismanagement, waste, and abuse have been widely reported in the organ-transplantation industry. Financial conflicts of interest between not-for-profit organizations and for-profit tissue processing companies have been documented. Much-needed transparency and accountability reforms have been opposed by lobbyists working on behalf of Organ Procurement Organizations (OPOs).

**Shocking Mismanagement Reported in Organ Procurement**

Nationally, there are 58 OPOs. According to one white paper, each of these OPOs "operates as an unchecked regional monopoly," and performance levels across OPOs are highly variable.<sup>1</sup> There is an "astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system," which is "allowing hundreds of thousands of potential organ donations to fall through the cracks."<sup>2</sup> One research analysis estimated there may be up to 28,000 available organs from deceased donors annually that are not ultimately transplanted into patients who need them, which equates to around 25,000 lives that are not saved even when

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This waste results from various problems afflicting OPOs and the United Network for Organ Sharing (UNOS), which operates as the national Organ Procurement Transplantation Network (OPTN). There are reports of gross mismanagement, such as the failure to hire enough staff to respond to all donation cases.<sup>5</sup> UNOS is plagued by reports of serious lapses in quality control, such as allowing a “startling number” of transplantable organs to be lost, damaged, or delayed in transit—including mistakenly being left on airplanes—to the extent that they become degraded and must be discarded or otherwise result in worse outcomes for patients.<sup>6</sup> There are also reports of financial impropriety.<sup>7</sup>

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Tens of thousands of patients are currently being underserved by poor-performing OPOs, and 33 Americans die every day for lack of an organ transplant. For these reasons, we look forward to working with you and the incoming Administration to accelerate enforcement of the final rule and begin decertifying failing OPOs as soon as possible.<sup>16</sup>

### **AOPO and OPOs Lobbied Against Proposed Reforms**

In response to this rule, AOPO has seemingly “ratcheted up dramatically” its lobbying expenditures to oppose the Executive Order and HHS’s proposed rule. One OPO executive stated at an official UNOS meeting that it was “fortunate” that federal agencies were dealing with the coronavirus, because that would allow OPOs to mount a “real congressional action campaign” to oppose new reforms. While AOPO, its members, and affiliated organizations

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<sup>13</sup> Department of Health and Human Services, *Press Release: Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply* (online at [www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html](http://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html)).

<sup>14</sup> Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020) (online at [www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos](http://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos)).

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While AOPO and the OPO industry have been lobbying against life-saving reforms, they have also engaged in lobbying efforts to receive federal funding intended to support frontline healthcare workers and struggling small businesses during the coronavirus pandemic. Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress established the \$175 billion Provider Relief Fund to support frontline health care providers.<sup>19</sup> AOPO requested from HHS that OPOs be given some of these discretionary funds, contending that “the Congressional intent of the Act is to provide an influx of funds to the healthcare industry, which the federally regulated OPOs service.”<sup>20</sup> An investigative report found that while AOPO and OPOs “battle Trump’s plan, some in the industry have been approved for what may total more than \$100 million” in Paycheck Protection Program (PPP) loans intended for struggling small businesses, “even though, in some cases, organ procurement industry borrowers involved in the lobbying are sitting on large financial assets, expensive real estate, or other reserves, in one case valued at more than \$112 million.”<sup>21</sup>

### **OPO Industry Conflicts of Interest and Misuse of Funds**

We are also concerned about possible conflicts of interests in the OPO industry that may detract from the OPOs’ core mission of recovering organs for transplant. Recent investigative reporting has exposed suspicious relationships between OPOs and other segments of the health sector unrelated to organ transplantation, such as the multi-billion dollar tissue business, medical examiners, and coroners.<sup>22</sup> A new report finds that “OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.”<sup>23</sup>

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<sup>17</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://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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<sup>22</sup> *How Organ and Tissue Donation Companies Worked Their Way into the County Morgue*, Los Angeles Times (Oct. 13, 2019) (online at [www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html](http://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html)).

<sup>23</sup> The Bridgespan Group, *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations* (Nov. 2020) (online at

Your OPO itself has raised some concerns. LifeNet operates a national tissue bank as well as a regional OPO, creating a conflict of interest between the OPO's organ transplantation mandate and its profitable tissue business. According to its 2018 tax return, LifeNet reported revenue of over \$392 million on "tissue processing," compared with only \$22.4 million for "organ procurement." As CEO, your compensation from LifeNet was nearly \$1.6 million.<sup>24</sup> Meanwhile, LifeNet's organ recovery operation is deemed out of compliance under CMS's new standards based on most recent data, and it would need over 100 more organ transplants per year to meet basic outcome standards.<sup>25</sup>

To assist the Subcommittee in its review of this matter, please provide the following information for LifeNet Health and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
3. All documents related to compliance with CMS's proposed or final performance standards, including analyses of past and projected future performance and plans to comply with standards;
4. All policies and procedures related to:
  - a. conflicts of interest;
  - b. Standard Acquisition Cost (SAC) fees for all organs, including their calculation and approval;
  - c. activities unrelated to organ transplantation, such as business with tissue banks, tissue processors, laboratories, coroners, and funeral homes (including documents related to whether the OPO runs its own tissue bank, tissue processor, laboratory, or other business operation unrelated to organ transplantation);
  - d. tissue processing, including avoiding conflicts with organ-recovery priorities and disclosures to donors about possible conflicts of interest, as well as all consent forms presented to donor families related to organ and tissue donation; and

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[www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf](http://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf)).

<sup>24</sup> New England Donor Services, IRS Form 990, Return of Organization Exempt from Income Tax, FY 2018 (dated Nov. 12, 2019) (online at [https://projects.propublica.org/nonprofits/display\\_990/237024479/12\\_2019\\_prefixes\\_22-23%2F237024479\\_201812\\_990\\_2019122616977523](https://projects.propublica.org/nonprofits/display_990/237024479/12_2019_prefixes_22-23%2F237024479_201812_990_2019122616977523)).

<sup>25</sup> Centers for Medicare and Medicaid Services, *Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule* (Nov. 20, 2020) (online at <https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf>).

- e. organs that are lost, delayed, damaged, or otherwise mishandled in transit, including all policies in place to ensure the successful tracking and transportation of organs; and
5. All documents related to any contract, grant, consulting agreement, or other relationship between the OPO and any other entity, including tissue processors, laboratories, coroners, or funeral homes, and a list of all transfers of funds under such arrangements and the transfer's purpose;
6. All documents related to meetings of the board of directors, including agendas, meeting minutes, and presentation slide decks, since January 1, 2014;
7. A list of all governing board members and officers, and for each board member or officer:
  - a. title(s);
  - b. length of service;
  - c. compensation from the OPO for the past four years;
  - d. compensation from any related foundation for the past four years;
  - e. compensation from any OPO-affiliated entity for the past four years;
  - f. income from other entities that have a contractual relationship with the OPO or any related foundation or other affiliated entity, for the past four years;
  - g. all terms of board membership or employment, at any time, at UNOS/OPTN, AOPO, or another OPO, OPO foundation, or OPO-affiliated entity;
  - h. all other employment for the past four years; and
  - i. a list of any family members of an OPO executive or board member employed by any OPO, OPO foundation, OPO-affiliated entity, or any other entity with which your OPO maintains a business relationship, including their position, compensation, and a description of how the relationship was disclosed; and
8. All employment contracts in which bonus or compensation is tied to volume-based incentives for organ, tissue, or any other medical products of human origin;
9. All documents related to reviews by the OPTN, UNOS and/or the UNOS Membership and Professional Standards Committee (MPSC), including all meeting transcripts and summaries, all corrective action plans generated, all follow-up reviews regarding corrective plans, all consultant agreements and referrals, and whether the OPO was every considered a Member Not in Good Standing (with corresponding dates);
10. All documents related to the calculation of the Standard Acquisition Cost (SAC) fees for all organs for years 2015 – 2019, broken down by each organ category, including:

- a. an itemized breakdown of how OPO costs were apportioned to determine the SAC; and
  - b. costs attributable to each organ type for multi-organ recoveries; and
11. For any jet or other form of private aviation that the OPO, through itself or any subsidiary or affiliate, owns, rents, or otherwise uses or controls, please provide:
- a. a full list of flights or legs of flights taken since January 1, 2014, indicating for which flights or legs of flights there was no associated UNOS ID#;
  - b. the passenger log for each such flight or leg of a flight;
  - c. the purpose of each such flight or leg of a flight; and
  - d. documentation showing to what entity each flight or leg of a flight was billed; and
12. All documents 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;
13. All emails and other communications between officers, employees, or board members of your OPO and UNOS/OPTN, AOPO, and/or other lobbyists or lobbying group(s) regarding HHS's proposed rule of December 17, 2019, or final rule from November 20, 2020, including any contemplated or planned outreach to HHS, CMS, HRSA and/or any of HRSA's contractors, and/or Congressional offices (personal and Committee staff); and
14. All documents related to any decision to apply for, receive, and keep or return PPP loans or other coronavirus-related loans or grants, including, board minutes, loan application documents, and receipt of transfer.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

  
\_\_\_\_\_  
Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy

  
\_\_\_\_\_  
Katie Porter  
Member of Congress

Mr. Rony Thomas  
Page 8

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051

MINORITY (202) 225-5074

<http://oversight.house.gov>

December 23, 2020

Ms. Susan Gunderson  
Chief Executive Officer  
LifeSource  
2225 West River Road North  
Minneapolis, MN 55411

Dear Ms. Gunderson:

The Subcommittee on Economic and Consumer Policy seeks documents and information about LifeSource's management and business activities. Mismanagement, waste, and abuse have been widely reported in the organ-transplantation industry. Financial conflicts of interest between not-for-profit organizations and for-profit tissue processing companies have been documented. Much-needed transparency and accountability reforms have been opposed by lobbyists working on behalf of Organ Procurement Organizations (OPOs).

**Shocking Mismanagement Reported in Organ Procurement**

Nationally, there are 58 OPOs. According to one white paper, each of these OPOs "operates as an unchecked regional monopoly," and performance levels across OPOs are highly variable.<sup>1</sup> There is an "astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system," which is "allowing hundreds of thousands of potential organ donations to fall through the cracks."<sup>2</sup> One research analysis estimated there may be up to 28,000 available organs from deceased donors annually that are not ultimately transplanted into patients who need them, which equates to around 25,000 lives that are not saved even when

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<sup>1</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>2</sup> Editorial Board, *She Beat Cancer. Now, She's in Another Fight for Her Life.*, New York Times (Aug. 20, 2019) (online at [www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html](http://www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html)).

organ donors are located.<sup>3</sup> The burden of OPO failures is disproportionately borne by patients of color, making OPO reform an urgent health care equity issue.<sup>4</sup>

This waste results from various problems afflicting OPOs and the United Network for Organ Sharing (UNOS), which operates as the national Organ Procurement Transplantation Network (OPTN). There are reports of gross mismanagement, such as the failure to hire enough staff to respond to all donation cases.<sup>5</sup> UNOS is plagued by reports of serious lapses in quality control, such as allowing a “startling number” of transplantable organs to be lost, damaged, or delayed in transit—including mistakenly being left on airplanes—to the extent that they become degraded and must be discarded or otherwise result in worse outcomes for patients.<sup>6</sup> There are also reports of financial impropriety.<sup>7</sup>

Meanwhile, OPOs have reportedly misrepresented their efficiency at finding and collecting potential transplantable organs.<sup>8</sup> OPOs have self-reported their performance measures, and expert analysis has shown that the vast majority of OPOs significantly exaggerate their organ procurement rates, and their recovery rates are significantly lower than reported.<sup>9</sup> This has led prominent healthcare analysts and scientists, such as Dr. DJ Patil, the former Chief Data Scientist of the United States, to refer to current data from OPOs as “functionally useless.”<sup>10</sup> The Association of Organ Procurement Organizations (AOPO) has even claimed that “self-reported” data could not be used to decertify an OPO because “accuracy and consistency of data cannot be assured.”<sup>11</sup>

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<sup>3</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>4</sup> Bloom Works, *The Costly Effects of an Outdated Organ Donation System: Inequity in Organ Donation* (online at <https://bloomworks.digital/organdonationreform/Inequity>).

<sup>5</sup> *Underperforming in New York: Nonprofit Struggles to Recover Transplantable Organs*, Washington Post (Dec. 20, 2018) (online at [www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7\\_story.html](http://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html)).

<sup>6</sup> *How Lifesaving Organs for Transplant Go Missing in Transit*, Kaiser Health News (Feb. 10, 2020) (online at <https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/>).

<sup>7</sup> *Taxpayers Help Pay for Organ Donor Groups’ Parties, Rose Parade Expenses*, Trib Live (Oct. 19, 2013) (online at <https://archive.triblive.com/local/pittsburgh-alleggheny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>).

<sup>8</sup> *Video Op-Ed: 11,000 American Patients Will Die This Year Waiting for Transplants*, New York Times (June 11, 2019) (online at [www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html](http://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html)).

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<sup>10</sup> Laura and John Arnold, *A Simple Bureaucratic Organ Donation Fix Will Save Thousands of Lives*, STAT, (July 23, 2019) (online at [www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/](http://www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/)).

<sup>11</sup> *Despite Low Performance, Organ Collection Group Gets New Federal Contract*, Washington Post (Feb. 10, 2019) (online at [www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc\\_story.html](http://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html)).

This litany of reports is an indictment against the industry and demonstrates the need for reform.

### **Health Authorities Attempt to Reform the Organ Procurement System**

On July 10, 2019, President Trump signed an executive order titled “Advancing American Kidney Health,” to “establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.”<sup>12</sup> On December 17, 2019, HHS announced a proposed rule from the Centers for Medicare and Medicaid Services (CMS) to improve OPO performance metrics and accountability.<sup>13</sup> On November 20, 2020, CMS finalized a rule to enforce new objective measures for donation and transplantation, update those benchmarks based on national OPO performance, allow for some competition for OPOs with middling performance, and require more frequent recertification reviews.<sup>14</sup>

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<sup>19</sup> Pub. L. No: 116-136, §15011.

<sup>20</sup> Letter from Kelly Ranum, President, Association of Organ Procurement Organizations, to The Honorable Alex M. Azar II, Secretary, Department of Health and Human Services (Apr. 30, 2020).

<sup>21</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>22</sup> *How Organ and Tissue Donation Companies Worked Their Way into the County Morgue*, Los Angeles Times (Oct. 13, 2019) (online at [www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html](http://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html)).

<sup>23</sup> The Bridgespan Group, *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations* (Nov. 2020) (online at

To assist the Subcommittee in its review of this matter, please provide the following information for LifeSource and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
3. All documents related to compliance with CMS's proposed or final performance standards, including analyses of past and projected future performance and plans to comply with standards;
4. All policies and procedures related to:
  - a. conflicts of interest;
  - b. Standard Acquisition Cost (SAC) fees for all organs, including their calculation and approval;
  - c. activities unrelated to organ transplantation, such as business with tissue banks, tissue processors, laboratories, coroners, and funeral homes (including documents related to whether the OPO runs its own tissue bank, tissue processor, laboratory, or other business operation unrelated to organ transplantation);
  - d. tissue processing, including avoiding conflicts with organ-recovery priorities and disclosures to donors about possible conflicts of interest, as well as all consent forms presented to donor families related to organ and tissue donation; and
  - e. organs that are lost, delayed, damaged, or otherwise mishandled in transit, including all policies in place to ensure the successful tracking and transportation of organs; and
5. All documents related to any contract, grant, consulting agreement, or other relationship between the OPO and any other entity, including tissue processors, laboratories, coroners, or funeral homes, and a list of all transfers of funds under such arrangements and the transfer's purpose;
6. All documents related to meetings of the board of directors, including agendas, meeting minutes, and presentation slide decks, since January 1, 2014;
7. A list of all governing board members and officers, and for each board member or officer:
  - a. title(s);
  - b. length of service;

- c. compensation from the OPO for the past four years;
  - d. compensation from any related foundation for the past four years;
  - e. compensation from any OPO-affiliated entity for the past four years;
  - f. income from other entities that have a contractual relationship with the OPO or any related foundation or other affiliated entity, for the past four years;
  - g. all terms of board membership or employment, at any time, at UNOS/OPTN, AOPO, or another OPO, OPO foundation, or OPO-affiliated entity;
  - h. all other employment for the past four years; and
  - i. a list of any family members of an OPO executive or board member employed by any OPO, OPO foundation, OPO-affiliated entity, or any other entity with which your OPO maintains a business relationship, including their position, compensation, and a description of how the relationship was disclosed; and
8. All employment contracts in which bonus or compensation is tied to volume-based incentives for organ, tissue, or any other medical products of human origin;
9. All documents related to reviews by the OPTN, UNOS and/or the UNOS Membership and Professional Standards Committee (MPSC), including all meeting transcripts and summaries, all corrective action plans generated, all follow-up reviews regarding corrective plans, all consultant agreements and referrals, and whether the OPO was ever considered a Member Not in Good Standing (with corresponding dates);
10. All documents related to the calculation of the Standard Acquisition Cost (SAC) fees for all organs for years 2015 – 2019, broken down by each organ category, including:
  - a. an itemized breakdown of how OPO costs were apportioned to determine the SAC; and
  - b. costs attributable to each organ type for multi-organ recoveries; and
11. For any jet or other form of private aviation that the OPO, through itself or any subsidiary or affiliate, owns, rents, or otherwise uses or controls, please provide:
  - a. a full list of flights or legs of flights taken since January 1, 2014, indicating for which flights or legs of flights there was no associated UNOS ID#;
  - b. the passenger log for each such flight or leg of a flight;
  - c. the purpose of each such flight or leg of a flight; and
  - d. documentation showing to what entity each flight or leg of a flight was billed; and
12. All documents 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;

13. All emails and other communications between officers, employees, or board members of your OPO and UNOS/OPTN, AOPO, and/or other lobbyists or lobbying group(s) regarding HHS's proposed rule of December 17, 2019, or final rule from November 20, 2020, including any contemplated or planned outreach to HHS, CMS, HRSA and/or any of HRSA's contractors, and/or Congressional offices (personal and Committee staff); and
14. All documents related to any decision to apply for, receive, and keep or return PPP loans or other coronavirus-related loans or grants, including, board minutes, loan application documents, and receipt of transfer.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy



Katie Porter  
Member of Congress

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051

MINORITY (202) 225-5074

<http://oversight.house.gov>

December 23, 2020

Ms. Alexandra K. Glazier  
President and Chief Executive Officer  
New England Donor Services  
60 First Avenue  
Waltham, MA 02451

Dear Ms. Glazier:

The Subcommittee on Economic and Consumer Policy seeks documents and information about New England Donor Services' management and business activities. Mismanagement, waste, and abuse have been widely reported in the organ-transplantation industry. Financial conflicts of interest between not-for-profit organizations and for-profit tissue processing companies have been documented. Much-needed transparency and accountability reforms have been opposed by lobbyists working on behalf of Organ Procurement Organizations (OPOs).

### **Shocking Mismanagement Reported in Organ Procurement**

Nationally, there are 58 OPOs. According to one white paper, each of these OPOs "operates as an unchecked regional monopoly," and performance levels across OPOs are highly variable.<sup>1</sup> There is an "astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system," which is "allowing hundreds of thousands of potential organ donations to fall through the cracks."<sup>2</sup> One research analysis estimated there may be up to 28,000 available organs from deceased donors annually that are not ultimately transplanted into patients who need them, which equates to around 25,000 lives that are not saved even when organ donors are located.<sup>3</sup> The burden of OPO failures is disproportionately borne by patients of color, making OPO reform an urgent health care equity issue.<sup>4</sup>

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<sup>1</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>2</sup> Editorial Board, *She Beat Cancer. Now, She's in Another Fight for Her Life.*, New York Times (Aug. 20, 2019) (online at [www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html](http://www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html)).

<sup>3</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>4</sup> Bloom Works, *The Costly Effects of an Outdated Organ Donation System: Inequity in Organ Donation* (online at <https://bloomworks.digital/organ donation reform/inequity>).

This waste results from various problems afflicting OPOs and the United Network for Organ Sharing (UNOS), which operates as the national Organ Procurement Transplantation Network (OPTN). There are reports of gross mismanagement, such as the failure to hire enough staff to respond to all donation cases.<sup>5</sup> UNOS is plagued by reports of serious lapses in quality control, such as allowing a “startling number” of transplantable organs to be lost, damaged, or delayed in transit—including mistakenly being left on airplanes—to the extent that they become degraded and must be discarded or otherwise result in worse outcomes for patients.<sup>6</sup> There are also reports of financial impropriety.<sup>7</sup>

Meanwhile, OPOs have reportedly misrepresented their efficiency at finding and collecting potential transplantable organs.<sup>8</sup> OPOs have self-reported their performance measures, and expert analysis has shown that the vast majority of OPOs significantly exaggerate their organ procurement rates, and their recovery rates are significantly lower than reported.<sup>9</sup> This has led prominent healthcare analysts and scientists, such as Dr. DJ Patil, the former Chief Data Scientist of the United States, to refer to current data from OPOs as “functionally useless.”<sup>10</sup> The Association of Organ Procurement Organizations (AOPO) has even claimed that “self-reported” data could not be used to decertify an OPO because “accuracy and consistency of data cannot be assured.”<sup>11</sup>

This litany of reports is an indictment against the industry and demonstrates the need for reform.

### **Health Authorities Attempt to Reform the Organ Procurement System**

On July 10, 2019, President Trump signed an executive order titled “Advancing American Kidney Health,” to “establish more transparent, reliable, and enforceable objective

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<sup>5</sup> *Underperforming in New York: Nonprofit Struggles to Recover Transplantable Organs*, Washington Post (Dec. 20, 2018) (online at [www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7\\_story.html](http://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html)).

<sup>6</sup> *How Lifesaving Organs for Transplant Go Missing in Transit*, Kaiser Health News (Feb. 10, 2020) (online at <https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/>).

<sup>7</sup> *Taxpayers Help Pay for Organ Donor Groups’ Parties, Rose Parade Expenses*, Trib Live (Oct. 19, 2013) (online at <https://archive.triblive.com/local/pittsburgh-allegheeny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>).

<sup>8</sup> *Video Op-Ed: 11,000 American Patients Will Die This Year Waiting for Transplants*, New York Times (June 11, 2019) (online at [www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html](http://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html)).

<sup>9</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>10</sup> Laura and John Arnold, *A Simple Bureaucratic Organ Donation Fix Will Save Thousands of Lives*, STAT, (July 23, 2019) (online at [www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/](http://www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/)).

<sup>11</sup> *Despite Low Performance, Organ Collection Group Gets New Federal Contract*, Washington Post (Feb. 10, 2019) (online at [www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc\\_story.html](http://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html)).

metrics for evaluating an OPO's performance."<sup>12</sup> On December 17, 2019, HHS announced a proposed rule from the Centers for Medicare and Medicaid Services (CMS) to improve OPO performance metrics and accountability.<sup>13</sup> On November 20, 2020, CMS finalized a rule to enforce new objective measures for donation and transplantation, update those benchmarks based on national OPO performance, allow for some competition for OPOs with middling performance, and require more frequent recertification reviews.<sup>14</sup>

In explaining the need for its rule, HHS found that OPOs may be choosing not to pursue procurement of organs from single-organ donors because the OPOs want an increased organs-per-donor metric. This means that life-saving organs are not collected. As HHS itself projected, compliance with the new OPO performance measures would lead to 5,600 to 7,300 additional organ transplants per year.<sup>15</sup>

Tens of thousands of patients are currently being underserved by poor-performing OPOs, and 33 Americans die every day for lack of an organ transplant. For these reasons, we look forward to working with you and the incoming Administration to accelerate enforcement of the final rule and begin decertifying failing OPOs as soon as possible.<sup>16</sup>

### **AOPO and OPOs Lobbied Against Proposed Reforms**

In response to this rule, AOPO has seemingly "ratcheted up dramatically" its lobbying expenditures to oppose the Executive Order and HHS's proposed rule. One OPO executive stated at an official UNOS meeting that it was "fortunate" that federal agencies were dealing with the coronavirus, because that would allow OPOs to mount a "real congressional action campaign" to oppose new reforms. While AOPO, its members, and affiliated organizations spent a total of only about \$160,000 per year on lobbying in 2017 and 2018 combined, their spending nearly tripled in 2019 to \$452,000. In the first half of 2020, lobbying expenditures had already reached \$450,000. AOPO reportedly told its members that it would change its nonprofit status from 501(c)(3) to (c)(6) to allow for freer spending on lobbying.<sup>17</sup> OPOs in Los Angeles,

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<sup>12</sup> Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 10, 2019) (online at [www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/](http://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/)).

<sup>13</sup> Department of Health and Human Services, *Press Release: Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply* (online at [www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html](http://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html)).

<sup>14</sup> Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020) (online at [www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos](http://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos)).

<sup>15</sup> *Id.*

<sup>16</sup> Editorial Board, *Many Die Waiting for Organs*. (Aug. 1, 2020) (online at [www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f\\_story.html](http://www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f_story.html)).

<sup>17</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

Chicago, New England, Philadelphia, Houston, Seattle, Minnesota, and Nashville began lobbying last year under a new coalition, the Organ Donation Advocacy Group.<sup>18</sup>

While AOPO and the OPO industry have been lobbying against life-saving reforms, they have also engaged in lobbying efforts to receive federal funding intended to support frontline healthcare workers and struggling small businesses during the coronavirus pandemic. Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress established the \$175 billion Provider Relief Fund to support frontline health care providers.<sup>19</sup> AOPO requested from HHS that OPOs be given some of these discretionary funds, contending that “the Congressional intent of the Act is to provide an influx of funds to the healthcare industry, which the federally regulated OPOs service.”<sup>20</sup> An investigative report found that while AOPO and OPOs “battle Trump’s plan, some in the industry have been approved for what may total more than \$100 million” in Paycheck Protection Program (PPP) loans intended for struggling small businesses, “even though, in some cases, organ procurement industry borrowers involved in the lobbying are sitting on large financial assets, expensive real estate, or other reserves, in one case valued at more than \$112 million.”<sup>21</sup>

### **OPO Industry Conflicts of Interest and Misuse of Funds**

We are also concerned about possible conflicts of interests in the OPO industry that may detract from the OPOs’ core mission of recovering organs for transplant. Recent investigative reporting has exposed suspicious relationships between OPOs and other segments of the health sector unrelated to organ transplantation, such as the multi-billion dollar tissue business, medical examiners, and coroners.<sup>22</sup> A new report finds that “OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.”<sup>23</sup>

Your OPO itself has raised some concerns. New England Donor Services operates two OPOs, LifeChoice Donor Services and New England Organ Bank. It also operates a tissue business, and its Senior Vice President of Tissue Donation Services is the Chair of the Board of Governors for the American Association of Tissue Banks, presenting potential conflicts of

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<sup>18</sup> Open Secrets, *Client Profile: Organ Donation Advocacy Group* (online at [www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038](http://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038)).

<sup>19</sup> Pub. L. No: 116-136, §15011.

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interest.<sup>24</sup> In 2018, New England Donor Services reported over \$35 million in assets and you as CEO earned nearly \$600,000 in total compensation.<sup>25</sup>

To assist the Subcommittee in its review of this matter, please provide the following information for New England Donor Services and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
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<sup>24</sup> American Association of Tissue Banks, *AATB Board of Governors* (online at [www.aatb.org/about-us/board-governors](http://www.aatb.org/about-us/board-governors)) (accessed Dec. 4, 2020).

<sup>25</sup> LifeNet Health, IRS Form 990, Return of Organization Exempt from Income Tax, FY 2018 (dated Nov. 15, 2019) (online at [https://projects.propublica.org/nonprofits/display\\_990/521273592/02\\_2020\\_prefixes\\_47-52%2F521273592\\_201812\\_990\\_2020021817159635](https://projects.propublica.org/nonprofits/display_990/521273592/02_2020_prefixes_47-52%2F521273592_201812_990_2020021817159635)).

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Sincerely,



Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy



Katie Porter  
Member of Congress

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND REFORM

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December 23, 2020

Mr. Thomas Mone  
Chief Executive Officer  
OneLegacy  
221 South Figueroa Street, Suite 500  
Los Angeles, CA 90012

Dear Mr. Mone:

The Subcommittee on Economic and Consumer Policy seeks documents and information about OneLegacy's management and business activities. Mismanagement, waste, and abuse have been widely reported in the organ-transplantation industry. Financial conflicts of interest between not-for-profit organizations and for-profit tissue processing companies have been documented. Much-needed transparency and accountability reforms have been opposed by lobbyists working on behalf of Organ Procurement Organizations (OPOs).

**Shocking Mismanagement Reported in Organ Procurement**

Nationally, there are 58 OPOs. According to one white paper, each of these OPOs "operates as an unchecked regional monopoly," and performance levels across OPOs are highly variable.<sup>1</sup> There is an "astounding lack of accountability and oversight in the nation's creaking, monopolistic organ transplant system," which is "allowing hundreds of thousands of potential organ donations to fall through the cracks."<sup>2</sup> One research analysis estimated there may be up to 28,000 available organs from deceased donors annually that are not ultimately transplanted into patients who need them, which equates to around 25,000 lives that are not saved even when

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<sup>1</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

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organ donors are located.<sup>3</sup> The burden of OPO failures is disproportionately borne by patients of color, making OPO reform an urgent health care equity issue.<sup>4</sup>

This waste results from various problems afflicting OPOs and the United Network for Organ Sharing (UNOS), which operates as the national Organ Procurement Transplantation Network (OPTN). There are reports of gross mismanagement, such as the failure to hire enough staff to respond to all donation cases.<sup>5</sup> UNOS is plagued by reports of serious lapses in quality control, such as allowing a “startling number” of transplantable organs to be lost, damaged or delayed in transit—including mistakenly leaving them on airplanes—to the extent that they become degraded and must be discarded or otherwise result in worse outcomes for patients.<sup>6</sup> There are reports of financial impropriety.<sup>7</sup>

Meanwhile, OPOs have reportedly misrepresented their efficiency at finding and collecting potential transplantable organs.<sup>8</sup> OPOs have self-reported their performance measures, and expert analysis has shown that the vast majority of OPOs significantly exaggerate their organ procurement rates, and their recovery rates are significantly lower than reported.<sup>9</sup> This has led prominent healthcare analysts and scientists, such as Dr. DJ Patil, the former Chief Data Scientist of the United States, to refer to current data from OPOs as “functionally useless.”<sup>10</sup> The Association of Organ Procurement Organizations (AOPO) has even claimed that “self-reported” data could not be used to decertify an OPO because “accuracy and consistency of data cannot be assured.”<sup>11</sup>

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<sup>6</sup> *How Lifesaving Organs for Transplant Go Missing in Transit*, Kaiser Health News (Feb. 10, 2020) (online at <https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/>).

<sup>7</sup> *Taxpayers Help Pay for Organ Donor Groups’ Parties, Rose Parade Expenses*, Trib Live (Oct. 19, 2013) (online at <https://archive.triblive.com/local/pittsburgh-alleggheny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>).

<sup>8</sup> *Video Op-Ed: 11,000 American Patients Will Die This Year Waiting for Transplants*, New York Times (June 11, 2019) (online at [www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html](http://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html)).

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<sup>10</sup> Laura and John Arnold, *A Simple Bureaucratic Organ Donation Fix Will Save Thousands of Lives*, STAT, (July 23, 2019) (online at [www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/](http://www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/)).

<sup>11</sup> *Despite Low Performance, Organ Collection Group Gets New Federal Contract*, Washington Post (Feb. 10, 2019) (online at [www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc\\_story.html](http://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html)).

This litany of reports is an indictment against the industry and demonstrates the need for reform.

### **Health Authorities Attempt to Reform the Organ Procurement System**

On July 10, 2019, President Trump signed an executive order titled “Advancing American Kidney Health,” to “establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.”<sup>12</sup> On December 17, 2019, HHS announced a proposed rule from the Centers for Medicare and Medicaid Services (CMS) to improve OPO performance metrics and accountability.<sup>13</sup> On November 20, 2020, CMS finalized a rule to enforce new objective measures for donation and transplantation, update those benchmarks based on national OPO performance, allow for some competition for OPOs with middling performance, and require more frequent recertification reviews.<sup>14</sup>

In explaining the need for its rule, HHS found that OPOs may be choosing not to pursue procurement of organs from single-organ donors because the OPOs want an increased organs-per-donor metric. This means that life-saving organs are not collected. As HHS itself projected, compliance with the new OPO performance measures would lead to 5,600 to 7,300 additional organ transplants per year.<sup>15</sup>

Tens of thousands of patients are currently being underserved by poor-performing OPOs, and 33 Americans die every day for lack of an organ transplant. For these reasons, we look forward to working with you and the incoming Administration to accelerate enforcement of the final rule and begin decertifying failing OPOs as soon as possible.<sup>16</sup>

### **AOPO and OPOs Lobbied Against Proposed Reforms**

In response to this rule, AOPO has seemingly “ratcheted up dramatically” its lobbying expenditures to oppose the Executive Order and HHS’s proposed rule. One OPO executive stated at an official UNOS meeting that it was “fortunate” that federal agencies were dealing with the coronavirus, because that would allow OPOs to mount a “real congressional action campaign” to oppose new reforms. While AOPO, its members, and affiliated organizations

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<sup>12</sup> Exec. Order No. 13879 (July 10, 2019) (online at [www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/](http://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/)).

<sup>13</sup> Department of Health and Human Services, *Press Release: Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply* (online at [www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html](http://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html)).

<sup>14</sup> Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020) (online at [www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos](http://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos)).

<sup>15</sup> *Id.*

<sup>16</sup> Editorial Board, *Many Die Waiting for Organs*. (Aug. 1, 2020) (online at [www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f\\_story.html](http://www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f_story.html)).

spent a total of only about \$160,000 per year on lobbying in 2017 and 2018 combined, their spending nearly tripled in 2019 to \$452,000. In the first half of 2020, lobbying expenditures had already reached \$450,000. AOPO reportedly told its members that it would change its nonprofit status from 501(c)(3) to (c)(6) to allow for freer spending on lobbying.<sup>17</sup> OPOs in Los Angeles, Chicago, New England, Philadelphia, Houston, Seattle, Minnesota, and Nashville began lobbying last year under a new coalition, the Organ Donation Advocacy Group.<sup>18</sup>

While AOPO and the OPO industry have been lobbying against life-saving reforms, they have also engaged in lobbying efforts to receive federal funding intended to support frontline healthcare workers and struggling small businesses during the coronavirus pandemic. Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress established the \$175 billion Provider Relief Fund to support frontline health care providers.<sup>19</sup> AOPO requested from HHS that OPOs be given some of these discretionary funds, contending that “the Congressional intent of the Act is to provide an influx of funds to the healthcare industry, which the federally regulated OPOs service.”<sup>20</sup> An investigative report found that while AOPO and OPOs “battle Trump’s plan, some in the industry have been approved for what may total more than \$100 million” in Paycheck Protection Program (PPP) loans intended for struggling small businesses, “even though, in some cases, organ procurement industry borrowers involved in the lobbying are sitting on large financial assets, expensive real estate, or other reserves, in one case valued at more than \$112 million.”<sup>21</sup>

### **OPO Industry Conflicts of Interest and Misuse of Funds**

We are also concerned about possible conflicts of interests in the OPO industry that may detract from the OPOs’ core mission of recovering organs for transplant. Recent investigative reporting has exposed suspicious relationships between OPOs and other segments of the health sector unrelated to organ transplantation, such as the multi-billion dollar tissue business, medical examiners, and coroners.<sup>22</sup> A new report finds that “OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.”<sup>23</sup>

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<sup>17</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>18</sup> *Client Profile: Organ Donation Advocacy Group*, Open Secrets (online at [www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038](http://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038)).

<sup>19</sup> Pub. L. No: 116-136, §15011.

<sup>20</sup> Letter from Kelly Ranum, President, Association of Organ Procurement Organizations, to The Hon. Alex Azar, Secretary, Department of Health and Human Services (Apr. 30, 2020).

<sup>21</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>22</sup> *How Organ and Tissue Donation Companies Worked Their Way into the County Morgue*, Los Angeles Times (Oct. 13, 2019) (online at [www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html](http://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html)).

<sup>23</sup> The Bridgespan Group, *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations* (Nov. 2020) (online at

Your OPO itself has raised some concerns. A 2010 federal audit of OneLegacy’s Medicare cost reports conducted by the HHS Office of the Inspector General (OIG) found that OneLegacy spent more than \$500,000 on “unallowable or poorly documented items.” The OIG found that OneLegacy “did not fully comply with Medicare requirements for reporting,” resulting in a total of \$531,460 in unallowable and unsupported costs, \$290,968 of which were unrelated to patient care. The audit found that OneLegacy had spent \$327,000 on the 2006 Rose Bowl football game and parade, “including float design and framework, football tickets, hotel rooms, limousines and flowers”—resulting in over \$85,000 overpayment by Medicare.<sup>24</sup>

Following the audit, OneLegacy established a foundation in order to use private donations to pay for the majority of the costs related to its Rose Bowl float.<sup>25</sup> In 2018, OneLegacy’s OPO entity gave \$10 million to the OneLegacy Foundation. The same year, your compensation as CEO exceeded \$900,000, and your board chair William Chertok received \$100,000 in taxpayer-funded compensation.<sup>26</sup>

Despite all of that expenditure and compensation, OneLegacy ranks in the lowest tier of performance under HHS’s new rule.<sup>27</sup>

To assist the Subcommittee in its review of this matter, please provide the following information for OneLegacy and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
3. All documents related to compliance with CMS’s proposed or final performance standards, including analyses of past and projected future performance and plans to comply with standards;

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[www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf](http://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf).

<sup>24</sup> Memorandum from Joseph E. Vengrin, Deputy Inspector General for Audit Services, HHS Office of Inspector General to Charlene Frizzera, Acting Administrator, Centers for Medicare & Medicaid Services (Jan. 21, 2010) (online at [oig.hhs.gov/oas/reports/region9/90800033.pdf](https://oig.hhs.gov/oas/reports/region9/90800033.pdf)).

<sup>25</sup> *Taxpayers Help Pay for Organ Donor Groups’ Parties, Rose Parade Expenses*, TribLIVE (Oct. 19, 2013) (online at <https://archive.triblive.com/local/pittsburgh-allegheeny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>).

<sup>26</sup> OneLegacy, IRS Form 990, Return of Organization Exempt from Income Tax, FY 2018 (dated Nov. 7, 2019) (online at <https://projects.propublica.org/nonprofits/organizations/953138799/201903169349306850/full>).

<sup>27</sup> Centers for Medicare and Medicaid Services, *Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule* (Nov. 20, 2020) (online at [www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf](https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf)).

4. All policies and procedures related to:
  - a. conflicts of interest;
  - b. Standard Acquisition Cost (SAC) fees for all organs, including their calculation and approval;
  - c. activities unrelated to organ transplantation, such as business with tissue banks, tissue processors, laboratories, coroners, and funeral homes (including documents related to whether the OPO runs its own tissue bank, tissue processor, laboratory, or other business operation unrelated to organ transplantation);
  - d. tissue processing, including avoiding conflicts with organ-recovery priorities and disclosures to donors about possible conflicts of interest, as well as all consent forms presented to donor families related to organ and tissue donation; and
  - e. organs that are lost, delayed, damaged, or otherwise mishandled in transit, including all policies in place to ensure the successful tracking and transportation of organs; and
5. All documents related to any contract, grant, consulting agreement, or other relationship between the OPO and any other entity, including tissue processors, laboratories, coroners, or funeral homes, and a list of all transfers of funds under such arrangements and the transfer's purpose;
6. All documents related to meetings of the board of directors, including agendas, meeting minutes, and presentation slide decks, since January 1, 2014;
7. A list of all governing board members and officers, and for each board member or officer:
  - a. title(s);
  - b. length of service;
  - c. compensation from the OPO for the past four years;
  - d. compensation from any related foundation for the past four years;
  - e. compensation from any OPO-affiliated entity for the past four years;
  - f. income from other entities that have a contractual relationship with the OPO or any related foundation or other affiliated entity, for the past four years;
  - g. all terms of board membership or employment, at any time, at UNOS/OPTN, AOPO, or another OPO, OPO foundation, or OPO-affiliated entity;
  - h. all other employment for the past four years; and
  - i. a list of any family members of an OPO executive or board member employed by any OPO, OPO foundation, OPO-affiliated entity, or any other entity with which your OPO maintains a business relationship, including their position, compensation, and a description of how the relationship was disclosed; and

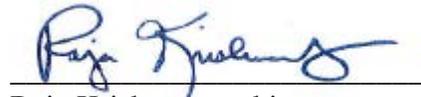
8. All employment contracts in which bonus or compensation is tied to volume-based incentives for organ, tissue, or any other medical products of human origin;
9. All documents related to reviews by the OPTN, UNOS and/or the UNOS Membership and Professional Standards Committee (MPSC), including all meeting transcripts and summaries, all corrective action plans generated, all follow-up reviews regarding corrective plans, all consultant agreements and referrals, and whether the OPO was every considered a Member Not in Good Standing (with corresponding dates);
10. All documents related to the calculation of the Standard Acquisition Cost (SAC) fees for all organs for years 2015 – 2019, broken down by each organ category, including:
  - a. an itemized breakdown of how OPO costs were apportioned to determine the SAC; and
  - b. costs attributable to each organ type for multi-organ recoveries; and
11. For any jet or other form of private aviation that the OPO, through itself or any subsidiary or affiliate, owns, rents, or otherwise uses or controls, please provide:
  - a. a full list of flights or legs of flights taken since January 1, 2014, indicating for which flights or legs of flights there was no associated UNOS ID#;
  - b. the passenger log for each such flight or leg of a flight;
  - c. the purpose of each such flight or leg of a flight; and
  - d. documentation showing to what entity each flight or leg of a flight was billed; and
12. All documents 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;
13. All emails and other communications between officers, employees, or board members of your OPO and UNOS/OPTN, AOPO, and/or other lobbyists or lobbying group(s) regarding HHS's proposed rule of December 17, 2019, or final rule from November 20, 2020, including any contemplated or planned outreach to HHS, CMS, HRSA and/or any of HRSA's contractors, and/or Congressional offices (personal and Committee staff); and
14. All documents related to any decision to apply for, receive, and keep or return PPP loans or other coronavirus-related loans or grants, including, board minutes, loan application documents, and receipt of transfer.

Mr. Thomas Mone

Page 8

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee’s request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy



Katie Porter  
Member of Congress

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051

MINORITY (202) 225-5074

<http://oversight.house.gov>

December 23, 2020

Mr. David DeStefano  
President and Chief Executive Officer  
We Are Sharing Hope SC  
3950 Faber Place Drive, Suite 400  
North Charleston, SC 29405

Dear Mr. DeStefano:

The Subcommittee on Economic and Consumer Policy seeks documents and information about We Are Sharing Hope SC's management and business activities. Mismanagement, waste, and abuse have been widely reported in the organ-transplantation industry. Financial conflicts of interest between not-for-profit organizations and for-profit tissue processing companies have been documented. Much-needed transparency and accountability reforms have been opposed by lobbyists working on behalf of Organ Procurement Organizations (OPOs).

### **Shocking Mismanagement Reported in Organ Procurement**

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<sup>5</sup> *Underperforming in New York: Nonprofit Struggles to Recover Transplantable Organs*, Washington Post (Dec. 20, 2018) (online at [www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7\\_story.html](http://www.washingtonpost.com/national/underperforming-in-new-york-nonprofit-struggles-to-recover-transplantable-organs/2018/12/20/55475aea-fa5c-11e8-863c-9e2f864d47e7_story.html)).

<sup>6</sup> *How Lifesaving Organs for Transplant Go Missing in Transit*, Kaiser Health News (Feb. 10, 2020) (online at <https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/>).

<sup>7</sup> *Taxpayers Help Pay for Organ Donor Groups’ Parties, Rose Parade Expenses*, Trib Live (Oct. 19, 2013) (online at <https://archive.triblive.com/local/pittsburgh-alleggheny/taxpayers-help-pay-for-organ-donor-groups-parties-rose-parade-expenses/>).

<sup>8</sup> *Video Op-Ed: 11,000 American Patients Will Die This Year Waiting for Transplants*, New York Times (June 11, 2019) (online at [www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html](http://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html)).

<sup>9</sup> The Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (updated Jan. 2019) (online at [www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf](http://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-12-2018.pdf)).

<sup>10</sup> Laura and John Arnold, *A Simple Bureaucratic Organ Donation Fix Will Save Thousands of Lives*, STAT, (July 23, 2019) (online at [www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/](http://www.statnews.com/2019/07/24/a-simple-bureaucratic-organ-donation-fix-will-save-thousands-of-lives/)).

<sup>11</sup> *Despite Low Performance, Organ Collection Group Gets New Federal Contract*, Washington Post (Feb. 10, 2019) (online at [www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc\\_story.html](http://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html)).

metrics for evaluating an OPO's performance."<sup>12</sup> On December 17, 2019, HHS announced a proposed rule from the Centers for Medicare and Medicaid Services (CMS) to improve OPO performance metrics and accountability.<sup>13</sup> On November 20, 2020, CMS finalized a rule to enforce new objective measures for donation and transplantation, update those benchmarks based on national OPO performance, allow for some competition for OPOs with middling performance, and require more frequent recertification reviews.<sup>14</sup>

In explaining the need for its rule, HHS found that OPOs may be choosing not to pursue procurement of organs from single-organ donors because the OPOs want an increased organs-per-donor metric. This means that life-saving organs are not collected. As HHS itself projected, compliance with the new OPO performance measures would lead to 5,600 to 7,300 additional organ transplants per year.<sup>15</sup>

Tens of thousands of patients are currently being underserved by poor-performing OPOs, and 33 Americans die every day for lack of an organ transplant. For these reasons, we look forward to working with you and the incoming Administration to accelerate enforcement of the final rule and begin decertifying failing OPOs as soon as possible.<sup>16</sup>

### **AOPO and OPOs Lobbied Against Proposed Reforms**

In response to this rule, AOPO has seemingly "ratcheted up dramatically" its lobbying expenditures to oppose the Executive Order and HHS's proposed rule. One OPO executive stated at an official UNOS meeting that it was "fortunate" that federal agencies were dealing with the coronavirus, because that would allow OPOs to mount a "real congressional action campaign" to oppose new reforms. While AOPO, its members, and affiliated organizations spent a total of only about \$160,000 per year on lobbying in 2017 and 2018 combined, their spending nearly tripled in 2019 to \$452,000. In the first half of 2020, lobbying expenditures had already reached \$450,000. AOPO reportedly told its members that it would change its nonprofit status from 501(c)(3) to (c)(6) to allow for freer spending on lobbying.<sup>17</sup> OPOs in Los Angeles,

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<sup>12</sup> Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 10, 2019) (online at [www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/](http://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/)).

<sup>13</sup> Department of Health and Human Services, *Press Release: Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply* (online at [www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html](http://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availability-organ-supply.html)).

<sup>14</sup> Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* (Nov. 20, 2020) (online at [www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos](http://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos)).

<sup>15</sup> *Id.*

<sup>16</sup> Editorial Board, *Many Die Waiting for Organs*. (Aug. 1, 2020) (online at [www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f\\_story.html](http://www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f_story.html)).

<sup>17</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

Chicago, New England, Philadelphia, Houston, Seattle, Minnesota, and Nashville began lobbying last year under a new coalition, the Organ Donation Advocacy Group.<sup>18</sup>

While AOPO and the OPO industry have been lobbying against life-saving reforms, they have also engaged in lobbying efforts to receive federal funding intended to support frontline healthcare workers and struggling small businesses during the coronavirus pandemic. Under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Congress established the \$175 billion Provider Relief Fund to support frontline health care providers.<sup>19</sup> AOPO requested from HHS that OPOs be given some of these discretionary funds, contending that “the Congressional intent of the Act is to provide an influx of funds to the healthcare industry, which the federally regulated OPOs service.”<sup>20</sup> An investigative report found that while AOPO and OPOs “battle Trump’s plan, some in the industry have been approved for what may total more than \$100 million” in Paycheck Protection Program (PPP) loans intended for struggling small businesses, “even though, in some cases, organ procurement industry borrowers involved in the lobbying are sitting on large financial assets, expensive real estate, or other reserves, in one case valued at more than \$112 million.”<sup>21</sup>

### **OPO Industry Conflicts of Interest and Misuse of Funds**

We are also concerned about possible conflicts of interests in the OPO industry that may detract from the OPOs’ core mission of recovering organs for transplant. Recent investigative reporting has exposed suspicious relationships between OPOs and other segments of the health sector unrelated to organ transplantation, such as the multi-billion dollar tissue business, medical examiners, and coroners.<sup>22</sup> A new report finds that “OPOs have greater financial incentives to focus more on tissue recovery compared to their incentives to recover lifesaving organs.”<sup>23</sup>

Your OPO itself has raised some concerns. Sharing Hope SC falls into CMS’s third tier of failing OPOs, and would need to recover 120 additional organs a year to meet new standards.<sup>24</sup> Recently, it was reported that Sharing Hope SC incorrectly identified the blood type

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<sup>18</sup> Open Secrets, *Client Profile: Organ Donation Advocacy Group* (online at [www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038](http://www.opensecrets.org/federal-lobbying/clients/summary?cycle=2019&id=F318038)).

<sup>19</sup> Pub. L. No: 116-136, §15011.

<sup>20</sup> Letter from Kelly Ranum, President, Association of Organ Procurement Organizations, to The Honorable Alex M. Azar II, Secretary, Department of Health and Human Services (Apr. 30, 2020).

<sup>21</sup> *Heartless: Organ Donation Contractors Lobby Against a Popular Health Care Initiative*, Project on Government Oversight (Oct. 5, 2020) (online at [www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/](http://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/)).

<sup>22</sup> *How Organ and Tissue Donation Companies Worked Their Way into the County Morgue*, Los Angeles Times (Oct. 13, 2019) (online at [www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html](http://www.latimes.com/business/la-fi-how-body-brokers-took-over-county-morgue-20190408-story.html)).

<sup>23</sup> The Bridgespan Group, *Transforming Organ Donation in America: Serving Patients by Expanding High-Performing Organ Procurement Organizations* (Nov. 2020) (online at [www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf](http://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-november2020.pdf)).

<sup>24</sup> Centers for Medicare and Medicaid Services, *Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements*

of an organ donor, resulting in the death of the transplant patient who received that donor's lung and the near-death injury of a patient who receiving that donor's liver.<sup>25</sup>

To assist the Subcommittee in its review of this matter, please provide the following information for Sharing Hope SC and any related foundation or other affiliated entity by January 13, 2021:

1. All charters, articles of incorporation, bylaws, and other governing documents;
2. All financial statements and consolidated records of revenues and expenses for the past four years, including a description of all assets and holdings;
3. All documents related to compliance with CMS's proposed or final performance standards, including analyses of past and projected future performance and plans to comply with standards;
4. All policies and procedures related to:
  - a. conflicts of interest;
  - b. Standard Acquisition Cost (SAC) fees for all organs, including their calculation and approval;
  - c. activities unrelated to organ transplantation, such as business with tissue banks, tissue processors, laboratories, coroners, and funeral homes (including documents related to whether the OPO runs its own tissue bank, tissue processor, laboratory, or other business operation unrelated to organ transplantation);
  - d. tissue processing, including avoiding conflicts with organ-recovery priorities and disclosures to donors about possible conflicts of interest, as well as all consent forms presented to donor families related to organ and tissue donation; and
  - e. organs that are lost, delayed, damaged, or otherwise mishandled in transit, including all policies in place to ensure the successful tracking and transportation of organs; and
5. All documents related to any contract, grant, consulting agreement, or other relationship between the OPO and any other entity, including tissue processors, laboratories, coroners, or funeral homes, and a list of all transfers of funds under such arrangements and the transfer's purpose;

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*for Organ Procurement Organizations; Final Rule* (Nov. 20, 2020) (online at [www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf](http://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf)).

<sup>25</sup> *He Died When He Got the Wrong Lungs. It Wasn't the Only Organ Error in SC That Day.*, Charleston Post and Courier (Sept. 11, 2020) (online at [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](http://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)).

6. All documents related to meetings of the board of directors, including agendas, meeting minutes, and presentation slide decks, since January 1, 2014;
7. A list of all governing board members and officers, and for each board member or officer:
  - a. title(s);
  - b. length of service;
  - c. compensation from the OPO for the past four years;
  - d. compensation from any related foundation for the past four years;
  - e. compensation from any OPO-affiliated entity for the past four years;
  - f. income from other entities that have a contractual relationship with the OPO or any related foundation or other affiliated entity, for the past four years;
  - g. all terms of board membership or employment, at any time, at UNOS/OPTN, AOPO, or another OPO, OPO foundation, or OPO-affiliated entity;
  - h. all other employment for the past four years; and
  - i. a list of any family members of an OPO executive or board member employed by any OPO, OPO foundation, OPO-affiliated entity, or any other entity with which your OPO maintains a business relationship, including their position, compensation, and a description of how the relationship was disclosed; and
8. All employment contracts in which bonus or compensation is tied to volume-based incentives for organ, tissue, or any other medical products of human origin;
9. All documents related to reviews by the OPTN, UNOS and/or the UNOS Membership and Professional Standards Committee (MPSC), including all meeting transcripts and summaries, all corrective action plans generated, all follow-up reviews regarding corrective plans, all consultant agreements and referrals, and whether the OPO was ever considered a Member Not in Good Standing (with corresponding dates);
10. All documents related to the calculation of the Standard Acquisition Cost (SAC) fees for all organs for years 2015 – 2019, broken down by each organ category, including:
  - a. an itemized breakdown of how OPO costs were apportioned to determine the SAC; and
  - b. costs attributable to each organ type for multi-organ recoveries; and
11. For any jet or other form of private aviation that the OPO, through itself or any subsidiary or affiliate, owns, rents, or otherwise uses or controls, please provide:

- a. a full list of flights or legs of flights taken since January 1, 2014, indicating for which flights or legs of flights there was no associated UNOS ID#;
  - b. the passenger log for each such flight or leg of a flight;
  - c. the purpose of each such flight or leg of a flight; and
  - d. documentation showing to what entity each flight or leg of a flight was billed; and
12. All documents 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;
  13. All emails and other communications between officers, employees, or board members of your OPO and UNOS/OPTN, AOPO, and/or other lobbyists or lobbying group(s) regarding HHS's proposed rule of December 17, 2019, or final rule from November 20, 2020, including any contemplated or planned outreach to HHS, CMS, HRSA and/or any of HRSA's contractors, and/or Congressional offices (personal and Committee staff); and
  14. All documents related to any decision to apply for, receive, and keep or return PPP loans or other coronavirus-related loans or grants, including, board minutes, loan application documents, and receipt of transfer.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi  
Chairman  
Subcommittee on Economic and  
Consumer Policy



Katie Porter  
Member of Congress

Enclosure

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy