

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
<https://oversight.house.gov>

November 10, 2022

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

Dear Ms. Bergin:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including Kentucky Organ Donor Affiliates, are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of Vast Restructuring*, *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network”* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that Kentucky Organ Donor Affiliates provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

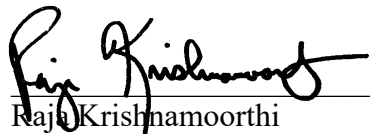
¹⁹ *Id.*

²⁰ *Id.*

4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;
5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (*e.g.*, age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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

Sincerely,



Raju Krishnamoorthi
Chairman
Subcommittee on Economic and
Consumer Policy



Katie Porter
Member
Subcommittee on Economic and
Consumer Policy

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
<https://oversight.house.gov>

November 10, 2022

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

Dear Ms. Davis:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including LifeLink Foundation, are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network”* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that LifeLink Foundation provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;
4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁹ *Id.*

²⁰ *Id.*

5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (e.g., age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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 Subcommittee'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
Subcommittee on Economic and
Consumer Policy

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
<https://oversight.house.gov>

November 10, 2022

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:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including We Are Sharing Hope SC, are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network”* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that We Are Sharing Hope SC provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

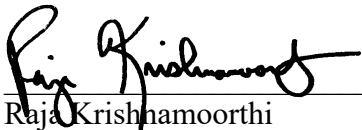
¹⁹ *Id.*

²⁰ *Id.*

4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;
5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (*e.g.*, age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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 Subcommittee'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
Subcommittee on Economic and
Consumer Policy

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
<https://oversight.house.gov>

November 10, 2022

Mr. Peter Farstad
Interim Chief Executive Officer
LifeSource
2225 West River Road North
Minneapolis, MN 55411

Dear Mr. Farstad:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including LifeSource, are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of ‘Vast Restructuring,’* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – ‘A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network’* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that LifeSource provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;
4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

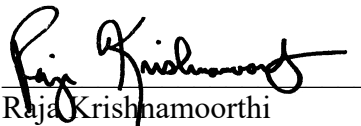
¹⁹ *Id.*

²⁰ *Id.*

5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (*e.g.*, age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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 Subcommittee'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
Subcommittee on Economic and
Consumer Policy

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
<https://oversight.house.gov>

November 10, 2022

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

Dear Mr. Garimella:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including OneLegacy, are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of Vast Restructuring*, *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network”* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that OneLegacy provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;
4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

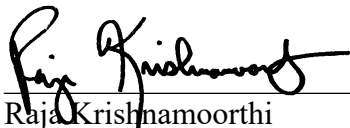
¹⁹ *Id.*

²⁰ *Id.*

5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (*e.g.*, age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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 Subcommittee'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
Subcommittee on Economic and
Consumer Policy

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
<https://oversight.house.gov>

November 10, 2022

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

Dear Ms. Glazier:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including New England Donor Services, are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of Vast Restructuring*, *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network”* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that New England Donor Services provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

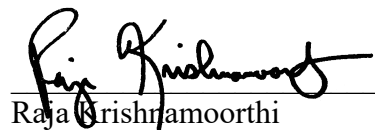
¹⁹ *Id.*

²⁰ *Id.*

4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;
5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (*e.g.*, age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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 Subcommittee'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
Subcommittee on Economic and
Consumer Policy

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
<https://oversight.house.gov>

November 10, 2022

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

Dear Ms. Grandas:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including DCI Donor Services, Inc., are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of Vast Restructuring*, *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network”* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that DCI Donor Services, Inc. provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;
4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

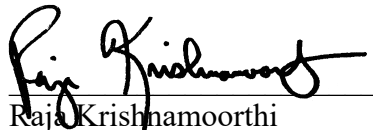
¹⁹ *Id.*

²⁰ *Id.*

5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (*e.g.*, age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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 Subcommittee'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
Subcommittee on Economic and
Consumer Policy

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
<https://oversight.house.gov>

November 10, 2022

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

Dear Mr. Meeks:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including Legacy of Hope, are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of Vast Restructuring*, *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network”* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that Legacy of Hope provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;
4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

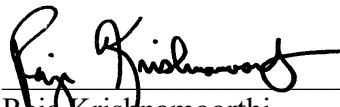
¹⁹ *Id.*

²⁰ *Id.*

5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (*e.g.*, age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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 Subcommittee'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
Subcommittee on Economic and
Consumer Policy

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
<https://oversight.house.gov>

November 10, 2022

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

Dear Dr. Salama:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including the Life Alliance Organ Recovery Agency, are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network”* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that the Life Alliance Organ Recovery Agency provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

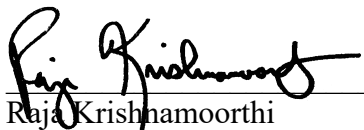
¹⁹ *Id.*

²⁰ *Id.*

4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;
5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (*e.g.*, age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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 Subcommittee'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
Subcommittee on Economic and
Consumer Policy

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

<https://oversight.house.gov>

November 10, 2022

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

Dear Mr. Thomas:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including LifeNet Health, are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of Vast Restructuring*, *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of Vast Restructuring*, *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network”* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that LifeNet Health provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;
4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁹ *Id.*

²⁰ *Id.*

5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (e.g., age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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 Subcommittee'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
Subcommittee on Economic and
Consumer Policy

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
<https://oversight.house.gov>

November 10, 2022

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

Dear Ms. Tremain:

For nearly two years, the Subcommittee on Economic and Consumer Policy has been investigating the organ donation and transplant system in the United States. We are writing regarding troubling new information obtained by the Subcommittee about inaccurate and incomplete data maintained by entities within the U.S. organ-sharing network. According to an assessment conducted by the United States Digital Service, these data weaknesses likely “are contributing to the current organ waste issues in the transplant ecosystem” and indicated that “a usable organ could go unused.”¹ This information raises serious questions about whether Organ Procurement Organizations (OPOs), including Indiana Donor Network, are taking the steps necessary to identify and secure viable organs to save Americans’ lives. The Subcommittee is seeking to better understand weaknesses in the data maintained by your organization and to assess the accuracy and completeness of information that your organization previously provided to the Subcommittee in this investigation.

Subcommittee Launched Its Investigation Following Reports that OPOs Are Failing to Deliver on Their Promise to Identify and Secure Viable Organs

The Subcommittee launched its investigation on December 23, 2020.² To date, the investigation has revealed how OPOs—geographically organized entities tasked with securing organs for transplant by identifying eligible donors and recovering organs from deceased donors across the United States—are failing to adequately provide this service, leaving hundreds of

¹ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

² House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Launches Investigation into Poor Performance, Waste, and Mismanagement in Organ Transplant Industry* (Dec. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and>).

thousands of Americans seeking organ transplants without essential healthcare.³ Problems at both individual OPOs and the Organ Procurement and Transplantation Network (OPTN), which manages the ecosystem in which OPOs operate, have contributed to as many as 25,000 unnecessary deaths per year, significant financial waste, and racial inequalities in health care.⁴

In May 2021, the Subcommittee confirmed via email to your organization’s counsel that its investigation included a request for:

All data for all donor referrals (de-identified to protect patient privacy) from 2016 to the present, including all events with time stamps, from hospital referral to ultimate outcome (e.g., referral, onsite response, approach, authorization, recovery), including for both organ and tissue donation, and all demographic patient data maintained (e.g., age, sex, race/ethnicity), as well as documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system.

The data requested is critical to understanding how OPOs receive reports of potentially viable organs from hospitals (“referral”), contact relevant stakeholders such as family and hospital staff to discuss the donation (“approach”), and ultimately obtain permission to complete the transplant (“authorization”)—three key steps in the organ procurement process.

Data relevant to the organ procurement process is so vital to successful organ donation that CFR § 486.328 sets out specific information that OPOs are required to collect under law, including:

1. Number of hospital deaths;
2. Results of death record reviews;
3. Number and timeliness of referral calls from hospitals;
4. Data related to non-recovery of organs;
5. Data about consents for donation;

³ See, e.g., House Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Held Bipartisan Hearing on Needed Reforms in Organ Transplant Industry* (May 4, 2021) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-held-bipartisan-hearing-on-needed-reforms-in-organ>).

⁴ Bridgespan Group, *Reforming Organ Donation in America: Saving 25,000 Lives Per Year and \$13 Billion in Taxpayer Funds over Five Years* (Jan. 2019) (online at www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf); Alvin E. Roth and Greg Segal, *Reforming and Improving Organ Transplant Systems Will Save Lives, Taxpayer Dollars*, STAT (Apr. 2, 2021) (online at www.statnews.com/2021/04/02/reforming-and-improving-organ-transplant-systems-will-save-lives-taxpayer-dollars/); Ben Jealous, Jayme Locke, and Greg Segal, *New Organ Donation Rule Is a Win for Black Patients and Health Equity*, Health Affairs (Dec. 17, 2020) (online at www.healthaffairs.org/doi/10.1377/forefront.20201211.229975/full/); Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 3: Inequity in Organ Donation* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

6. Number of donors;
7. Number of organs recovered, by type of organ; and
8. Number of organs transplanted, by type of organ.⁵

Furthermore, upon request of the Secretary of Health and Human Services (HHS), OPOs “must provide individually identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and HHS.”⁶ In addition, OPOs “must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.”⁷

An OPO’s failure at any point in the organ donation process can prevent a successful transplant. Researchers estimate that large numbers of potential organs are lost at each step of this process as a result of insufficient OPO efforts to approach and receive authorizations from the families of potential donors.⁸ That is why the Subcommittee, with the goal of bringing full transparency and accountability to OPO performance, has sought data from OPOs related to these steps in the organ donation process.

New Evidence of Data Collection and Management Problems in the U.S. Organ Sharing Community

New reporting and documents obtained by the Subcommittee demonstrate heightened concern about data collection and management issues affecting OPOs and the organ-sharing ecosystem more generally. The overall organ transplant system in the United States is managed by the United Network for Organ Sharing (UNOS), a non-profit agency that contracts with the U.S. government.⁹ UNOS runs the database that OPOs use to share information about available organs and match donors with recipients.¹⁰ Accordingly, it relies on complete and accurate data from individual OPOs.

On July 31, 2022, the *Washington Post* reported that the U.S. organ sharing system “relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws,” adding that “[t]ransplant doctors have complained for years about archaic aspects of the technology for sharing data and

⁵ CFR § 486.328(a).

⁶ *Id.*

⁷ CFR § 486.328(b).

⁸ Bloom Works, *The Costly Effects of an Outdated Organ Donation System, Chapter 4: OPO Best Practices* (Oct. 2020) (online at <https://bloomworks.digital/organdonationreform/Inequity/>).

⁹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹⁰ Department of Health and Human Services, Health Resources & Services Administration, *Data* (online at <https://optn.transplant.hrsa.gov/data/>) (accessed Aug. 1, 2022).

getting organs to the right place as quickly as possible.”¹¹ The *Washington Post* article relied on a United States Digital Service (USDS) report dated January 5, 2021, which had concluded that “the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for life-saving transplants.”¹² Among other things, USDS found that the UNOS organ sharing system was plagued by significant data collection, sharing, and transparency issues.¹³ On August 3, 2022, the Senate Committee on Finance held a hearing focused on UNOS’s failures. In an accompanying staff memorandum, the Committee highlighted how data issues broadly plague the OPTN, writing that the

archaic IT [information technology] system [used by OPOs and maintained by UNOS] results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs because of its dependence on staff manually entering hundreds of donor and transplant candidate data points rather than upgrading to systems better able to transfer data across Electronic Medical Record platforms.¹⁴

This Subcommittee recently obtained an internal staff memorandum from the USDS that sheds light on the significant data quality problems at OPOs. This document, which was shared with USDS leadership, describes findings from USDS’s work reviewing the OPTN system for the Health Resources and Services Administration.

The memorandum notes that the data systems at OPOs and at UNOS rely to a significant degree on “manual entry, manually copying data from transplant hospital systems, to OPO systems, to the UNOS systems.”¹⁵ This manual entry of large quantities of data creates a greater risk of error in each data system “and makes it difficult to track down where errors have occurred.”¹⁶ As a result, each data system can have different errors, and a “single source of truth

¹¹ Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of Vast Restructuring*, *Washington Post* (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/).

¹² United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (online at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement); see also Senate Committee on Finance, *Hearing on A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network* (Aug. 3, 2022) (online at www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network).

¹³ See generally United States Digital Service, *Lives are at Stake: The Government’s Role in Modernizing the OPTN* (Jan. 5, 2021) (available for download at www.finance.senate.gov/download/other-documents-related-to-the-report-on-organizational-failures-of-the-united-states-organ-procurement).

¹⁴ Senate Committee on Finance, *Hearing – “A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network”* (Aug. 3, 2022) (online at [www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\).pdf](http://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE).pdf)).

¹⁵ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

¹⁶ *Id.*

for data does not exist.”¹⁷ The memorandum noted that these errors create the risk that “it is possible that a usable organ looks unusable in the system because individual data points about that organ are incorrect.”¹⁸ OPO staff are responsible for identifying errors in the data, but the internal USDS memorandum suggests that they sometimes “don’t do this proactively” or “don’t have time to track this down,” meaning “a usable organ could go unused.”¹⁹ USDS staff concluded that these deficiencies likely contribute to poor outcomes for patients and to “the current organ waste issues in the transplant ecosystem.”²⁰

This lack of transparent, reliable data raises serious questions about the quality of the data maintained and relied upon by the individual OPOs, including your organization. In light of the serious data collection and management issues across the organ-sharing community, the Subcommittee is concerned that your organization’s previous data production to the Subcommittee could be incomplete or inaccurate.

Request for Information

Without complete transparency and accountability, life-saving organs will continue to be lost while potential transplant recipients die on the waiting list.

Accordingly, the Subcommittee asks that Indiana Donor Network provide the following information and documents, for each OPO under its management, by November 18, 2022:

1. A detailed description of the data collection practices that your organization has adopted pursuant to CFR § 486.328, related regulations, and relevant internal policies;
2. A detailed description of any data collection or retention weaknesses, inaccurate data, or missing data that your organization has identified;
3. All documents—including any internal or external assessments, analyses, audits, or reviews—regarding the accuracy or completeness of the data your organization maintains pursuant to CFR § 486.328, related regulations, and relevant internal policies;
4. A detailed description of any steps your organization plans to take to address weaknesses in your data collection and management practices;

¹⁷ *Id.*; see also Joseph Menn and Lenny Bernstein, *Thousands of Lives Depend on a Transplant Network in Need of “Vast Restructuring,”* Washington Post (July 31, 2022) (online at www.washingtonpost.com/health/2022/07/31/unos-transplants-kindeys-hearts-technology/).

¹⁸ United States Digital Service, *OPTN Modernization Issues: UNOS Lacks the Capability to Modernize* (undated internal memorandum prepared by USDS staff for USDS leadership in connection with USDS’s engagement by the Health Resources and Services Administration to review the federal government’s management of the Organ Procurement and Transplantation Network).

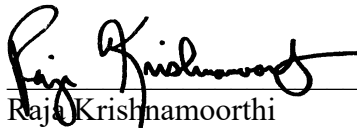
¹⁹ *Id.*

²⁰ *Id.*


5. An explanation of whether the data and documents that your organization previously provided in response to the Subcommittee's May 2021 request was complete and accurate, meaning that it included all data required to be collected under CFR § 486.328, all data for all donor referrals (de-identified to protect patient privacy) from hospital referral through ultimate outcome, all demographic patient data (*e.g.*, age, sex, race/ethnicity, religious preference (if any)), and all documents sufficient to identify the number of hospital referrals not reflected in these data or any referral management system;
6. Supplemental data, as necessary, to cure any deficiencies or inaccuracies in your organization's previous production provided in response to the Subcommittee's May 2021;
7. Updated data responsive to the Subcommittee's May 2021 request collected since your organization's previous production; and
8. To the extent that your organization does not have any portion of the requested information in its possession, custody, or control, an explanation for why it does not have this data.

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 Subcommittee'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
Subcommittee on Economic and
Consumer Policy

Enclosure

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