To: **SFC Majority/Minority Health LA's**
Subject: **Hearing - - "A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network"**
Date: **August 3, 2022, 2:30PM**

I. Introduction

On August 3, 2022, at 2:30 p.m. in room 215 of the Dirksen Senate Office Building, the U.S. Senate Committee on Finance (herein referred to as the "Committee") will hold a hearing titled "A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network."

The purpose of this hearing is to update Committee members on Chairman Wyden and Senator Grassley's bipartisan investigation into the United Network of Organ Sharing (UNOS) and to share their concerns with UNOS's oversight of the U.S. Organ Procurement and Transplantation Network (OPTN), specifically concerning its policy compliance and patient safety activities related to organ procurement organizations (OPOs).

II. Witnesses

a. Brian Shepard, *CEO, United Network for Organ Sharing (UNOS)*

Brian Shepard has been with UNOS since 2010 and has served as Chief Executive Officer since 2012.[1] On June 28, 2022, UNOS announced that Shepard "will depart the organization at the end of September, following the completion of his contract."[2] Prior to joining UNOS, he served 15 years in various high-level positions in Virginia state government. Shepard is a Virginia native, with a bachelor's degree in history from Virginia Tech and a master's degree in business administration from the University of Virginia.[3]

b. Diane Brockmeier, RN, *President and CEO, Mid-America Transplant*

Diane Brockmeier is the CEO of Mid-America Transplant, an OPO headquartered in St. Louis Missouri. She first joined Mid-American Transplant in 1986 as an organ procurement coordinator, and has been president and CEO since February 2016. As president and CEO of Mid-America Transplant, Brockmeier oversees strategic operations, including key partnerships with more than 120 hospitals and transplant centers located throughout Missouri, northeast Arkansas and southern Illinois.[4] From 2020 to 2022, Brockmeier served as the Chair for the OPTN OPO Committee and was a member of the UNOS board from 2018-2020. She has served

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[1] *Leadership*, UNITED NETWORK FOR ORGAN SHARING, https://unos.org/about/leadership/brian-shepard/ (last visited July 26, 2022).
[2] *Press Release*, UNITED NETWORK FOR ORGAN SHARING, https://unos.org/news/unos-in-the-news/unos-ceo-brian-shepard-to-leave-organization-after-a-decade-of-service/ (last visited July 26, 2022).
[3] *Leadership*, UNITED NETWORK FOR ORGAN SHARING, https://unos.org/about/leadership/brian-shepard/ (last visited July 26, 2022).
[4] *Press Release*, MID-AMERICA TRANSPLANT, https://www.midamericatransplant.org/news/diane-brockmeier-receives-most-influential-business-women-award (last visited July 26, 2022).

on the Executive Committee of the Association of Organ Procurement Organizations (AOPO) both as the Secretary-Treasurer (2012 – 2014) and as the AOPO President from 2018 – 2019.

c. Barry Friedman, RN, *Executive Director at Advent Health Transplant Institute*

Barry Friedman is the Executive Director at Advent Health Transplant Institute, in Orlando Florida. Friedman has over 30 years of clinical/administrative experience in health care. He attended Southern Illinois University, and graduated with a bachelor's in nursing and an MBA with a minor in health care administration. His civilian career Organ Transplantation began in 1984 as an ICU Staff Nurse in St Louis, Missouri. In 1976, he began his military career becoming a commissioned officer in 1985 as an Aeromedical Flight Nurse. He returned to the transplant community as an Organ Procurement Coordinator with Mid America Transplant in 1986. Over his career, Friedman has worked in a variety of roles and leadership positions at transplant centers across the country. From 2012 – 2016 he was the Chief of Clinical Global Services for Minnesota International Medicine, where he consulted in seven countries on matters related to organ transplant and procurement. Currently, he serves as the Executive Director at Advent Health Transplant Institute where he provides regulatory, administrative and fiscal oversight, including on chronic and end stage organ failure, solid organ transplant, and mechanical circulatory support programs.

Friedman is an active member of the transplant community. He has been a member of the American Society of Transplantation (AST), where he served as the Chairperson of Membership and is a past President of the North American Transplant Coordinators Organization (NATCO). He has served on various committees including the Board of Directors at UNOS and the Eastern Missouri National Kidney Foundation. He also has served as the Transplant Coordinator representative for Studies in Pediatric Liver Transplant, SPLIT. He currently serves with UNOS as Chair of the Ad Hoc International Relations Committee.[5]

d. Calvin Henry, *Double lung transplant recipient, Patient Affairs Committee representative*

Calvin Henry is a transplant recipient from Georgia. He received a double lung transplant in 2012 at Houston Methodist Hospital.[6] He was diagnosed with idiopathic pulmonary fibrosis, considered a terminal illness. He has a background in healthcare information. He is currently a Region 3 Representative on the UNOS Patient Affairs Committee.[7] Mr. Henry now runs marathons, most recently completing the Aramco Half Marathon in January of this year, and volunteers as a patient mentor for his local transplant center in Georgia, connecting those on the waitlist with educational and financial resources.

e. Jayme Locke, M.D., MPH, *Director Division of Transplantation, Heersink School of Medicine, University of Alabama at Birmingham (UAB)*

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[5] *Profile*, ORGAN DONATION AND TRANSPLANTATION ALLIANCE, https://www.organdonationalliance.org/profile/barry-friedman/ (last visited July 26, 2022).
[6] *Double lung transplant recipient returns to Houston to run Aramco Half Marathon*, ABC13, Jan. 15, 2020, https://abc13.com/chevron-houston-marathon-aramco-half-double-lung-transplant-runner/11473456/ (last visited July 26, 2022).
[7] *Patient Affairs Committee*, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/about/committees/patient-affairs-committee/ (last visited July 26, 2022).

Dr. Locke is an abdominal transplant surgeon who specializes in innovative strategies for the transplantation of incompatible organs, disparities in access to and outcomes after solid organ transplantation, and transplantation of HIV-infected end-stage patients. Her research interests include complex statistical analysis and modeling of transplant outcomes and behavioral research focused on health disparities.[8] Locke completed her undergraduate degree at Duke University, her medical degree at East Carolina University and her surgical residency at Johns Hopkins, where she received training in general surgery and multi-visceral abdominal transplantation. Dr. Locke additionally completed her Master of Public Health (MPH) degree while at Johns Hopkins. She joined the surgical faculty at University of Alabama at Birmingham (UAB) after completion of her surgical residency.

Locke is a well-published investigator, authoring 52 articles and 11 book chapters. She currently holds an NIH K23 Career Development Award and a Clinical Science Faculty Development Grant through the American Society of Transplantation. In addition, Locke is an Associate Editor for Transplantation and is a regular peer reviewer for several journals, including the American Journal of Transplantation and the Journal of the American Society of Nephrology to name a few. She is an invited member of the ASTS Providing Better Access to Organs Task Force and Diversity Affairs Committee, the AST Kidney-Pancreas Committee, The Transplantation Society Young Member Committee, and the UNOS Pediatric Transplant Committee.[9]

III. Summary and Findings

As of June, approximately 20,600 organ transplants were performed in the United States for FY2022.[10] However, the high transplant rate, due in part to increased suicide and opioid-related deaths in recent years, masks a myriad of problems within the transplant industry.[11] According to the Health Resources and Services Administration (HRSA), around 6,000 Americans die each year while waiting for organ transplants.[12] This problem is even more acute for people of color and people in rural communities. For example, according to a report by Critical Care Medicine, Black Americans are less likely to be given opportunities to consider donation, contributing to the shortage in available organs.[13] Experts estimate that, by reforming government regulations and

[8] *Faculty*, DEPARTMENT OF SURGERY, HEERSINK SCHOOL OF MEDICINE, UNIVERSITY OF ALABAMA AT BIRMINGHAM, https://www.uab.edu/medicine/surgery/transplantation/faculty/locke (last visited July 26, 2022).
[9] *Faculty*, DEPARTMENT OF SURGERY, HEERSINK SCHOOL OF MEDICINE, UNIVERSITY OF ALABAMA AT BIRMINGHAM, https://www.uab.edu/medicine/surgery/transplantation/faculty/locke (last visited July 26, 2022).
[10] *Data and Trends*, UNOS, https://unos.org/data/ (last visited July 21, 2022).
[11] Brian Owens, *Organ Donations from Overdose Deaths on the Rise but Stigma Remains*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5988527/. During the course of this investigation, UNOS often cited to increased donation rates to highlight the success of its operations. However, UNOS failed to address the increase in organs discarded, now 25% of kidneys are discarded. *See* Amanda Robinson et al., *Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report*, (July 1, 2022) https://optn.transplant.hrsa.gov/media/p2oc3ada/data_report_kidney_full_20220624_1.pdf
[12] *Organ Donation Statistics*, HRSA, https://www.organdonor.gov/learn/organ-donation-statistics#glance (last visited July 21, 2022) (According to HRSA, 17 people die each day waiting for an organ transplant.).
[13] Laura A. Siminoff et al, *Comparison of Black and White Families' Experiences and Perceptions Regarding Organ Donation Requests*, 31 Critical Care Medicine 146 (2003). https://journals.lww.com/ccmjournal/Abstract/2003/01000/Comparison_of_black_and_white_families_.23.aspx.

holding OPOs accountable, 28,000 more organs could be transplanted each year.[14] Experts also project that improvements to the OPTN could save the federal government and taxpayers up to $40 billion over the next decade, particularly through reductions in dialysis and treatment of End Stage Renal Disease which accounts for $36 billion in Medicare spending each year.[15]

This bipartisan investigation began in February 2020 when then-Chairman Charles Grassley, then-Ranking Member Ron Wyden, Senator Todd Young, and Senator Benjamin Cardin sent a letter to UNOS expressing their concerns about the adequacy of patient safety standards and belief that OPOs are failing to recover thousands of viable organs each year.[16] The letter also highlighted an investigation by the Department of Health and Human Services, Office of Inspector General (HHS OIG) and news reports, shining a light on "lapses in patient safety, misuse of taxpayer dollars, and tens of thousands of organs going unrecovered or not transplanted," leading to questions about the adequacy of UNOS' oversight of OPOs."[17]

In 2021, the investigation continued under the leadership of now-Chairman Wyden and Ranking Member Grassley of the Senate Judiciary Committee with a series of bipartisan requests for information sent to HHS,[18] CMS,[19] HRSA, and the Office of Management and Budget. Staff also broadened the scope of the investigation to include concerns about the inadequacy of the OPTN information technology system and its impact on patients.

In February 2021, nearly a year into the investigation, the Committee issued a subpoena to UNOS demanding documents in support of the investigation.[20] In response to the subpoena, the Committee received hundreds of thousands of pages of documents and internal memoranda, which helped inform the findings of this investigation. Based on information collected for this investigation, between 2010 and 2020, a total of 1,118 complaints were submitted against all 57 OPOs (some more than others) by various stakeholders, including transplant centers, families,

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[14] *Summary of Findings*, BLOOMWORKS, https://bloomworks.digital/organdonationreform/Summary/#key-findings-and-opportunities (last reviewed July 21, 2022).

[15] *Summary of Findings*, BLOOMWORKS, https://bloomworks.digital/organdonationreform/Summary/#key-findings-and-opportunities (last reviewed July 21, 2022).

[16] Press Release, Finance Committee Members Probe U.S. Organ Transplant System (Feb. 12, 2020), https://www.grassley.senate.gov/news/news-releases/finance-committee-members-probe-us-organ-transplant-system.

[17] Letter to Brian Shepard, Chief Executive Officer of United Network for Organ Sharing, from the Senate Committee on Finance (Feb.10, 2020), https://www.finance.senate.gov/imo/media/doc/2020-02-10%20Grassley,%20Wyden,%20Young,%20Cardin%20to%20UNOS%20(Information%20Request%20on%20Organ%20Transplant%20System).pdf.

[18] Letter to Norris Cochran, Acting Secretary for the Department of Human and Health Services from Senate Committee on Finance (Mar. 16, 2021), https://www.finance.senate.gov/imo/media/doc/031621%20Bipartisan%20Bicameral%20HHS%20OPO%20Rule%20Support%20Letter.pdf.

[19] Letter to Xavier Becerra, Secretary for the Department of Health and Human Services, and Chiquita Brooks-LaSure, Administrator for Centers for Medicare and Medicaid Services, from the Senate Committee on Finance (July 19, 2021), https://www.finance.senate.gov/imo/media/doc/071921%20Wyden%20Grassley%20Young%20Bipart%20Bicam%20OPO%20letter%20to%20HHS.pdf.

[20] Press Release, Grassley, Wyden Subpoena the United Network for Organ Sharing as part of Continued Investigation into U.S. Organ Transplant System (Feb. 4, 2021), https://www.finance.senate.gov/ranking-members-news/grassley-wyden-subpoena-the-united-network-for-organ-sharing-as-part-of-continued-investigation-into-us-organ-transplant-system.

anonymous individuals, UNOS staff, and OPOs themselves.[21] Based on documents and internal memoranda, the Committee found that:

- The OPTN is failing to provide adequate oversight of the nation's 57 OPOs, resulting in fewer organs available for transplant.

- The lack of oversight by UNOS causes avoidable failures in organ procurement and transplantation resulting in risks to patient safety. These failures include testing procedure errors, transportation issues resulting in life saving organs being lost or destroyed in transit, and process and procedure failures.

- UNOS lacks technical expertise to modernize the OPTN IT system, resulting in risk of system interruption or technical failure with the potential to harm patients across the country.

IV. Background

a. Establishment of the OPTN

Following the passage of the National Organ Transplant Act (NOTA) in 1984, the Secretary of HHS established, by contract, a national computerized system for matching patients with organs, referred to as the Organ Procurement and Transplantation Network (OPTN).[22] NOTA provides grants to OPOs and established the first national network to facilitate matching deceased donor organs to transplant candidates.[23] Today, the OPTN has over 391 members, including 252 transplant centers and 57 OPOs.[24] UNOS was awarded the first OPTN contract in 1986 and has received all seven subsequent contract awards for the OPTN.[25]

b. The OPTN Contract

By law, the OPTN is operated under contract between HHS and a non-profit entity with expertise in organ donation and transplantation. UNOS is the only contractor to ever hold, or bid for, the OPTN contract. Under the OPTN contract with HHS, UNOS performs the following functions:[26]

1. Supporting the operating and governance activities of the OPTN Board of Directors;
2. Maintaining the national OPTN waiting list of individuals in need of one or more organ(s) for transplantation;

[21] Document on file with Committee.
[22] 42 U.S.C. §274.
[23] 42 U.S.C. §273.
[24] *Organ Procurement & Transplantation Network*, https://optn.transplant.hrsa.gov/about/ (last visited July 21, 2022).
[25] *Organ Procurement & Transplantation Network*, https://optn.transplant.hrsa.gov/about/ (last visited July 21, 2022).
[26] 42 U.S.C. §273(a)(2).

3. Matching organs to individuals on the national OPTN waiting list;
4. Supporting, establishing, and enforcing OPTN membership criteria for member entities and designated transplant program requirements;
5. Conducting reviews and evaluations of OPTN members and taking actions consistent with the OPTN final rule and the OPTN Bylaws for OPTN member non-compliance, including referring matters to the Secretary;
6. Developing policies for the allocation of donated organs and other policies authorized by the OPTN final rule consistent with the OPTN final rule;
7. Maintaining a twenty-four-hour system to facilitate organ-recipient matching;
8. Assisting OPOs in the nationwide distribution of organs;
9. Collecting, analyzing, and publishing organ donation and transplantation data; and,
10. Working actively to increase the supply and utilization of donated organs.

As highlighted above, UNOS was awarded the first OPTN contract in 1986 and has since received all seven contract awards for the OPTN.[27] In September 2021, the OPTN estimated that the annual operating costs would be approximately $63.9 million.[28] Of this figure, approximately $6.5 million is from federally appropriated funds and the remainder comes from OPTN registration fees.[29] The OPTN registration fee is collected by UNOS from transplant centers when they add a patient to the OPTN waiting list.[30] As of FY2022, the OPTN registration fee was $868.[31] The cost to operate the OPTN in 2023 is estimated to increase to $72,482,500, and the patient registration fee is proposed to be $944.[32] In addition to these fees, UNOS also charges additional fees, separately from the registration fee, for providing data, support services, transportation, conferences, and educational materials to OPOs and to outside parties.[33]

c. Organ Procurement Organizations

OPOs are not-for-profit organizations responsible for the procurement of organs for transplantation in the United States.[34] OPOs are responsible for working with donor hospitals to identify opportunities for organ donation, working with donor families to obtain consent for organ donation, when necessary, conducting testing to identify potential for disease transmission or other

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[27] *Organ Procurement & Transplantation Network*, https://optn.transplant.hrsa.gov/about/ (last visited July 21, 2022).
[28] *OPTN Budget and OPTN Registration Fee Set for New Fiscal Year*, September 2, 2021. https://optn.transplant.hrsa.gov/news/optn-budget-and-optn-registration-fee-set-for-new-fiscal-year/.
[29] *OPTN Budget and OPTN Registration Fee Set for New Fiscal Year*, September 2, 2021. https://optn.transplant.hrsa.gov/news/optn-budget-and-optn-registration-fee-set-for-new-fiscal-year/.
[30] *OPTN Budget and OPTN Registration Fee Set for New Fiscal Year*, September 2, 2021. https://optn.transplant.hrsa.gov/news/optn-budget-and-optn-registration-fee-set-for-new-fiscal-year/.
[31] *OPTN Budget and OPTN Registration Fee Set for New Fiscal Year*, September 2, 2021. https://optn.transplant.hrsa.gov/news/optn-budget-and-optn-registration-fee-set-for-new-fiscal-year/.
[32] *Organ Procurement and Transplantation Network: OPTN Charter*,https://optn.transplant.hrsa.gov/about/optn-charter/#:~:text=This%20Charter%20governs%20the%20structure,Act%2C%20as%20amended%2C%2042%20U.S.C.(last viewed July 21, 2022).
[33] United Network for Organ Sharing, *Financial Statements and Supplementary Information*, (2021), at 4, https://unos.org/wp-content/uploads/2021-Audited-Financial-Statement.pdf.
[34] United Network for Organ Sharing, *Increasing Organ Donation*, https://unos.org/transplant/opos-increasing-organ-donation/ (last viewed July 21, 2022).

safety issues, and safely procuring and transporting all transplantable organs based on OPTN policies.[35] There are 57 OPOs and each is assigned a donor service area (DSA) covering every potential donor hospital in the country.[36]

At the time that NOTA was enacted, OPOs had already existed and received payment for activities under Medicare. They arose organically, first as organ banks to preserve organs within a hospital's transplant center. These organ banks eventually coordinated organ sharing among multiple transplant centers, especially when an organ would have otherwise gone unused at the hospital that the organ bank was affiliated with. As the organ banks' functions grew, they became independent entities, evolving into the OPOs as they function today.

d. Federal Regulation and Oversight of the OPTN

HHS promulgated regulations to establish the structure and operations of the OPTN in 1998. These regulations are known as the OPTN final rule.[37] The final rule was delayed several times, but ultimately went into effect in March 2000.[38] There was no regulatory framework in the period between enactment of NOTA and the final rule. The OPTN was governed solely by NOTA statutory requirements and the terms of the OPTN contract.

The Division of Transplantation within the Health Systems Bureau of HRSA is the primary entity responsible for oversight of the OPTN.[39] Under NOTA, OPOs and transplant hospitals participating in Medicare and Medicaid must be members of the OPTN.[40] The OPTN board of directors, with the advice of the OPTN membership, is responsible for developing policies for organ allocation and donation.[41] However, in order for an OPTN policy to become enforceable, the OPTN must submit the policy for approval to the Secretary of HHS at least 60 days prior to the proposed implementation date.[42] OPTN policies are not enforceable until approved by the Secretary.[43]

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

[36] United Network for Organ Sharing, *Increasing Organ Donation*, https://unos.org/transplant/opos-increasing-organ-donation/ (last viewed July 21, 2022).

[37] 42 C.F.R. Part 121.

[38] 65 C.F.R. § 15252. The OPTN final rule also established: 1) requirements for the structure and responsibilities of the OPTN Board of Directors; 2) minimum requirements for listing transplant candidates; 3) minimum expectations for organ procurement and testing; 4) minimum requirements for packaging and transportation of organs; 5) high-level goals for organ allocation policies; and 6) authority for review, evaluation of OPTN members and enforcement of OPTN rules. *Id.*

[39] *Health Systems Bureau*, HRSA https://www.hrsa.gov/about/organization/bureaus/hsb/index.html (last viewed July 21, 2022).

[40] 42 C.F.R. § 121.3(b).

[41] 42 C.F.R. § 121.4(a).

[42] 42 C.F.R. § 121.4(b)(2).

[43] 42 C.F.R. § 121.4(b)(2).

Although the OPTN operates under a contract from HRSA, OPOs are certified by CMS every 4 years.[44] If an OPO fails to meet conditions for coverage, it must submit an acceptable plan of correction or risk decertification. However, despite historical underperformance and records of deficiencies in policy compliance and patient safety, no OPO has ever been decertified by the federal government.[45] Additionally, CMS also maintains Conditions of Coverage for transplant hospitals.[46] These conditions establish the requirements for OPOs and transplant centers to participate in and receive payment under Medicare and Medicaid.

In November 2020, CMS issued a final rule changing the methodology used to evaluate OPO performance (the "OPO final rule").[47] This rule followed former President Trump's Executive Order on "Advancing American Kidney Health," and its stated policy is to prevent kidney failure, increase choice for patients with end-stage renal disease, and to modernize organ recovery and transplantation in the United States.[48] On January 20, 2021, President Biden's Administration issued a memo requesting that all rules, guidance, or agency actions which did not take effect prior to January 20, 2021 be delayed to provide agency officials with the opportunity for further review of the issues of fact, law, and policy raised by such rules.[49] Subsequently, CMS provided an additional 30-day comment period for the OPO final rule, which then became effective March 30, 2021.[50] The OPO final rule applied two new outcome measures, a donation rate measure, and a transplantation rate measure.[51] For example, CMS plans to use death certificate information obtained by the Centers for Disease Control to measure OPO performance.[52] CMS explained that this change is necessary because:

> "[C]urrent OPO outcomes measures are not sufficiently objective and transparent to ensure appropriate accountability in assessing OPO performance, nor do they properly incentivize the adoption of best practices and optimization of donation and organ placement rates."

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[44] *Organ Procurement Organization Final Rule Takes Effect*, FOLEY & LARDNER LLP (Apr. 14, 2021), https://www.foley.com/en/insights/publications/2021/04/organ-procurement-organization-final-rule-effect#:~:text=CMS%20conducts%20OPO%20performance%20surveys,of%20correction%20or%20risk%20decertification.

[45] *Oversight*, Bloomworks, https://bloomworks.digital/organdonationreform/Oversight/ (last viewed July 21, 2022).

[46] 42 C.F.R. Parts 413, 441, 486 and 498.

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

[48] Exec. Order No. 13879, 3 C.F.R. 247 (2007), https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-kidney-health.

[49] MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES (Jan. 20, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/.

[50] 42 C.F.R. Parts 486.

[51] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.

[52] 42 CFR Part 486 at 36, https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf.

Based on 2018 data, CMS estimated that 22 of the 57 OPOs would fall into "Tier 3" status, meaning that they would fail the new outcome measures and be decertified.[53] However, in its current form the rule does not provide for decertification of OPOs until 2026.[54]

V. Investigative Findings and Concerns

a. OPOs Continue to Underperform

As explained in greater detail above, CMS estimated that, under the OPO final rule, 22 of the 57 OPOs would fail the new outcome measures and be decertified.[55] Meanwhile, around 6,000 Americans die each year while waiting for an organ transplant.[56] Based on the findings of this investigation, OPO underperformance and lack of improvement incentives contribute to these shortcomings. In fact, CMS estimated that, if OPOs increased their performance, approximately 5,600 more organs per year could be transplanted.[57]

According to HRSA, the number of patients awaiting organ transplantation far outstrips the supply of donated organs, and every ten minutes, another person is added to the national waitlist. These problems continue despite reporting that OPOs are failing to recover thousands of viable organs each year. In fact, Kaiser Health News reports that organs recovered often do not get transplanted due to OPO errors stating that "a startling number of lifesaving organs are lost or delayed while being shipped on commercial flights, the delays often rendering them unusable."[58]

Based on information collected for this investigation, between 2010 and 2020, a total of 1,118 complaints were submitted against all 57 OPOs (some more than others) by various stakeholders, including transplant centers, families, anonymous individuals, UNOS staff, and OPOs themselves.[59] Furthermore, the HHS Office of the Inspector General (OIG), Federal Bureau of Investigation, and others have identified inappropriate use of Medicare funds by OPOs, along with other illegal financial arrangements, ranging from seeking reimbursement for unallowable and unsupported expenditures on activities such as entertainment, meals, lobbying, and donations and gifts to an illegal kickback scheme between an OPO and a local funeral home, which led to

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[53] 42 CFR Part 486 at 59, https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf.
[54] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.
[55] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.
[56] Health Resources and Services Administration, *Organ Donation Statistics*, https://www.organdonor.gov/learn/organ-donation-statistics#glance.
[57] U.S. Centers for Medicare and Medicaid Services, *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F* https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.
[58] JoNel Aleccia, *How Lifesaving Organs for Transplant Go Missing in Transit*, KHN (Feb. 10, 2020), https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/.
[59] On file with the Committee.

the OPO leadership serving time in federal prison. The complaints concern a variety of issues, including data entry, labeling, packaging, and organ allocation, as well as process and procedure errors.

Testing Failures – Between 2010 and 2020, 104 complaints were submitted to UNOS regarding "testing procedure" errors.[60] These complaints include issues like donor blood type mix ups (referred to as ABO incompatibility), infectious diseases not identified pre-transplant, or required blood and urine tests not being completed on the donor pre-transplant.[61] More specifically, from January 2008 to September 2015, 211 donors transmitted disease and 249 total recipients developed donor derived disease. From these 249 transmissions, 70 died from donor-derived disease.[62] This data illustrates the lethality of diseases contracted during a transplantation and the need for exacting scrutiny of such transmissions. Of the patients that developed a disease from their donor's organ, 28% of them died.[63]

The investigation identified several examples of cases illustrative of these testing failures and their impact on patient safety:

1. ABO Incompatibility Case 1 (Donor Network West,[64] San Francisco, CA) – In December 2020, one transplant recipient nearly died after receiving an organ with the wrong blood type and two recipients required the transplanted organs be removed to avoid fatal risks.[65]

2. ABO Incompatibility Case 2 (We Are Sharing Hope,[66] Charleston, SC) – On November 28, 2018, a transplant recipient died after receiving an organ with the wrong blood type.[67]

3. Cancer Transmission Case 1 (Life Connection of Ohio,[68] Kettering, OH) – On June 4, 2020, during a routine follow up, a transplant recipient was told that he had accidentally received a transplant from a donor with cancer. The recipient was told by his surgeon he "may likely die within 3 years."[69]

4. Cancer Transmission Case 2 (LifeQuest Organ Recovery Services,[70] Gainesville, FL) – On February 18, 2018, a transplant recipient contracted cancer unknowingly from a donor. A year later, a germ cell tumor was discovered during a routine transplant follow up appointment.[71]

[60] On file with the Committee.
[61] On file with the Committee.
[62] UNOS_2_000003539, at 3552-3553.
[63] UNOS_2_000003539, at 3552-3553.
[64] Services most of Northern California.
[65] See Appendix A.
[66] Services most of South Carolina.
[67] See Appendix B.
[68] Services Northwest Ohio.
[69] See Appendix C.
[70] Services Northern Florida.
[71] See Appendix D.

5. Kidney Death Case (Nevada Donor Network,[72] Las Vegas, NV) – On July 14, 2017, two kidney transplant recipients contracted a rare infection after transplant surgery. One recipient died days later.[73]

Transportation Failures – Between 2010 and 2020, 53 complaints were submitted to UNOS regarding "transportation" failures.[74] These complaints include incidents that negatively impact the organ's quality or expected arrival time to the transplant center. Below are failures exemplifying complaints that impacted patient safety:

1. Courier Case 1 (Mississippi Organ Recovery Agency,[75] Flowood, MS) – On February 25, 2017, two incidents were reported to UNOS where the courier service requested by the OPO did not arrive in time to get the organs to their flight. This resulted in three cancelled transplants and one discarded kidney.[76]

2. Courier Case 2 (Donor Alliance,[77] Denver CO) – On March 28, 2018, a courier did not pick up all of the organs it was instructed to transport due to a lack of communication. The kidney was subsequently declined by the transplant center due to the delay.[78]

3. Airline Case 1 (We Are Sharing Hope,[79] Charleston, SC) – On September 15, 2015, an organ missed two flights, resulting in the transplant center declining the organ due to increased cold ischemic time (CIT). CIT determines whether a kidney remains viable on ice without blood flow.[80]

4. Airline Case 2 (We Are Sharing Hope,[81] Charleston, SC) – On March 6, 2017, an organ missed the flight to a transplant center. Due to the delay, the organ experienced such prolonged CIT that the transplant surgeon determined it was not viable and had to be discarded.[82]

Process and Procedure Failures – Between 2010 and 2020, 109 complaints were submitted to UNOS regarding "recovery procedures."[83] Below are failures exemplifying complaints that impacted patient safety:

[72] Services most of Nevada.
[73] See Appendix E.
[74] On file with the Committee.
[75] Services most of Mississippi.
[76] See Appendix F.
[77] Services Colorado and most of Wyoming.
[78] See Appendix G.
[79] See Appendix H.
[80] See Appendix H.
[81] See Appendix I.
[82] See Appendix I.
[83] On file with the Committee.

1. Allocation Error Case (LifeGift Organ Donation Center,[84] Houston, TX) – Multiple instances reported between 2018 and 2019 of an OPO not following the heart lung allocation procedures in place, resulting in one instance of a discarded heart.[85]

2. Donation after Circulatory Death Case 1 (Indiana Donor Network,[86] Indianapolis, IN) – On February 24, 2017, an anonymous complaint submitted to UNOS alleged that, when the Operating Room team opened the donor surgically, the donor's heart was still beating. Death was not declared until 10 minutes later.[87]

3. Donation after Circulatory Death Case 2 (Life Alliance Organ Recovery Agency,[88] Miami, FL) – On November 28, 2018, Life Alliance Recovery Organization (FLMP) in Miami, FL recovered organs from a donor before the donor's heart stopped and against the family's wishes. The family had only consented for Donation after Cardiac Death (DCD).[89]

4. Kidney Trash Case (Indiana Donor Network, Indianapolis, IN) – On June 12, 2020, OPO staff accidentally threw a kidney in the trash after procurement, rendering it not sterile and, therefore, not usable.[90]

Failures Outside of OPTN Policy Between 2010 and 2020, 58 complaints were submitted to UNOS defined as "Other" and 28 defined as "Non-Issue."[91] Below is an example of a complaint that fell outside of OPTN policies.

1. Financial Allegations Case (Alabama Organ Center,[92] Birmingham, AL) – In February 2011, UNOS received a complaint from a former OPO staff member who alleged the Executive Director had participated in money laundering and financial improprieties, calling the profits "blood money."[93] These individuals were eventually sentenced to prison.[94]

b. OPTN/UNOS Failing to Provide Adequate Oversight

Under the OPTN contract, UNOS is responsible for establishing membership criteria and policies for the safe and efficient operation of the OPTN.[95] This role is largely addressed through the work of the OPTN Membership and Professional Standards Committee (MPSC), which is

[84] Services parts of Texas, including the Houston area and Northern Texas.
[85] See Appendix J.
[86] Services most of Indiana.
[87] See Appendix K.
[88] Services the Southern tip of Florida.
[89] See Appendix L.
[90] See Appendix M.
[91] On file with the Committee.
[92] Services Alabama.
[93] See Appendix N.
[94] Press Release, Dep't of Justice, Former Alabama Organ Center Executive Sentenced for Fraud (May 16, 2012), https://archives.fbi.gov/archives/birmingham/press-releases/2012/former-alabama-organ-center-executive-sentenced-for-fraud.
[95] *About*, https://optn.transplant.hrsa.gov/about/ (last viewed July 21, 2022).

supported by staff in the UNOS Department of Member Quality.[96] The MPSC is made up of approximately 38 to 42 volunteers with expertise in organ transplant and procurement from more than 11 regions across the country.[97] According to the OPTN website, "the MPSC maintains membership criteria and monitors OPTN member compliance with OPTN membership criteria, OPTN bylaws and policies, and the OPTN Final Rule."[98] Most importantly, the MPSC reviews patient safety risks and provides feedback to OPOs and other members to improve performance and compliance with OPTN rules.

The MPSC takes action or makes recommendations for further action to the OPTN Board of Directors as needed. However, the complaint process is not transparent, as the MPSC only examines cases that UNOS staff refers to it. UNOS staff will refer a case if "any potential patient safety or policy or bylaw noncompliance may exist."[99]Additionally, staff use the HRSA "Wakefield" Criteria to determine when a case needs to be escalated to HRSA, the UNOS board, and the MPSC. However, "a report will also not become a case if it solely pertains to something outside of the OPTN's authority," or if it does not violate a policy.[100] In some years, less than half of safety events identified by UNOS are referred to the MPSC. MPSC findings are not publicly disclosed. Additionally, UNOS does not follow up regarding the outcomes with the individuals who submitted the complaints.

The OPTN website also states that through peer review the MPSC:[101]

1. Reviews events identified as presenting a risk to patient safety, public health or the integrity of the OPTN;
2. Evaluates and supports OPTN members by providing feedback on and recommendations to improve members' performance, compliance, and quality systems; and,
3. Reviews applications for membership in the OPTN, approval of designated transplant programs, and changes in OPTN member key personnel.

The MPSC also:

1. Identifies opportunities for transplant community education to improve patient safety and safeguard the integrity of the transplant system, often through

[96] *Membership & Professional Standards Committee (MPSC)*, https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/ (last reviewed July 21, 2022).
[97] *Membership & Professional Standards Committee (MPSC)*, https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/ (last reviewed July 21, 2022).
[98] *Membership & Professional Standards Committee (MPSC)*, https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/ (last reviewed July 21, 2022).
[99] UNOS Presentation to Investigative Staff of the Senate Finance Committee – UNOS Process for reviewing OPOs.
[100] UNOS Presentation to Investigative Staff of the Senate Finance Committee – UNOS Process for reviewing. OPOs.
[101] *Membership & Professional Standards Committee (MPSC)*, https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/ (last reviewed July 21, 2022).

dissemination of successful examples of membership engagement and sharing of best practices; and,

2. Develops bylaws and policies related to membership criteria or the oversight responsibilities of the MPSC that align with the OPTN mission to maximize organ supply, provide efficient and safe care, and provide equitable access to transplantation.

On June 2, 2022, Chairman Wyden and Senator Grassley's staff interviewed Jacqui O'Keefe, Director of Member Quality at UNOS.[102] As Director of Member Quality, Ms. O'Keefe manages a staff of approximately 65 people from different functional areas within UNOS, including site surveyors, compliance, allocation, and membership, whose job is to support the MPSC.[103] According to Ms. O'Keefe, her team reviews patient safety complaints submitted to UNOS and then refers some, but not all, of those cases to the MPSC for further review.

During her interview, staff asked Ms. O'Keefe how patient safety cases are elevated to the MPSC. Ms. O'Keefe explained that patient safety cases are often submitted to UNOS via its UNet patient safety portal. She further explained that, when a patient safety case is entered into the system, a patient safety analyst reviews the information, requests additional information from the member, and then discusses with their manager on its disposition. The case is then forwarded to a multidisciplinary group, which includes UNOS's Chief Medical Officer, who decides if the case should be forwarded to the MPSC for further review. If the case is elevated to the MPSC, the patient safety analyst compiles staff summaries, patient records, and prior MPSC recommendations to help inform the MPSC's decision. According to Ms. O'Keefe, it takes approximately 2-3 months to complete this process before the MPSC reviews the case.

During this investigation, staff found that, in recent years, less than half of patient safety events identified by Ms. O'Keefe's team were referred to the MPSC. For example, of the 1,118 complaints, 444 complaints were referred to the MPSC (40% of cases) and 674 complaints were not referred to the MPSC (60% of cases).[104] To illustrate even further:

1. 104 complaints were submitted to UNOS regarding "testing procedure" errors.[105] Approximately 70% were not referred to the MPSC.[106]

2. 53 complaints were submitted to UNOS regarding "transportation" errors.[107] Approximately 94% were not referred to the MPSC.[108]

[102] *Jacqueline O'Keefe*, https://unos.org/about/leadership/jacqueline-okeefe/ (last viewed July 21, 2022).
[103] Ms. O'Keefe interview was informal and not transcribed. However, staff took detailed notes which helped form the basis for their findings.
[104] Document on file with Committee.
[105] Document on file with Committee.
[106] Document on file with Committee.
[107] Document on file with Committee.
[108] Document on file with Committee.

3. 109 complaints were submitted to UNOS regarding "recovery procedure" errors.[109] Approximately 83% were not referred to the MPSC.[110]

4. 58 complaints were submitted to UNOS defined as "Other" and 28 defined as "Non-Issue."[111] Approximately 90% did not get referred to the MPSC and of the "Non-Issue" complaints only 1 case was referred to the MPSC.[112]

5. Of the 444 complaints referred to the MPSC:
    a. 1 case resulted in "Probation,"
    b. 3 cases resulted in "Peer Visit,"
    c. 63 cases resulted in a "Letter of Warning" or "Letter of Reprimand,"
    d. 298 cases resulted in "Notice of Noncompliance" or "Uncontested Violation," and,
    e. 68 cases were "Closed with No Action." (It is important to note that the only public adverse actions are "Probation" and "Member Not in Good Standing.")

Staff also observed that certain stakeholders' complaints were more likely to be referred to the MPSC than others. For example, UNOS staff and self-reports were more likely to be referred to the MPSC than anonymous and patient family complaints.

During Ms. O'Keefe's interview, Senator Grassley's staff also asked how the MPSC addresses recurring and systemic patient safety issues (i.e., repeated transportation failures or ABO incompatibility issues). Ms. O'Keefe said that these issues help inform OPTN policy changes, but that it was not the MPSC's job to address broader trends in OPO non-compliance. Instead, Ms. O'Keefe suggested broader trends in non-compliance are forwarded to the Operations and Safety Committee (OSC) for further review.

On June 23, 2022, Chairman Wyden and Senator Grassley's staff interviewed Chris Curran, Chair of the OSC. (Mr. Curran's term ended approximately one week after staff conducted this interview.) According to the OPTN website, the OSC "seeks to improve quality, safety, and efficiency of the organ transplant system [. . .] and reviews de-identified transplant and donation-related adverse events and near misses reported to the OPTN."[113] According to Mr. Curran, the OSC fulfills its mission through policy work, but underscored that the OSC is not an enforcement body. Senator Grassley's staff asked Mr. Curran how the OSC addresses recurring and systemic patient safety issues. Mr. Curran responded that individual cases are not referred to OSC. Instead, OSC uses de-identified data to consider changes to existing OPTN policy and procedures. Mr. Curran also stated that certain issues, like disease transmission,[114] are sent to other committees within UNOS and that UNOS's board has broader oversight of net trends.

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[109] Document on file with Committee.
[110] Document on file with Committee.
[111] Document on file with Committee.
[112] Document on file with Committee.
[113] *Operations & Safety Committee*, https://optn.transplant.hrsa.gov/about/committees/operations-safety-committee/ (last viewed July 21, 2022).
[114] *Ad Hoc Disease Transmission Advisory Committee*, https://optn.transplant.hrsa.gov/about/committees/ad-hoc-disease-transmission-advisory-committee/ (last viewed July 21, 2022).

The Committee's investigation shows that despite the efforts of UNOS and its internal committees, OPOs continue to experience recurring and systemic patient safety issues, including packaging and labeling errors, transportation failures, failure to identify transmissible diseases in donors, and even allegations of fraud. Each of these errors has the potential to have deadly impacts. However, UNOS seems focused on making OPTN policy changes rather than conducting actual oversight of OPOs and other members, including conducting root cause analyses, providing community education on OPTN policies and procedures, or providing support to rectify problems at OPOs. Instead, based on staff's impression, UNOS points fingers and suggests it is up to the OPOs or the federal government to fix the failures of its membership.

c. UNOS IT System Failures and Safety Concerns

While not the sole focus of the Committee's investigation, Senator Grassley and Senator Wyden's staff also heard concerns from patients, transplant center staff, and OPO staff that UNOS lacks technological expertise or the willingness to develop and maintain an adequate IT infrastructure. Staff also heard concerns that the archaic IT system 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.

These concerns were validated in a report from the independent U.S. Digital Service (USDS), which is housed within the Executive Office of the President and provides consultation services to federal agencies on information technology.[115] The report, titled *Lives Are at Stake*, states that UNOS has been able to wiggle through and around most new contract requirements for the OPTN technology by hand-waving at change with technical jargon, while making no substantive progress. The USDS also states that:[116]

- UNOS is incapable of modernizing the OPTN IT infrastructure;
- the core systems are fragile;
- OPTN technology limits policy development;
- UNOS is resistant to change; and,
- OPTN system is dependent on a disjointed and inadequate user experience.

Ultimately, USDS determined that these technological failings are in fact placing lives at stake and recommended that HHS take action to create a better organ transplant system and enable better patient outcomes, including updating NOTA to create flexibility in how the OPTN is serviced by contractors.

VI. Resistance to Requests for Information and a Valid Subpoena

[115] U.S. DIGITAL SERVICE, LIVES ARE AT STAKE – THE GOVERNMENT'S ROLE IN MODERNIZING THE OPTN (Jan. 5, 2021).
[116] U.S. DIGITAL SERVICE, LIVES ARE AT STAKE – THE GOVERNMENT'S ROLE IN MODERNIZING THE OPTN. (Jan. 5, 2021).

Throughout the course of the Committee's investigation, UNOS sought to withhold documents relevant to the Committee's inquiry. In response to requests for information in February and July 2020, UNOS CEO Brian Shepard asserted that "[w]e are sincere in our desire to support the committee's [sic] work by providing meaningful information in a helpful form."[117] Yet, in the same letter, UNOS provided only partial responses to the Committee's questions, citing "obligations to the hospital and OPO members who participate in our peer review processes."[118] Shepard raised a similar concern in an August 4, 2020 email to Committee staff, asking that the Committee "exhaust all the other ways of reviewing this information that would leave the confidential peer review process in place," but also conceded that UNOS "fully [understood] that the Committee is ultimately able to access those identified records through a request of the Secretary of HHS or by subpoena."[119]

Yet, even after the Committee issued a subpoena to UNOS on February 3, 2021, UNOS continued to withhold relevant information from the Committee without asserting a recognized constitutional, federal statutory, or federal common-law privilege applicable in response to a valid federal subpoena. On August 3 2021, one year after Mr. Shepard acknowledged that a valid subpoena would require UNOS to provide information relevant to the Committee's investigation, UNOS continued to produce information with "limited redactions for material that is protected by the peer-review privilege and that also implicates the privacy interests of organ donors or members' staff."[120]

These redactions included the names of OPOs; names of senior OPO employees; time zones, addresses, and other contextual information; and, information that appears to be public information, like the names of presenters at open sessions of an UNOS conference. In some instances, donor IDs appear to be redacted, significantly inhibiting the Committee's ability to analyze the information provided. Ultimately, the Committee only received information necessary to its investigation after repeatedly demanding it from UNOS counsel in a series of written and verbal communications.

VII. Conclusion

From the top down, the U.S. transplant network is not working, putting Americans' lives at risk. The Committee found:

- The OPTN is failing to provide adequate oversight of the nation's 57 OPOs resulting in fewer organs available for transplant.
- The lack of oversight of OPOs by UNOS causes avoidable failures in organ procurement and transplantation resulting in risks to patient safety. These failures include testing procedure errors, transportation issues resulting in life saving organs being lost or destroyed in transit, and process and procedure failures.

[117] On file with Committee.
[118] On file with Committee.
[119] On file with Committee.
[120] On file with Committee.

- UNOS lacks technical expertise to modernize the OPTN IT system resulting in the risk of system interruption or technical failure with the potential to harm patients across the country.

VIII. Recommendations:

Based on the investigation's findings, Committee staff makes the following recommendations to improve the OPTN:

- Remove barriers to competition by removing the specific requirement for HHS to contract only with a "non-profit entity that has an expertise in organ procurement and transplantation;"

- Increase the pool of potential bidders by clarifying that the OPTN functions described in NOTA and subsequent amendments may be operated by more than one contractor, since few contractors will have adequate clinical knowledge and expertise in IT, policy development, and data collection and reporting, and policy compliance activities;

- Promote innovation in all OPTN functions (e.g., policy development, compliance and patient safety mentoring, IT infrastructure, coordinating transport of organs, etc.) as the best qualified entities with distinct skill sets could compete for contracts for these functions;

- Remove a major barrier for entry for bidders by providing authority for HHS to procure a government owned, contractor operated modern IT system to facilitate the OPTN functions;

- Increase security and innovation in the OPTN system by ensuring the new IT system is based on current technologies and operated and maintained by a contractor with adequate IT knowledge and experience;

- Ensure the continued viability of the OPTN by authorizing HHS to collect fees from transplant hospitals when adding a patient to the national organ transplant waitlist. This would replace a current fee structure authorized by regulation which is not flexible enough to provide funding for multiple contracts;

- Increase transparency and accountability for chain of custody and transportation of organs procured for transplant by providing for public reporting, as appropriate, on the status of organs in transport; and,

- Increase accountability for organs lost, damaged, or delayed in transport by requiring oversight and corrective action for such incidents.

APPENDICES A – N

APPENDIX A
Donor Network West (CADN)
Re: Testing Failures and Process Failures

On December 23, 2020, CADN recovered multiple organs (heart, kidney, pancreas, and kidney) from a 15-year-old donor.[121] According to internal UNOS correspondence, the donor suffered gunshot wounds and died after receiving multiple ABO O blood transfusions.[122] CADN staff assigned blood type O to the donor, despite mixed results and ABO typing discrepancies.[123] Post-transplant, it became clear that the donor was actually blood type B.[124] As a result, three recipients, except for the liver recipient, experienced graft rejection, meaning that their immune system attacked the transplanted organ.[125]

Documents produced to the Committee show that CADN had serious concerns about the blood type assignment during the organ transplant process. For example, on December 21, 2020, a representative from CADN called UNOS for help, asking "at what point do we feel comfortable with [the results of a blood typing test] from a hospital when we know [the donor has been transfused with over 30 units of type O blood]."[126] CADN noted that the donor's "red cells are identifying as O however the serum is identifying as B"[127] and stated that CADN can "[get his blood] tested further, but it'll take two days and he is ready for allocation now."[128] UNOS advised CADN "to [put] something in donor highlights, big and bold, so everyone sees it . . . and notify primary [transplant] centers," and that "you should be okay."[129] CADN asked the UNOS representative if they had experienced a case like this before.[130] The UNOS representative stated, "this is a fairly new situation for me."[131]

It's important to note here that this is <u>not</u> a new situation within UNOS. In fact, UNOS updated its ABO policy as recently as June 2020, months before this incident, adding "indeterminate" testing (the policy violation at issue in this case) to the UNOS policy guidelines.[132] (In an interview with Senator Grassley and Senator Wyden's staff, Chris Curran,

[121] UNOS_7_000029172.
[122] UNOS_7_000029172, at 29173.
[123] UNOS_4_00033024.
[124] UNOS_4_00033024.
[125] For the liver recipient, the transplant center plasmapheresed the transplant recipient in advance so that their body would accept the ABO B liver. This process filters the blood, removes harmful antibodies, and allows the recipient to receive a donation from a donor of a different blood type. *See* UNOS_4_000330241, at 330243.
[126] UNOS_4_000330241, at 330300.
[127] UNOS_4_000330241, at 330300.
[128] UNOS_4_000330241, at 330301.
[129] UNOS_4_000330241, at 330301-02.
[130] UNOS_4_000330241, at 330302.
[131] UNOS_4_000330241, at 330302.
[132] *Notice of implemented actions*, OPTN, https://optn.transplant.hrsa.gov/policies-bylaws/notices-of-implemented-actions/ (lasted reviewed July 22, 2022).

former-Chair of UNOS's Operations & Safety Committee, highlighted the emphasis UNOS places on addressing blood typing issues.)

In its post-case review, UNOS noted that CADN should have conducted additional and more specific genetic blood testing in this case.[133] In fact, internal memoranda show that Stanford Health Care transplant center asked CADN to delay the procurement due to the discrepancy in ABO typing and requested additional testing. CADN denied the request, pointing to a variety of factors including "confidence in the ABO," lack of ICU bed space, and the fact that other centers had accepted other organs.[134] According to UNOS's internal staff summary, on December 22, 2020: [135]

- Hours before the donor OR, **CASU**, who had accepted the heart, expressed concerns about donor ABO accuracy and requested a 48-72 hour delay for additional ABO testing. **CADN** declined the request due to confidence in the ABO, two accepting centers with blood bank expert consults, lack of available ICU space, and donor family concerns for length of case. **CASU** declined the heart, which **CASD** subsequently accepted.

Following the transplant, CADN self-reported the incident to UNOS, noting that CADN staff incorrectly assigned ABO O to a donor who had undergone a massive blood transfusion.[136] On December 31, 2020, UNOS sent an inquiry letter to CADN about the event.[137] In response to the UNOS inquiry letter, CADN staff describe the "gaps" in policy that contributed to this error over emails to UNOS staff.[138] One gap identified was that, when CADN staff became aware of the inconclusive results, they did not escalate the issue to clinical leadership, as their "interim instructional" guidance stated. [139] The email follows:[140]

[133] UNOS_4_000330241, at 330317.
[134] UNOS_4_000330241, at 330245.
[135] UNOS_4_000330241, at 330245.
[136] UNOS_4_000330241.
[137] UNOS_4_000330241, at 330264.
[138] UNOS_6_000096902, at 96903.
[139] UNOS_ 4_000330241, at 330261; UNOS_6_000096902, at 969006.
[140] UNOS_6_000096902, at 96903.

Hi [redacted]

Upon review of our process, we see a few possible gaps:

- 2.1.4.2.1. says "All available typing and subtyping results must be assessed and found to be equivalent (e.g. hospital results, first laboratory result, second laboratory result)". We think we may not have recognized cancelled tests as a "result", and in general not considered all results.
- 2.1.4.6.2 indicates resolving discrepancy by testing at donor hospital "or" other designated testing site. This conflicts with the following bullet that indicates using the guidelines, which indicate testing at hospital and an outside lab.
- 2.2.2.2 indicates a huddle if discrepancies cannot be resolved

The interim instructional statement says:

- "All ABO tests must be considered when determining a donor's blood type. If any test indicates anything other than a conclusive result (including cancellation), or is in any way inconsistent with other ABO testing; all results must be reviewed by organ program clinical leadership and must follow SE-M-001, Section 2.2, Guidelines for Handling Conflicting Primary Blood Type Results. This includes testing by an outside (non-hospital) lab"

We believe this statement emphasizes the need to consider all results as stated in 2.1.4.2.1; it addresses 2.1.4.6.2 by requiring a result from an outside lab, and it indicates a huddle much earlier in the process (when conflicting results are identified).

The impact of this ABO typing error was nearly fatal for three of the four organ recipients. For example, the heart transplant recipient received extracorporeal membrane oxygenation post-transplant.[141] This is a life sustaining treatment where "blood is pumped outside of your body to a heart-lung machine that removes carbon dioxide and sends oxygen-filled blood back to tissues in the body," requiring intensive care unit monitoring.[142] The kidney recipients both required removal of the transplanted organs to avoid further complications.[143]

According to UNOS's internal staff summary, it appears that one reviewer recommended a finding of non-conformance while also sending the case to the full MPSC board "as it resulted in graft loss for multiple patients."[144] A second reviewer recommended UNOS issue CADN a "notice of non-compliance at minimum" because of "clear communication and disclosure of ABO discrepancies with accepting transplant centers."[145] A third reviewer also recommended a notice of non-compliance at a minimum and referral to the full MPSC. The Committee did not receive information from UNOS on the final disposition of this case.

[141] UNOS_ 4_000330241, at 330252.
[142] *Extracorporeal membrane oxygenation (ECMO)*, MAYO CLINIC (Apr. 19, 2022), https://www.mayoclinic.org/tests-procedures/ecmo/about/.
[143] UNOS_ 4_000330241, at 330315.
[144] UNOS_ 4_000330241, at 330242.
[145] UNOS_ 4_000330241, at 330242.

APPENDIX B
We Are Sharing Hope (SCOP)
Re: ABO Blood Type Mix Up

On November 28, 2018, We Are Sharing Hope (SCOP), the organ procurement organization (OPO) serving South Carolina, reported a blood typing incident that impacted multiple transplant recipients. For some transplant recipients, the event was fatal. Between November 27 and 28, 2018, three of the four accepting transplant hospitals experienced patient safety events related to this blood typing error and reported the events to UNOS.[146] This case was made public in 2020, when the patient's family filed a lawsuit against SCOP.[147] On November 28, 2018, after receiving the safety incidents, UNOS notified the Health Resources and Services Administration (HRSA), in accordance with Wakefield criteria, which include any issue that may pose a serious threat to patient safety.[148]

Prior to the organ retrieval, the donor received a massive blood transfusion. A massive blood transfusion is a type of blood transfusion given to patients who require a rapid and large replacement of their blood volume, and is often required after a traumatic event.[149] Blood transfusions are one of several clinical situations that result in unreliable blood typing results, as the transfusion antibodies can mix with the patient's antibodies and temporarily cause inconsistent blood typing results, making these donors potentially high risk.[150] However, if the donor's blood type is tested before the transfusion, this problem can be avoided. In this incident, the donor's initial blood type test drawn pre-transfusion had "hemolyzed," meaning the blood cells had ruptured to the point of being unreadable, and were therefore unusable.[151] Therefore, the OPO had to rely on blood typing tests obtained after multiple blood transfusions. The summary of the incident follows:[152]

[146] UNOS_2_000014076, at 14078-84.
[147] Mary Katherine Wildeman, *He died when he got the wrong lungs. It wasn't the only organ error in SC that day*, THE POSE AND COURIER (Sep. 11, 2020), https://www.postandcourier.com/health/he-died-when-he-got-the-wrong-lungs-it-wasnt-the-only-organ-error-in/article_c6a6e386-e704-11ea-91ce-2783df6c6f2d.html.
[148] UNOS_3_000088965. The Wakefield criteria is a set of patient safety criteria, developed by HRSA to help UNOS determine what cases must be escalated to HRSA, the Membership and Professional Standards Committee (MPSC), and UNOS leadership as well as how quickly a case needs to be escalated.
[149] *UpToDate*, https://www.uptodate.com/contents/massive-blood-transfusion (last visited July 19, 2022).
[150] *Organ Procurement & Transplantation Network*, https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/guidance-for-addressing-blood-type-determination/ (last visited July 19, 2022).
[151] UNOS_2_000014075, 14154.
[152] UNOS_2_000014075.

OPO 02412N allocated the lungs, heart, liver, pancreas, left kidney, and right kidney from a donor who had undergone massive transfusion with ABO O blood products. The OPO subsequently determined that the donor was ABO O. Testing later revealed that the donor was actually ABO A1.

Hospital 41473N received the heart and transplanted it into an ABO B recipient. After release of crossclamp, the heart stiffened and became edematous. Hospital 41473N was unable to get the recipient off of CPB, and converted to VA ECMO. After six days the heart recipient was re-transplanted. The heart recipient is doing well and was discharged home 22 days after the second transplant.

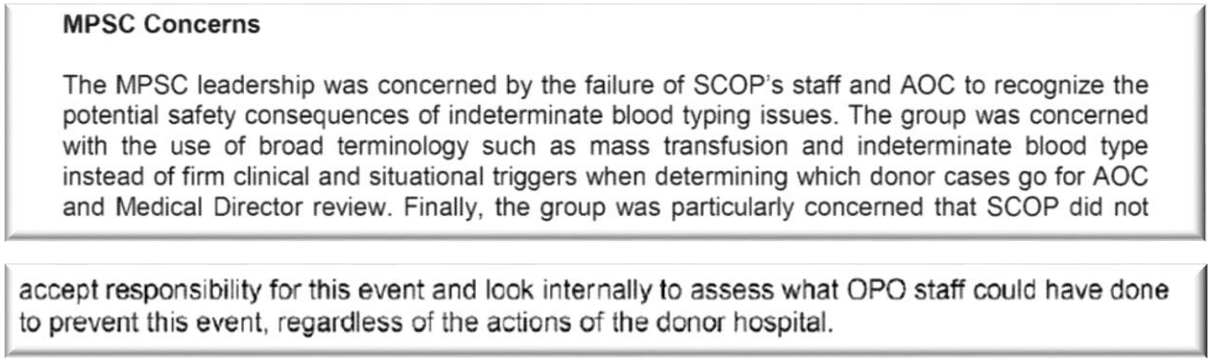
Hospital 46029N received the liver and transplanted it into an ABO O recipient. The recipient is doing well and is not expected to have an adverse course related to the incompatible ABO.

Before SCOP allocated the organs, it obtained a series of inconclusive blood typing samples. The initial ABO sample showed an indeterminate result. However, "the donor hospital also does not report indeterminate results per internal policy, so the OPO was not aware of the initial indeterminate result."[153] A second ABO was drawn and sent to an outside lab for testing. This sample was also found to be indeterminate.[154] SCOP later admitted that had they "known that the first ABO typing was also indeterminate in addition to the second typing at the serology lab, this would have been a 'red flag.'"[155] Instead, SCOP drew a third sample, which had a similar result as the second sample. SCOP "considered this ABO as confirmation of the first ABO and a resolution of the discrepant ABO typing found at the outside lab."[156]

SCOP staff then notified the Administrator on Call (AOC) and the Clinical Donation Coordinator (CDC) of the results. However, "given that there were two ABOs drawn at the donor hospital on different dates with the same results the AOC did not notify the Medical Director of the 'indeterminate' results."[157] SCOP staff then notified the transplant centers that the donor was "hemodiluted and therefore PHS Increased Risk."[158] "Given that there were two ABOs drawn at the donor hospital on different dates with the same results the CAT did not notify the transplant programs of the indeterminate ABO result."[159] On November 28, 2018, one day after procurement, the transplant hospital who accepted the donor's pancreas notified SCOP that a (now fourth) sample they had tested resulted as ABO A. The OPO alerted the other transplant centers, but the other organs had already been transplanted.[160]

[153] UNOS_2_000014075, at 14076.
[154] UNOS_2_000014075, at 14076.
[155] UNOS_2_000014075, at 14076.
[156] UNOS_2_000014075, at 14076.
[157] UNOS_2_000014075, at 14076.
[158] UNOS_2_000014075, at 14076.
[159] UNOS_2_000014075, at 14076.
[160] UNOS_2_000014075, at 14089.

On December 10, 2018, UNOS staff sent an inquiry letter to SCOP requesting additional information about the case and, on December 24, 2018, SCOP sent their response.[161] Over the coming weeks, UNOS staff sent multiple inquiries and received multiple responses from SCOP that ultimately resulted in the Membership and Professional Standards Committee's (MPSC) request for an informal discussion with SCOP.[162] In its request, the MPSC expressed multiple concerns with what it had discovered up to this point:[163]

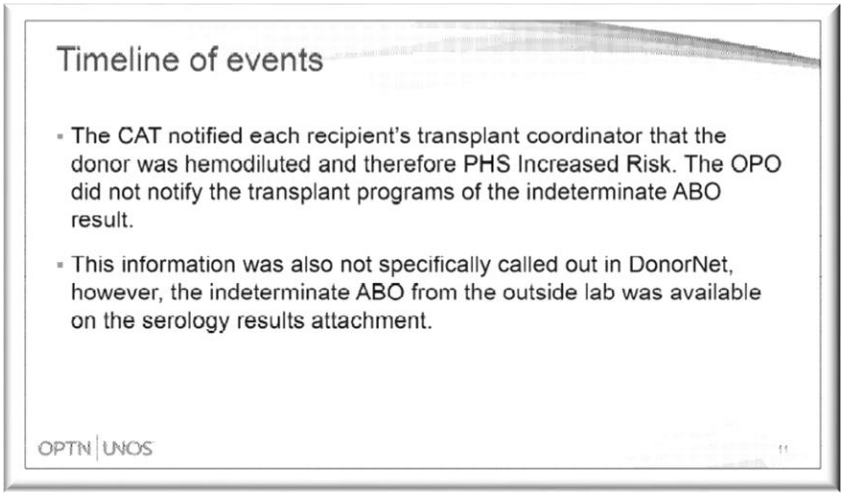


MPSC Concerns

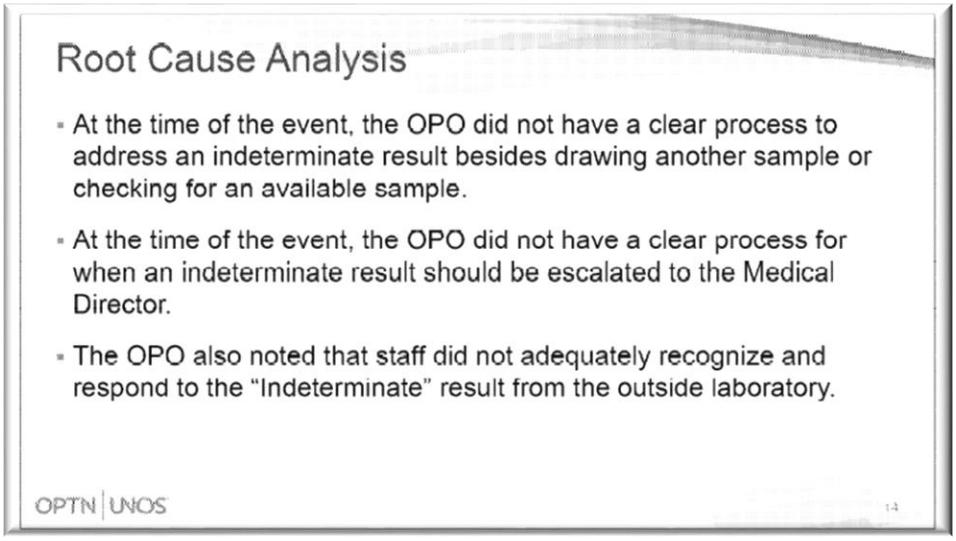
The MPSC leadership was concerned by the failure of SCOP's staff and AOC to recognize the potential safety consequences of indeterminate blood typing issues. The group was concerned with the use of broad terminology such as mass transfusion and indeterminate blood type instead of firm clinical and situational triggers when determining which donor cases go for AOC and Medical Director review. Finally, the group was particularly concerned that SCOP did not accept responsibility for this event and look internally to assess what OPO staff could have done to prevent this event, regardless of the actions of the donor hospital.

In a MPSC presentation dated February 26-27, 2019, the MPSC Compliance Operations Analyst discussed this case.[164] After reviewing the timeline of events, the MPSC discovered that, although the blood typing results from the outside lab was made available to transplant centers in an attachment, the information was not explicitly stated on DonorNet and not clearly relayed. DonorNet is the UNOS platform that, "match[es] each unique organ to the best-suited candidates, and send[s] automated organ offers to transplant surgeons for acceptance or refusal."[165] The timeline of events follows:[166]

[161] UNOS_2_000014075, at 14076.
[162] UNOS_2_000015134.
[163] UNOS_2_000015134-15135.
[164] UNOS_2_000015338.
[165] *Technology for transplants*, UNOS, https://unos.org/technology/technology-for-transplantation/ (last reviewed July 22, 2022).
[166] UNOS_2_000015338, at 15349.



Additionally, the root cause analysis (RCA) found a variety of contributing factors at SCOP:[167]



SCOP took multiple corrective actions to address the error, including an immediate containment plan to prevent this from happening again and the developed of a "hard stop" playbook to trigger the containment plan.[168]

On February 27, 2019, the MPSC met and reviewed all of SCOP's documentation as well as the subcommittee's recommendations.[169] On March 19, 2019, the MPSC issued a "Notice of Noncompliance to SCOP for failure to follow policy 2.6.A 'Deceased Donor Blood Type

[167] UNOS_2_000015338, at 15351.
[168] UNOS_2_000015338, at 15352.
[169] UNOS_6_000067181.

Determination.'" Ultimately, this case resulted in the death of the lung recipient, near-death of the heart recipient, and two kidney discards.[170]

This was not the first incident of a blood typing error gone wrong at SCOP. In 2003, a teenager died after a blood typing error related to a heart and lung transplant.[171] Furthermore, in the MPSC presentation, dated February 26-27, 2019, the Compliance Operations Analyst discussed another ABO case gone wrong at a different OPO, happening only two months prior to the SCOP event.[172] As a result of these incidents, the OPTN Operations and Safety Committee (OSC), revised the OPTN policy at issue. (The OSC's mission it to, "identify potential improvements and policy revisions that may prevent future such occurrences."[173]) In September 2020, OSC modified the OPTN guidance and policy to address blood type determination, adding "indeterminate" to the conflicting results criteria.

[170] UNOS_2_000015338, at 15350.
[171] Mary Katherine Wildeman, *He died when he got the wrong lungs. It wasn't the only organ error in SC that day*, THE POSE AND COURIER (Sep. 11, 2020), https://www.postandcourier.com/health/he-died-when-he-got-the-wrong-lungs-it-wasnt-the-only-organ-error-in/article_c6a6e386-e704-11ea-91ce-2783df6c6f2d.html.
[172] UNOS_2_000015338, at 15375.
[173] *Organ Procurement and Transplantation Network*, https://optn.transplant.hrsa.gov/policies-bylaws/notices-of-implemented-actions/ (last visited July 19, 2022).

APPENDIX C
Life Connection of Ohio (OHLC)
Re: Cancer Transmission Case

On March 29, 2020 at 04:25AM EST, Life Connection of Ohio (OHLC), an organ procurement organization (OPO) serving northwest Ohio, received an organ donation referral from St. Luke's Hospital for a patient diagnosed with intracerebral hemorrhage, or bleeding into the brain.[174] OHLC conducted a medical record review of the patient on March 29, 2020 at 9:20 a.m.[175] The patient's condition continued to deteriorate and, on March 31, 2020, OHLC began an organ match run against donor waiting lists.[176] Several organs were matched, including the donor's heart.[177]

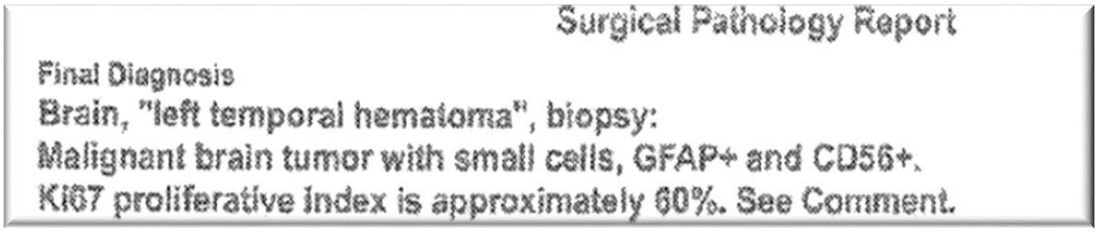
The patient was determined to be brain dead by her attending physician on April 1, 2020 at 9:31 p.m. and OHLC was called for organ recovery.[178] OHLC recovered multiple organs between April 1, 2022 and the early morning of April 2, 2020.[179]

On March 30, 2020, one day after OHLC conducted their medical record review of the patient, but two days before brain death, organ match runs, and organ recovery, the donor hospital received a surgical pathology report from a brain biopsy of the donor.[180] Stated in the report was the preoperative diagnosis with a note:[181]


Clinical Information
Procedure: CRANIOTOMY.
Preoperative diagnosis: HEAD PAIN, RULE OUT BRAIN TUMOR.

The surgical pathology report was signed April 1, 2020 at 10:23 a.m., 11 hours before donor brain death and subsequent organ recover, and notes the final diagnosis as "[m]alignant brain tumor with small cells." [182]

[174] UNOS_3_000046430, at 46431.
[175] UNOS_3_000046430, at 46431.
[176] UNOS_3_000046430, at 46431.
[177] UNOS_3_000046430, at 46432.
[178] UNOS_3_000046430, at 46437.
[179] UNOS_3_000046430, at 46431.
[180] UNOS_3_000046430, at 46431.
[181] UNOS_3_000046430, at 46439.
[182] UNOS_3_000046430, at 46439.



Surgical Pathology Report

Final Diagnosis
Brain, "left temporal hematoma", biopsy:
Malignant brain tumor with small cells, GFAP+ and CD56+.
Ki67 proliferative index is approximately 60%. See Comment.

On April 22, 2020, OHLC discovered that a brain biopsy occurred prior to organ recovery.[183] After learning about the cancerous biopsy results, OHLC notified each transplant center that accepted organs from the donor and submitted a "Potential Disease Transmission Report" to UNOS.[184]

OHLC also reached out to Community Tissue Services, an organ and tissue bank, to inquire about the incident, writing:

> "this was just forwarded to me. Do you know why this was performed? Was there suspicion?"[185]

Community Tissue Services replied:

> "There was mention of malignant brain tumor in the hospital chart and the slides were sent to UM for further evaluation. We just followed up to make sure the further evaluation did not reveal anything of concern."[186]

On June 4, 2020, UNOS received a complaint about OHLC from a transplant recipient who received a heart transplant from a donor who died of cancer.[187] The complaint alleges OHLC failed to identify the donor's cause of death due to metastatic glioblastoma and that the transplant recipient was informed they "may likely die within 3 years" due to the donor's malignancy.[188] The patient's complaint followed that his transplant doctor told him "he doesn't know how [the OPO] 'messed up' and did not catch this prior to [transplant]."[189]

UNOS opened a review on June 22, 2020.[190] In response to UNOS's inquiry, OHLC stated that their medical record review, which occurred days before recovery, found "no documentation of malignancy" or mention that specimens were sent to pathology prior to organ recovery.[191] OHLC also stated that the discharge note did not include a mention of a brain malignancy.[192] In addition to evidence a donor brain tumor was received by the donor hospital in the days between OHLC's medical record review and the donor's brain death and organ

[183] UNOS_3_000046430, at 46431.
[184] UNOS_3_000046430, at 46431.
[185] UNOS_3_000046430, 46438
[186] UNOS_3_000046430, 46438
[187] UNOS_3_000046449.
[188] UNOS_3_000046451.
[189] UNOS_3_000046451.
[190] UNOS_3_000086246.
[191] UNOS_3_000046430, at 46431.
[192] UNOS_3_000046430, at 46431.

donation, records available at the time of OHLC's initial review also contain indicia of a brain tumor. Medical records produced to the Committee show that documentation was available to OHLC from a head CT performed on March 28, 2020 which states that an "underlying mass or infarct not entirely excluded," meaning that the radiologist could not rule out a brain mass.[193]

OHLC responded on July 7, 2020 with responses to UNOS's questions concerning the sequence of events and procedures followed.[194] In addition to providing clinical information, OHLC noted they updated their policies to prevent these events by requiring the Patient Transplant Coordinator to review all pathology reports during the initial donor evaluation as well as prior to going to the operating room for recovery.[195] On July 31, 2020, UNOS informed OHLC that they were not requesting additional information and would not forward this case to the MPSC.[196]

[193] UNOS_3_000046430, at 46431.
[194] UNOS_3_000046430.
[195] UNOS_3_000046430, at 46433.
[196] UNOS_3_000046456.

APPENDIX D
LifeQuest Organ Recovery Services (FLUF)
Re: Cancer Transmission Case

On February 18, 2018, FLUF recovered a liver and heart for transplant.[197] According to FLUF, "[o]rgan recovery was unremarkable."[198] However, documentation available to FLUF prior to organ procurement indicated otherwise stating, "redness/irritation noted between the legs/scrotal area with scrotum having notable swelling."[199] On February 19, 2018, an autopsy further noted, "numerous hemorrhagic nodules were noted on the right testicle."[200] Pathology later found testicular embryonal carcinoma.[201] The root cause analysis reported to UNOS's Disease Transmission Advisory Committee (DTAC) stated: [202]

2.19.18 0918 EST	The pathologist in the District Two Leon County Medical Examiner's office performed the autopsy on 2/19/18 at 0918 EST. According to the autopsy report, during the autopsy, "numerous hemorrhagic nodules were noted on the right testicle." Pathology later revealed right testicular embryonal carcinoma, and this was included in the final autopsy report. Also included, was a statement in all capital letters: "EVIDENCE OF MEDICAL INTERVENTION AND ORGAN PROCUREMENT". There were several other statements regarding organ recovery throughout the report.

Despite the notation: "EVIDENCE OF MEDICAL INTERNVENTION AND ORGAN PROCUREMENT," the organ procurement organization (OPO) did not receive the results of the autopsy until approximately June 11, 2018, more than 4 months after the autopsy.[203] LifeQuest's Medical Director reviewed the autopsy report, dated, initialed, and submitted it to the quality assurance (QA) staff to be scanned into the donor record.[204] However, the Medical Director did not note that the donor had testicular cancer.[205]

According to FLUF, on February 15, 2019, FLUF's "Director of Clinical Operations received a call from a Mayo Clinic transplant coordinator, who stated that during the liver transplant recipient's one-year follow up appointment, an ultrasound revealed a large liver mass and was confirmed by MRI."[206] In addition, "[b]iopsy of the mass indicated that it was a germ cell tumor, probably embryonal."[207]

[197] UNOS_2_000010576, at 10577.
[198] UNOS_2_000010576, at 10580.
[199] UNOS_2_000010576, at 10597.
[200] UNOS_2_000010576, at 10580.
[201] UNOS_2_000010576, at 10580.
[202] *Ad Hoc Disease Transmission Advisory Committee*, OPTN, https://optn.transplant.hrsa.gov/about/committees/ad-hoc-disease-transmission-advisory-committee/ (last reviewed July 21, 2022); *see also* UNOS_2_000010576, 10580.
[203] UNOS_2_000010576, at 10580.
[204] UNOS_2_000010576, at 10580.
[205] UNOS_2_000010576, at 10580.
[206] UNOS_2_000010576, at 10580.
[207] UNOS_2_000010576, at 10580.

2.15.19 0900	On the morning of February 15, **2019**, the Director of Clinical Operations received a call from a Mayo Clinic transplant coordinator, who stated that during the liver transplant recipient's one-year follow up appointment, an ultrasound revealed a large liver mass and was confirmed by MRI. Biopsy of the mass indicated that it was a germ cell tumor probably embryonal. It was asked by the Mayo coordinator if we would review our donor record to determine if this could have been donor derived.
2.15.19 0930	The Director of Clinical Operations quickly began reading through the donor record and eventually found the autopsy report from the ME office that revealed testicular embryonal carcinoma. She immediately notified the Associate Executive Director who then notified the Executive Director.

2

Following this call, FLUF's Director of Clinical Operations found the autopsy report that revealed testicular embryonal carcinoma.[208] In a call to Duke later that morning, FLUF was told the heart recipient died of multi-system organ failure in November 2018, although that patient did not demonstrate evidence of cancer, and was also told that "treatment would begin" for the liver recipient.[209] The case was entered into the UNOS's patient safety portal later that same day.[210]

2.15.19 1000-1300	Between the hours of 1000-1300 Mayo (liver), Duke (heart) and DTAC were notified of the finding. During the call to Duke, the transplant coordinator stated that the heart patient died of multi-system organ failure in November of 2018, and never demonstrated any evidence of cancer. The Mayo liver surgeon indicated that treatment would begin for the recipient and that they reported this possible disease transmission to DTAC.
2.15.19 1605 EST	The Executive Director called the Medical Director to inform him.

Nine days later, on February 28, 2019, UNOS notified FLUF that it would look into the report and asked questions concerning the incident.[211] FLUF responded on the same day.[212] On March 7, 2019, UNOS notified FLUF of an MPSC review into the case.[213] In documents produced to UNOS in response to that inquiry, FLUF reported that "[t]he LifeQuest medical director overlooked this critical finding when he originally viewed the Medical Examiner's autopsy report on June 11, 2018. This is the reason why the autopsy findings were not communicated to Mayo nor UNOS/DTAC."[214]

Ultimately, MPSC issued a "Notice of Noncompliance" for policy Violation 15.4 (Host OPO Requirements for Reporting Post-Procurement Test).[215] UNOS's remedial action was not public.

[208] UNOS_2_000010576, at 10581.
[209] UNOS_2_000010576, at 10580-10581.
[210] UNOS_2_000010569.
[211] UNOS_2_000010650.
[212] UNOS_2_000010576, at 10577.
[213] UNOS_2_000010610.
[214] UNOS_2_000010612.
[215] On file with the Committee.

APPENDIX E
Nevada Donor Network (NVLV)
Re: Kidney Death Case and Testing Failures

On July 13, 2017, a kidney transplant recipient died six days post-transplant from a rare bacterial infection.[216] When the Centers for Disease Control (CDC) learned about this incident on July 19, 2017, they contacted UNOS for additional information about this "public health emergency."[217] UNOS knew of the incident 5 days prior, but did not share any information with the CDC until the CDC reached out to UNOS. Furthermore, UNOS staff did not have any knowledge of the event because, it appears, the UNOS safety analyst who received the initial incident report did not escalated it to UNOS leadership, the Health Resources and Services Administration (HRSA), or the CDC when UNOS was first alerted about the patient death.[218]

On July 14, 2017, the Nevada Donor Network (NVLV), an organ procurement organization (OPO) in Nevada, self-reported through UNOS's patient safety portal information about two transplant recipients who had developed serious complications shortly after transplant, leading to the death of one recipient.[219] In its submission, NVLV stated that, a "report from NVUM revealed [the patient] deteriorated post-transplant and ultimately expired on 7/13/17."[220] The UNOS safety analyst who received this case labeled it a "low" priority.[221]

The recipients had contracted a rare infection known as tularemia.[222] Tularemia is "a rare infectious disease caused by the bacterium Francisella tularensis."[223] The infection "attacks the skin, eyes, lymph nodes and lungs," and is "also known as rabbit fever or deer fly fever," as it primarily affects rodents such a squirrels, rabbits and hares.[224]

On July 17, 2017, UNOS staff reached out to NVLV to confirm receipt.[225] The notification follows:[226]

[216] UNOS_1_000042009.
[217] UNOS_6_000015441, at 15442-43.
[218] UNOS_1_000042009, at 42010.
[219] UNOS_1_000042009. UNOS_6_000015447 at 15449.
[220] UNOS_1_000042009.
[221] UNOS_1_000042009, at 42010.
[222] UNOS_6_000015447, at 15449.
[223] *Tularemia*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/tularemia/ (last updated Nov. 6, 2020).
[224] *Tularemia*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/tularemia/ (last updated Nov. 6, 2020).
[225] UNOS_1_000042015.
[226] UNOS_1_000042015.

UNOS' Member Quality Department received your correspondence through the UNet℠ Patient Safety Portal concerning a deceased kidney recipient. Specifically, you have raised concerns that the kidney recipient died 6 days post-transplant, and that both kidney recipients had a similar post-transplant course of illness. At this time, investigation into possible disease transmission, contamination, or other causes of the death are pending.

Two days later, on the morning of July 19, 2017, CDC received notification about the event from state public health labs and began communicating with HRSA and UNOS.[227] CDC expressed their serious concerns to UNOS writing: [228]

Sent from my iPhone
On Jul 19, 2017, at 2:50 PM, [redacted]@cdc.gov> wrote:

Dear all,
We just received a call from our bacterial diseases group at CDC as they were notified of two patients (in CA and NV) who have confirmed tularemia infection – both were recipients of kidneys from a common donor. One (NV) recipient has died.

Have you (UNOS) received a report on this? CDC obviously will accept the investigation. We do not know yet if there are other organ recipients or tissues were recovered.

Please let us know as soon as you hear back about this
I am available at all times at below contact information

[redacted]

[redacted]
Office of Blood, Organ, and Other Tissue Safety
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

The email continues:[229]

Sent from my iPhone
On Jul 19, 2017, at 2:57 PM, [redacted]cdc.gov> wrote:

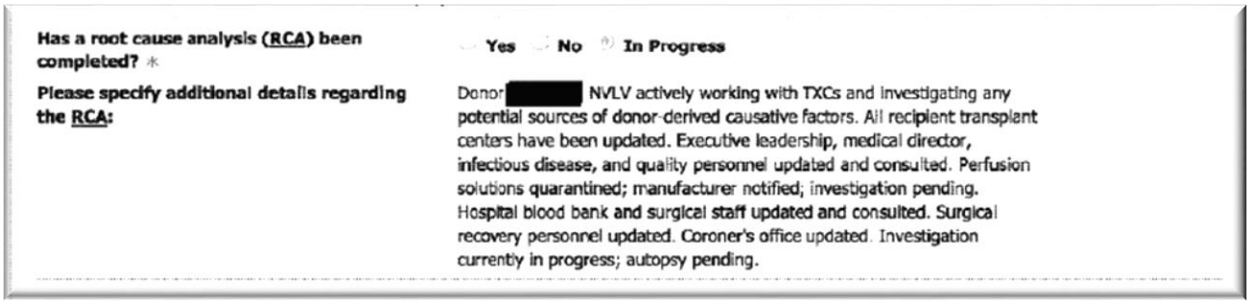
Just to clarify—our CDC contact did not know which OPO or which transplant centers were involved.

She was notified by the state public health labs and had otherwise scant information.

This is obviously a public health emergency so we wanted to get to work on this immediately as there may be dozens of healthcare workers at risk in addition to organ/tissue recipients.

[227] UNOS_6_000015447, at 15443 and 15449.
[228] UNOS_6_000015441, at 15443.
[229] UNOS_6_000015441, at 15442.

CDC requested information from UNOS about what transplant centers were aware of the event and for all recipient and transplant center information.[230] UNOS staff told the CDC that they were made aware of the event by the transplant center for the "left kidney recipient," but did not mention NVLV's self-report submitted five days prior.[231] Additionally, UNOS staff did not appear to be aware of the fact that NVLV had already alerted all of the transplant centers about the potential risk, which would have been valuable information for the CDC:[232]



Has a root cause analysis (RCA) been completed? *	Yes No In Progress
Please specify additional details regarding the RCA:	Donor [redacted] NVLV actively working with TXCs and investigating any potential sources of donor-derived causative factors. All recipient transplant centers have been updated. Executive leadership, medical director, infectious disease, and quality personnel updated and consulted. Perfusion solutions quarantined; manufacturer notified; investigation pending. Hospital blood bank and surgical staff updated and consulted. Surgical recovery personnel updated. Coroner's office updated. Investigation currently in progress; autopsy pending.

Additionally, it does not appear that the complaint received on July 14, 2020 was escalated through to UNOS leadership, which is required under OPTN policy as a threat to public health or patient safety.[233] Ultimately, the outcome of this case is unclear based on the documents reviewed by the Committee.

[230] UNOS_6_000015441-42.
[231] UNOS_6_000015441.
[232] UNOS_1_000042009.
[233] *See, e.g.*, UNOS_3_000039007, at 39010. Staff were unable to locate an intake form from this event.

APPENDIX F
Mississippi Organ Recovery Agency (MSOP)
Re: Late Kidney

On February 27, 2017, the transplant center at Mayo Clinic Hospital in Arizona, reported 2 instances within 3 ½ months where kidneys were delayed in transit, resulted in extended cold ischemic time (CIT) on 2 kidneys and the discard of a third kidney.[234]

The first incident occurred on December 17, 2016 and the second occurred on February 25, 2017.[235] According to the report submitted by the Mayo Clinic to UNOS's patient safety portal:[236]

> AZMC [or, Mayo Clinic Hospital in Arizona] is reporting two instances where NGL (Network Global Logistics) was used as the transportation courier service and the organs did not arrive to the airport in time to make the flight. This resulted in 3 cancelled kidney transplants due to prolonged cold ischemic time.

On March 27, 2017, UNOS reached out to MSOP to inquire about the incident:[237]

> We are currently reviewing a kidney allocation by Mississippi Organ Recovery Agency for donor [Redacted]. Our preliminary analysis indicates that a courier was unable to deliver the kidney to the airport in time to make the scheduled flight. The kidney was ultimately discarded.

Despite UNOS requesting further information from the organ procurement organization (OPO) and reportedly receiving a response,[238] the case was closed with no apparent action. In UNOS's closure letter, UNOS indicated that the MPSC would not review the case, even though it resulted in a discarded organ.[239]

It is interesting to note that, unless a complaint is submitted under the "donor" section of UNOS's patient safety portal, the complainant does not have the option to indicate the case resulted in a discard. In this case, the discard was only noted in the complaint's text.[240] This indicates that UNOS's systems may not be able to track these types of incidents.

[234] UNOS_3_000076146-47.
[235] UNOS_3_000076146-47.
[236] UNOS_3_000076146-47.
[237] UNOS_3_000076155-57.
[238] The response was not provided to the Committee.
[239] UNOS_3_000076166.
[240] UNOS_3_000076146.

APPENDIX G
Donor Alliance (CORS)
Re: Kidney Courier Case (Transportation Failure/Organ Discarded)

On April 21, 2018, Donor Alliance, the organ procurement organization (OPO) serving Colorado and most of Wyoming, filed a patient safety event report regarding Sterling Courier services and UNOS.[241] The report stated that, due to a data entry error, Sterling Courier left the right kidney at CORS because their paperwork only instructed them to pick up the left kidney.[242] The report also stated that communication failures at the UNOS Organ Center, the division of UNOS that assists in supporting organ transportation, and the intended recipient's transplant center regarding alternate transportation resulted in extended delays.[243] The description of the event as reported in the patient safety portal is as follows:

> A kidney for transplant was left at the Donor Alliance Recovery Center by Sterling Courier. According to their paperwork, they were to only pick up the left kidney. There was a data entry error by Sterling Courier that led to the right kidney not being added to the job with the left kidney. There was additional miscommunication between UNOS and NYRT on acceptance of the right kidney and arranging transport of the right kidney. Donor Alliance was never made aware that the right kidney was not picked up with the left kidney. DA was also not notified when alternate arrangements were supposed to be made by UNOS for right kidney to NYRT UNOS did not have proper handoff between shifts and to DA. The consequence of the errors in communication is that a transplantable organ had to be discarded and a recipient who was expecting to receive that kidney was not going to get a transplant.[244]

Following this event, Sterling Courier, UNOS, and CORS each conducted a root cause analysis (RCA) of the event.[245] It appears these entities completed their RCAs before Donor Alliance submitted the report to UNOS, as all three RCAs were included with the report that was entered into the patient safety portal one month following the event.[246]

UNOS's RCA found there was "lack of clear or complete communication during hand off from one shift to the next."[247] UNOS recommended corrective actions and announced a pilot a program that would list active transportation as "active cases" on their dashboard to eliminate gaps during shift changes.[248] Sterling's RCA found that their internal shipment tracking system, QuickTrak, did not save the job due to a customer service representative not hitting the right key upon exiting.[249] Lastly, CORS's RCA found that their organ staff did not communicate with tissue staff regarding courier pick up.[250] As a

[241] UNOS_3_000039007.
[242] UNOS_3_000039003, at 39004.
[243] UNOS_3_000039003, at 39011.
[244] UNOS_3_000039003-05.
[245] UNOS_3_000039003, at 39005.
[246] UNOS_3_000039003, at 39005.
[247] UNOS_3_000039003, at 39005.
[248] UNOS_3_000039003, at 39005.
[249] UNOS_3_000039003, at 39005.
[250] UNOS_3_000039003, at 39005.

corrective action, CORS staff planned, "to implement a communication process (white board and log for communication between organ and tissue teams.")[251]

On July 12, 2021, CORS staff reached out to UNOS requesting documentation that the matter was closed, as they did not have anything in their records.[252] UNOS responded to CORS, explaining: [253]

> Good Morning [redacted]
>
> [redacted] forwarded my team your email regarding closure of an event submitted by CORS in April 2018. Our protocol is to send formal closure correspondence for events when we've first sent an inquiry to request additional information (and sometimes RCAs, CAPs) from a member. I've just reviewed the case and see that UNOS didn't send an inquiry, so no closure letter would've been sent. I'm attaching the Acknowledgement letter that was sent when your team submitted the event to the system. This will be the only correspondence to CORS for this case. Please let me know if you have questions about this.

This email correspondence seems to suggest that UNOS never conducted additional inquiries or an investigation into this matter. Ultimately, the right kidney was discarded as these errors in communication lead to increased cold ischemic time that left the kidney non-viable.[254] There was no MPSC outcome for this complaint, as it never became a UNOS patient safety case, which demonstrates UNOS's lack of effort to address transportation errors and enforce best practices among its members.

[251] UNOS_3_000039003, at 39005.
[252] UNOS_6_000022475.
[253] UNOS_6_000106060.
[254] UNOS_3_000039007-11.

APPENDIX H
We Are Sharing Hope (SCOP)
Re: Airline Case 1

On September 25, 2015, Jackson Memorial Hospital Transplant Center in Miami (FLJM) reported a patient safety event via UNOS's patient safety portal (PSP).[255] FLJM identified errors transporting a kidney which ultimately resulted in the organ being discarded.[256] The intake form notes that a right kidney was accepted from We Are Sharing Hope (SCOP), a South Carolina based organ procurement organization (OPO), for transport and was "misplaced by American Airlines."[257] When it was found at 7:00 a.m., the transplant team declined the kidney because extended cold ischemic time (CIT) rendered it unusable.[258] CIT is the time from when an organ has no blood flow and is cooled down for transportation to the time it is warmed up again for transplant and blood flow is restored.[259] On the PSP submission, SCOP notes that they completed a root cause analysis (RCA) and found that a "non-standard airline [was] used due to flight availability."[260] The September 25, 2015, patient safety submission follows:[261]

> Right kidney accepted for transplant at FLJM from SCOP. Organ sent by SCOP using courier NGO and American Airlines. Organ misplaced by American Airlines and transplant cancelled. Per [redacted] (OPO coordinartor: [redacted] organ found @ 0700 and sent make to OPO for discard. Cold time making organ usage impossible.

At their weekly meeting on September 30, 2015, UNOS staff reviewed this case. As a next step, UNOS decided to "reach out to SCOP to ensure that there is no responsibility on behalf of the OPO and this was truly an airline issue. If so, can close as done with previous cases." [262] A week later, on October 6, 2015, UNOS requested information from SCOP about the case and, on October 14, 2015, SCOP responded to UNOS, citing the change in airline carriers by their courier service as the source of the problem. The email follows:[263]

> Here is a time line of the transportation issues that we had with the right kidney on [redacted] We use Network Global Logistics (NGL) for out of state courier services. NGL normally uses Delta Airlines as primary and United Airlines as secondary on all jobs. On this particular day, Delta's systems were down and could not accept shipments. United did not have a flight that arrived in Miami before the American Airlines flight. Therefore, we used American for this shipment.

[255] UNOS_3_000086989-90.
[256] UNOS_3_000086985.
[257] UNOS_3_000086985.
[258] UNOS_3_000086985.
[259] *Cold ischemia time*, NATIONAL CANCER INSTITUTE https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cold-ischemia-time (last reviewed July 22, 2022).
[260] UNOS_3_000086989, at 86990.
[261] UNOS_3_000086990.
[262] UNOS_5_000034100.
[263] UNOS_3_000086992.

SCOP further noted that, due to the change in airline services, the courier service was not aware that the new airline did not automatically place a "lifeguard" status on organs and therefore did not request it.[264] The OPO admits, "had they done this, it is unlikely that the package would have been lost as easily." [265] SCOP also explained that the kidney was:[266]

> located on a luggage trolley in the ramp area. [redacted] told me that American Airlines does not automatically place a "lifeguard" status on organ shipments like Delta and United do. Since NGL doesn't routinely use American for these shipments, his CSR's did not think to request this urgent status for this shipment. Had they done this, it is unlikely that the package would have been lost as easily. NGL will be reviewing their policies and training their CSRs to always request lifeguard status on shipments of organs.

On October 21, 2015, UNOS again discussed this case again at their weekly meeting:[267]

> Email confirmed that SCOP's courier used a different airline than normal, American versus Delta. American had accidently left the kidney on a luggage tug and by the time it was found, there was too much CIT for reallocation. Reviewed again with group and group in agreement to close.

UNOS closed this case never sent it to the Membership and Professional Standards Committee (MPSC). As noted above, the kidney was discarded due to the extended CIT, which rendered it non-viable. This was one of three transportation errors at SCOP between 2015 and 2017.[268]

[264] UNOS_3_000086992, at 86993.
[265] UNOS_3_000086992, at 86993.
[266] UNOS_3_000086992, at 86993.
[267] UNOS_5_000034100.
[268] UNOS_6_000007958.

APPENDIX I
We Are Sharing Hope (SCOP)
Re: Airline Case 2

On March 29, 2017, UNOS sent an inquiry letter to We Are Sharing Hope (SCOP), the organ procurement organization (OPO) for South Carolina, to request information about a potential allocation error.[269] Earlier that month, on March 2, 2017, two kidneys had missed their flight.[270] However, SCOP was able to re-route the organs to a local transplant center at the last minute and another candidate received the organs. In its March 29, 2017 letter, UNOS states:[271]

> We are currently reviewing a matter of a kidney allocation from We Are Sharing Hope SC for donor [redacted]. Our preliminary analysis indicates that both kidneys were allocated to the center at sequence #1; after two flights were missed, the kidneys had to be re-allocated to a local center.

UNOS also asks about potential violations of their allocation policy, questions "[w]hy the kidneys were unable to be placed on the scheduled flights," and requests that SCOP provide any root cause analysis (RCA) completed or corrective action plans (CAP) implemented.[272] On April 12, 2020, SCOP responded that their courier service, MNX Global Logistics (MNX), had completed a RCA and explained that the carrier's failure to load the kidney in time for the departure flight was the cause of the delay. SCOP's response follows:[273]

> The incident was reviewed by MNX Courier in conjunction with Delta Airlines. MNX indicated that the root cause was failure of Delta Airlines to load the right kidney on the originally booked flight and subsequent flight to LAX.

As a corrective action, the airline planned to brief their ramp personnel and management on the issue:[274]

> **MNX root cause-** Failure of Delta Airlines to load the right kidney on the originally booked flight and subsequent flight to LAX.
>
> **Corrective Action:** MNX has reviewed this with Delta Management and they are aware of the severity of this incident and will brief their ramp personnel/ramp management.

[269] UNOS_3_000088813.
[270] UNOS_3_000088813.
[271] UNOS_3_000088813.
[272] UNOS_3_000088813.
[273] UNOS_3_000088815, at 88816.
[274] UNOS_3_000088815, at 88822.

However, Committee staff believe that the airline was not the only cause of the delay. For example, on March 2, 2017, at 8:28 p.m., the courier service called the OPO to let them know that the kidney was not on the intended flight because "someone mistakenly put tomorrow's date for fly out."[275] SCOP staff contacted the receiving center to let them know that the kidney would miss its original flight due to this error. SCOP reported the following timeline of events:[276]

03/02/2017	20:28	CAT received a call from [redacted] CSR with MNX, who advised that the kidney outbound for Cedars-Sinai was not placed on the intended flight (Delta 1218) and then someone mistakenly put tomorrow's date for fly out. Kidney should now fly out on Delta flight 1128 and arrive at LAX at 0008 PST with delivery by 0200. She said her manager [redacted] is involved as is upper management trying to resolve this. They will give me an update later. CAT notified Legacy One (OPO) at 2035 and spoke to [redacted] a coordinator, explained what had happened with the kidney missing the flight, advised of new anticipated delivery time, and answered her questions. The CAT then updated AOC at 2049.

That same night, the courier service again notified SCOP that, despite receiving the GPS coordinates, Delta Airlines was unable to locate the organ in time for the second scheduled flight. The courier service offered to charter the kidney, to which the clinical allocation coordinator (CAT) at the OPO responded, "almost certainly not and requested next available commercial flight to LAX tomorrow morning."[277] It is unclear why the CAT did not take the courier service up on their offer when a chartered flight would have gotten the kidney to its intended location on time.

SCOP then decided that the "best plan is to try get [the] kidney back to Charleston presuming [the transplant center] declines for cold time."[278] The receiving center again reached out to SCOP, this time asking if there was an earlier flight. Despite SCOP's offer to move the kidney onto an earlier American Airlines flight, the transplant center ultimately declined due to the prolonged cold ischemic time (CIT), or the time from which an organ has no blood flow and is cooled down for transportation to when it is warmed up for transplant and blood flow is restored.

During its weekly case review meeting held on April 18, 2017, UNOS staff identified the airline carrier as the cause of the event and reported: "Delta failed to load kidney on first flight, then, despite being given GPS coordinates, was unable to find it to load onto second flight."[279] UNOS staff "agreed to close" this case during the meeting.[280] UNOS also wrote to SCOP, stating that it did not require additional information and would not forward the case to the Membership and Professional Standards Committee (MPSC).[281] Therefore, the MPSC did not review this

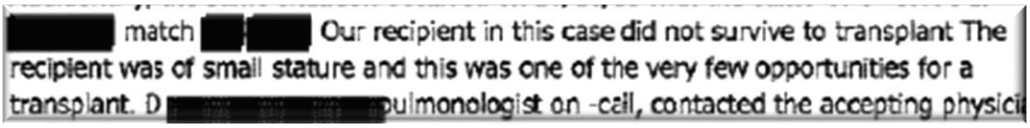
[275] UNOS_3_000088815, at 88820.
[276] UNOS_3_000088815, at 88820.
[277] UNOS_3_000088815, at 88821.
[278] UNOS_3_000088815, at 88821.
[279] UNOS_5_000034100.
[280] UNOS_5_000034100.
[281] UNOS_3_000088831.

case. Although this organ was transplanted at a local transplant center, the original recipient missed their opportunity for a life-saving transplant. This was one of three transportation errors at SCOP between 2015 and 2017.[282]

[282] UNOS_6_000007958.

APPENDIX J
LifeGift Organ Donation Center (TXGC)
Re: Allocation Error Case

On February 7, 2019, UNOS received a complaint that LifeGift Organ Donation Center (TXGC), an organ procurement organization (OPO) in Houston, Texas, improperly allocated a heart and lungs recovered from a donor.[283] The reporting hospital stated that this was the second occurrence of this issue with the OPO. The hospital also noted that their waitlisted patient, who they believed should have received the organs as a matter of OPTN policy, did not survive to transplant.[284]


[redacted] match [redacted] Our recipient in this case did not survive to transplant The recipient was of small stature and this was one of the very few opportunities for a transplant. D[redacted]pulmonologist on -call, contacted the accepting physici

The report described two separate cases, one dated October 2018 and the other February 2019, where TXGC offered the donor's lungs separate from the heart. In the first instance, the lungs were matched before the heart was offered to the waiting list.[285] In the second instance, the OPO received a provisional acceptance for the heart first, and then matched the lungs while the heart offer was still provisional.[286] The provisional heart match was then declined.[287]

In both instances, the heart was eventually matched with the reporting hospital whose patient needed both a heart and lungs.[288] In both instances, the hospital that matched with the heart requested that TXGC rescind the lung offer so both could be allocated to their patient, per OPTN Policy 6.5.F Allocation of Heart-Lungs:[289]

Relevant OPTN Policies:
6.5.F Allocation of Heart-Lungs: "When a heart-lung candidate is allocated a heart, the lung from the same deceased donor must be allocated to the heart-lung candidate." (Policy in effect prior to October 18, 2018)

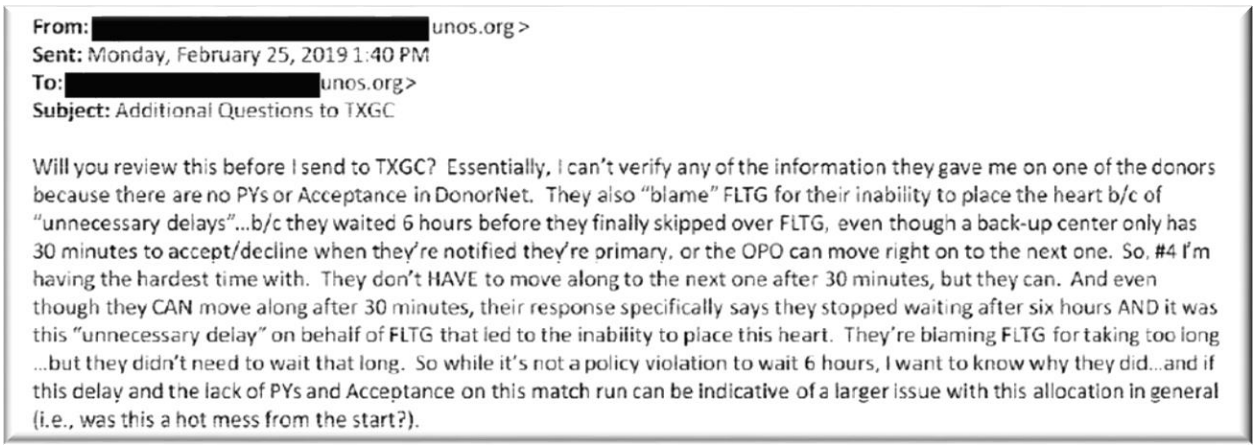
TXGC refused this request, believing that, because the lungs had already been matched, rescinding the offer would itself be a violation of OPTN policy.[290] The October 2018 case does not appear to have been immediately submitted to UNOS for assistance resolving the disagreement.[291] In the February 2019 case, not only did the same disagreement between the

[283] UNOS_4_000281833, at 281835.
[284] UNOS_4_000281833, at 281835.
[285] UNOS_4_000281833-34.
[286] UNOS_4_000281833-34.
[287] UNOS_4_000281833-34.
[288] UNOS_4_000281833-34.
[289] UNOS_4_000281833-34.
[290] UNOS_4_000281833-34.
[291] UNOS_4_000281833-34.

same entities result in the death of a waitlisted patient who died before transplant, the repeat dispute caused "unnecessary delays" and the recovered heart was discarded without being transplanted.[292]

After receiving a report of both incidents, UNOS sent a letter to TXGC on February 13, 2019[293] and, on February 20, 2019, TXGC sent their follow up response.[294] TXGC stated that neither a root cause analysis nor a post case review had been performed and provided corrective actions including that "placement staff will enter code 898 and specify that the center refused when a center refuses to provide or confirm decline codes," in effect placing blame entirely on the transplant hospital for the incident.[295]

On February 25, 2019, UNOS staff wrote to a colleague questioning TXGC's decision to delay allocation and asked for guidance on their response to TXGC:[296]

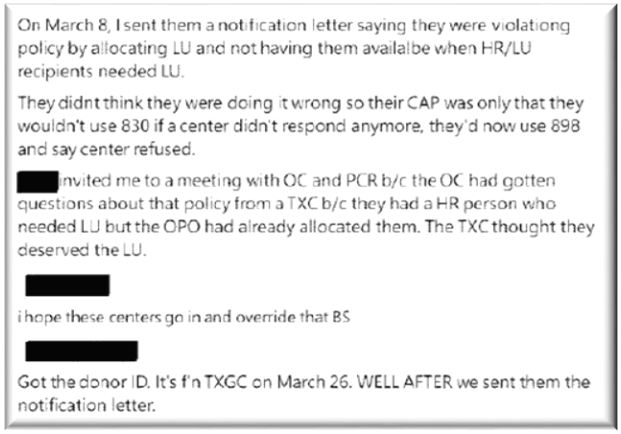


From: [redacted]unos.org>
Sent: Monday, February 25, 2019 1:40 PM
To: [redacted]unos.org>
Subject: Additional Questions to TXGC

Will you review this before I send to TXGC? Essentially, I can't verify any of the information they gave me on one of the donors because there are no PYs or Acceptance in DonorNet. They also "blame" FLTG for their inability to place the heart b/c of "unnecessary delays"...b/c they waited 6 hours before they finally skipped over FLTG, even though a back-up center only has 30 minutes to accept/decline when they're notified they're primary, or the OPO can move right on to the next one. So, #4 I'm having the hardest time with. They don't HAVE to move along to the next one after 30 minutes, but they can. And even though they CAN move along after 30 minutes, their response specifically says they stopped waiting after six hours AND it was this "unnecessary delay" on behalf of FLTG that led to the inability to place this heart. They're blaming FLTG for taking too long ...but they didn't need to wait that long. So while it's not a policy violation to wait 6 hours, I want to know why they did...and if this delay and the lack of PYs and Acceptance on this match run can be indicative of a larger issue with this allocation in general (i.e., was this a hot mess from the start?).

After UNOS notified TXGC that it had potentially committed a policy violation, TXGC once again allocated organs in a way that violated the same OPTN policy. According to internal UNOS staff correspondence:[297]

[292] UNOS_4_000281833-34.
[293] UNOS_4_000281833, at 281837-39.
[294] UNOS_4_000281833, at 281837-39 and 281843.
[295] UNOS_4_000281833 at 281845; UNOS_4_000281432.
[296] UNOS_6_000011277.
[297] UNOS_6_000010682.


On March 8, I sent them a notification letter saying they were violationg policy by allocating LU and not having them availalbe when HR/LU recipients needed LU.

They didnt think they were doing it wrong so their CAP was only that they wouldn't use 830 if a center didn't respond anymore, they'd now use 898 and say center refused.

[redacted] invited me to a meeting with OC and PCR b/c the OC had gotten questions about that policy from a TXC b/c they had a HR person who needed LU but the OPO had already allocated them. The TXC thought they deserved the LU.

[redacted]

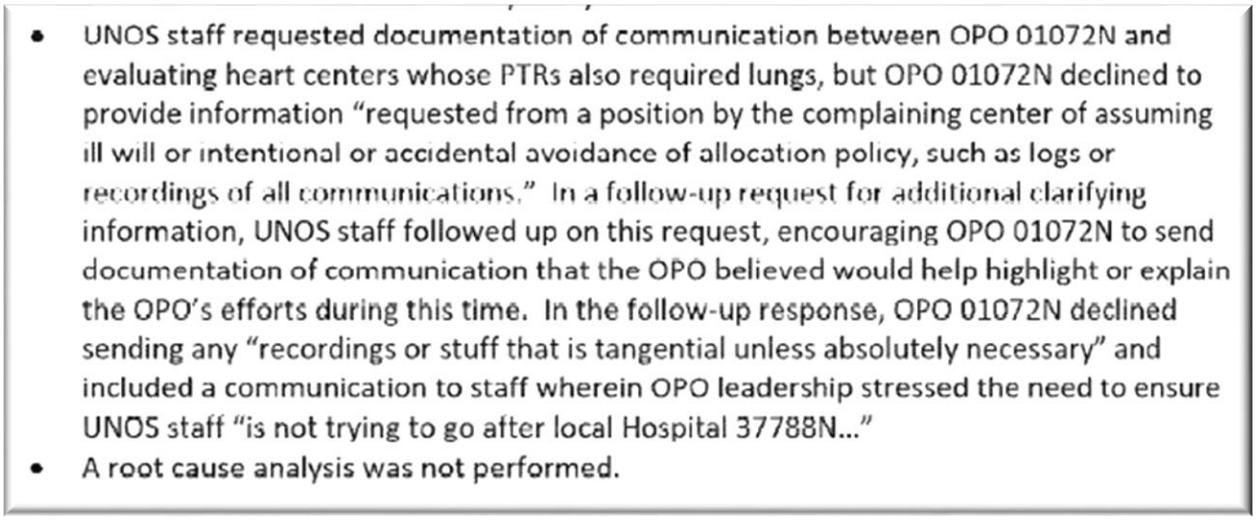
i hope these centers go in and override that BS

[redacted]

Got the donor ID. It's f'n TXGC on March 26. WELL AFTER we sent them the notification letter.

On May 2, 2019, UNOS staff discussed UNOS's reluctance to look into the case further. They stated that senior UNOS staff were "reluctant" to take the case because the "OC [Organ Center]" does not refer every "potential violation" and that it would be unfair if UNOS staff investigated this case further since UNOS does not investigate all similar cases.[298] Another staffer responded: "unless the issue represent (sic) a threat to patient safety or to the fairness of allocation, I don't think we need to see all of it."[299] This implies UNOS staff do not consider all cases resulting in the death of transplant recipient or when an organ is discarded, as threats to patient safety. UNOS did not pursue the third case.[300]

In addition to UNOS not investigating the case, TXGC also resisted efforts by UNOS to investigate the matter. According to summary materials prepared by UNOS:[301]


- UNOS staff requested documentation of communication between OPO 01072N and evaluating heart centers whose PTRs also required lungs, but OPO 01072N declined to provide information "requested from a position by the complaining center of assuming ill will or intentional or accidental avoidance of allocation policy, such as logs or recordings of all communications." In a follow-up request for additional clarifying information, UNOS staff followed up on this request, encouraging OPO 01072N to send documentation of communication that the OPO believed would help highlight or explain the OPO's efforts during this time. In the follow-up response, OPO 01072N declined sending any "recordings or stuff that is tangential unless absolutely necessary" and included a communication to staff wherein OPO leadership stressed the need to ensure UNOS staff "is not trying to go after local Hospital 37788N..."
- A root cause analysis was not performed.

Despite TXGC's efforts, the case was eventually referred to the Membership and Professional Standards Committee (MPSC) to review its corrective action plan and determine if

[298] UNOS_6_000010639.
[299] UNOS_6_000010639.
[300] UNOS_6_00009979, at 10003.
[301] UNOS_4_000281432.

any policy violations occurred. In advance of the MPSC's review, UNOS staff created a "Staff Summary" and noted that cases such as these typically result in a "Notice of Noncompliance." [302]

> **Historical MPSC actions:** The MPSC would typically issue a Notice of Noncompliance in cases involving allocation policy violations. The MPSC has considered higher actions (Letter of Warning, etc.) if the member has a significant compliance history, if the nature of the violation poses a significant patient safety risk, if the member did not adequately correct the root cause of the violation, etc.

In addition to this recommendation, the staff summary prepared by UNOS also contained initial review by three MPSC members. Two agreed with issuing a "Notice of Noncompliance," except one, Alex Glaizer, a close confidant of UNOS CEO Brian Shepard, who recommended closing with no action. [303]

> **Reviewer Comments:**
>
> **Reviewer 1:** I agree with Notice of Noncompliance for Policies 6.5.F and 6.6.F.i.
>
> **Reviewer 2:** I am not clear why this is a policy violation at all? The sequence of allocation appears to be that the OPO appropriately allocated lungs and then later in the allocation process the ctr with a heart candidate needing lungs requested the OPO rescind the prior lung offer? This seems like an inappropriate request by the ctr. Will that behavior be addressed by the MPSC? My question for the OPO is, in these circumstances where heart allocation has to resume after lungs have been placed, why is the OPO offering a heart to a candidate listed as needing heart/lungs? If the lungs are no longer available, those candidates should be screened off to avoid this type of frustrating circumstance. I think this case should be closed with no action and I think there should be correspondence back to the Ctr about making requests for OPOs to rescind offers.
>
> **Reviewer 3:** Agree with notice of noncompliance for applicable policies.

Despite these recommendations, at a July 2019 MPSC meeting, reviewers voted to close the case with no action.[304]

During the July MPSC meeting, UNOS staff responsible for handling the TXGC matter discussed the case with a coworker over a digital chat.[305] She wrote, "I'm pissed though," to which her colleague responds, "I know, but lots of OPO peeps in here. strong opinions." The UNOS staff replies, "No joke. Poor outnumbered thoracic peeps. Policy clearly says "must." There are hardly any policies that say "must." The staffer then follows up noting to their colleague that, in a similar instance, the OPO admitted they had been wrong to allocate the lungs out of order from the heart:[306]

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[302] UNOS_4_000281432-33.
[303] UNOS_4_000281432-33; UNOS_7_000001938.
[304] UNOS_2_000000019, at 28.
[305] UNOS_6_000009977-78.
[306] UNOS_6_000009977-78.

Well they're getting one from NYRT, who admits that their staff's decision to let the LU stay primary b/c they'd been waiting for 12 hours was wrong b/c they know that HR/LU people get the LU.

They admit that they should hold LU until HR is placed.

On the same day, this UNOS staffer simultaneously discussed the TXGC case over digital chat with a second UNOS staffer. The conversation follows:[307]

[redacted]

if history is any indication, this will be a close or a NON b/c TXGC is impenetrable

The colleague responded:

so

uh

still no problem??

they really just want to focus on the superficials of the case

[redacted]

sure, look at their volume...but also look at their history.

[redacted]

and not probe I guess

[redacted]

YES [308]

After some back and forth, this UNOS staff wrote their colleague again saying: [309]

[307] UNOS_6_00009979, at 10000.
[308] UNOS_6_00009979, at 10001.
[309] UNOS_6_00009979, at 10003.

[310]

It is important to note that UNOS has not issued guidance on how OPTN members should interpret this policy in relation to multi-organ transplant candidates. This lack of clarity was also not addressed in recent policy changes intended to clarify multi-organ allocation policy approved by the OPTN Board in June 2021.[311]

[310] UNOS_6_00009979, at 10003.
[311] *Notice of OPTN Policy Changes, Clarify Multi-Organ Allocation Policy*, OPTN (2021), https://optn.transplant.hrsa.gov/media/4698/clarify_multi-organ_june_2021_policy_notice.pdf.

APPENDIX K
Indiana Donor Network (INOP)
Re: DCD Case

On February 24, 2017, UNOS received an anonymous tip from a caller who said, "[t]hat he had heard things that had been weighing on him and he wanted to ensure that UNOS knew and looked into it."[312] The caller reported the following concerns to UNOS:[313]

Concerns:

- Donor was alive when he was opened to recover organs.
- Support was withdrawn in the OR and the team monitored the HR for 5 minutes.
- Donor was opened.
- After the donor was opened, a heartbeat was identified. Heart rate was again monitored, and ten minutes later the donor died.
- Sources have told the reporter that the recovering surgeon was the physician who declared death, then proceeded with organ recovery.
- The attending may have been in the room the whole time, but reporter says he is privy to information that says otherwise and that the recovering surgeon declared the patient dead.
- He wants to ensure that we review the DCD vitals in the attachments and take note of times.

On the same day, at 3:06 p.m., the UNOS safety analyst proceeded to fill out the Member Quality Intake Form, checking "no" for the question that states, "[w]as there direct and specific harm to an identified patient or patients?"[314] The analyst also marked this as a "medium" case, which required the Assistant Director or Director to notify the Executive Director within three days of intake.[315] Three days later, on February 27, 2017, the same safety analyst wrote to their superior and colleagues asking, "[w]ill there be time to discuss my INOP case at today's huddle or right after? I found some stuff in DonorNet, and I'm not convinced this should be a medium case."[316]

UNOS closed this case and never referred it to the MPSC. However, based on documents reviewed by the Committee, it is unclear what transpired after this email exchange. UNOS noted, "all appropriate documentation provided by OPO. No policy violations identified," although it is unclear what, if any, communication, or follow up, UNOS had with INOP regarding this case.[317]

Failing to submit cases generated by anonymous complaints to the MPSC is part of a broader trend identified by the Committee. Senate staff found that anonymous complaints were referred to the MPSC only 27% of the time.[318] Whereas complaints submitted by an Organ Procurement and Transplantation Network (OPTN) member were referred to the MPSC 62% of the time.[319]

[312] UNOS_3_000007163.
[313] UNOS_3_000007163.
[314] UNOS_3_000007164.
[315] UNOS_3_000007164, at 7166.
[316] UNOS_6_000016228.
[317] On file with the Committee.
[318] On file with the Committee.
[319] On file with the Committee.

Additionally, at the time of this event, INOP was under scrutiny by both UNOS and the Centers for Medicare and Medicaid Services (CMS) regarding brain death declaration and documentation. For example, on September 23, 2016, CMS wrote a letter to INOP stating the OPO was "out of compliance" finding, "deficiencies so serious they constitute an immediate threat to patient health and safety."[320] The letter stemmed from INOP's failure to verify and document pronouncement of the donor's death in accordance with local, state, and federal laws (and OPO policy) in three cases.[321]

INOP was also undergoing a corrective action plan to address issues identified in a UNOS Member Quality Review.[322] The audit from this site survey covered cases from July 1, 2014 to July 1, 2016, and found donor records without documentation verifying death in accordance with applicable laws.[323] A few months later, on October 4, 2016, UNOS site surveyors issued a report documenting six donor records with irregularities in brain death pronouncement documentation and testing.[324] INOP was ultimately placed on probation in November 2016, and was serving that probation at the time this incident was reported to UNOS.[325]

Based on documents identified by the Committee, it appears UNOS did not notify CMS about this complaint, despite their concern with INOP's, "deficiencies so serious they constitute an immediate threat to patient health and safety."[326]Additionally, as noted above, this complaint was never referred to the MPSC for further review.

[320] UNOS_3_000001436.
[321] UNOS_3_000001436, at 1440.
[322] UNOS_3_000001147.
[323] UNOS_3_000002608.
[324] UNOS_3_000002605.
[325] UNOS_3_000004004.
[326] UNOS_3_000001436.

APPENDIX L
Life Alliance Recovery Organization (FLMP)
Re: DCD Case

According to a complaint received by UNOS, on November 28, 2018, Life Alliance Recovery Organization (FLMP), an organ procurement organization (OPO) based in Miami, Florida, recovered organs from a donor before the donor's heart stopped and against the family's wishes.[327] The UNOS summary of the case follows:[328]

> **Staff Summary:** An individual called to report this event to UNOS Member Quality staff. A brain dead patient was authorized as a DCD donor because the family wanted to be in the OR when the heart stopped. Despite this, the OPO began recovery prior to cardiac asystole after communicating to staff that the case was not a DCD case because the patient had already been declared brain dead. As a corrective action, the OPO stated it would no longer recover brain dead patients as DCD donors. If a family did not authorize brain dead recovery, the OPO would shut down the case.

On November 19, 2018, a 41-year-old donor was admitted to the hospital after a motor vehicle accident and was declared brain dead on November 24, 2018.[329] The family decided to proceed with donation, but only after cardiac death (DCD).[330] However, when it came time to recover the organs, the family changed their mind regarding DCD donation.[331] Despite this, "the OPO began recovery prior to cardiac asystole after communicating to staff that the case was not a DCD case because the patient had already been declared brain dead."[332] The MPSC staff summary further states:[333]

> After extubation, the mother "became traumatized, changed her mind about witnessing cardiac standstill and left the OR and instructed the OPO to proceed with organ recovery."
> The OPO chose to recover organs based on the previous day's brain death declaration, prior to asystole, based on "verbal agreement from the mother and brother."

On July 19, 2019, the Member and Professional Standards Committee (MPSC) began its review of the case and requested an informal discussion with FLMP.[334] The committee noted they were "concerned by the lack of a root cause analysis (RCA) and the decision to no longer permit brain dead patients to be DCD donors."[335] After this informal discussion, which took place on September 25, 2019, the subcommittee remained concerned about the OPO's decision to decline donation in the future if a brain dead patient's family is only willing to authorize a

[327] UNOS_1_000011869, at 11870.
[328] UNOS_1_000023933.
[329] UNOS_1_000011869-70.
[330] UNOS_1_000011869, at 11870.
[331] UNOS_1_000011885.
[332] UNOS_1_000023933.
[333] UNOS_1_000026510, at 26511.
[334] UNOS_1_000023933.
[335] UNOS_1_000023933.

DCD recovery. The subcommittee was also concerned by the OPO's decision to proceed with organ recovery prior to asystole in this case and requested the OPO conduct an RCA. On October 14, 2019, FLMP submitted its responsive RCA to the MPSC.[336] Additionally, as requested, FLMP "consulted with other OPOs regarding their policies and processes for DCD recoveries of brain-dead donors, and created and amended some of its policies and procedures."[337]

On November 7, 2019, the MPSC reviewed FLMP's submission.[338] After its review, the Committee remained concerned "about FLMP's continued assertion that the root cause of this issue was the emotional state of the donor's mother."[339] By proceeding with the type of donation for which FLMP did not have authorization, the MPSC believed FLMP potentially jeopardized the donor family and OR staffs' trust in the donation process and transplant system."[340]

In December 2019, the Centers for Medicare and Medicaid Services (CMS) conducted a complaint survey specifically about this case.[341] Through its survey, CMS reviewed "the case record, interviewed staff and reviewed FLMP's policies. CMS approved FLMP's corrective measures and found the OPO compliant."[342]

On February 26, 2020, during an interview conducted by MPSC, FLMP's Executive Director read a statement reportedly provided by the donor's mother.[343] The statement, written in Spanish and translated by FLMP staff, was intended to demonstrate that the mother wished to proceed with brain death recovery and not DCD recovery.[344] It is unclear when this letter was signed and whether or not the MPSC verified the authenticity of the letter.[345] After its in-person review in February, the MPSC decided to issue FLMP a Letter of Warning, for violation of Policy 2.15.H (Organ Recovery) on March 12, 2020.[346] In its decision, the MSPC expressed deep concerns about the operation and culture of the OPO: [347]

[336] UNOS_1_000023933.
[337] UNOS_ 1_000011885, at 11886.
[338] UNOS_ 1_000011885.
[339] UNOS_ 1_000011885, at 11186.
[340] UNOS_ 1_000011885, at 11186.
[341] UNOS_7_000028921-27.
[342] UNOS_1_000011869, at 11871.
[343] UNOS_1_000011869, at 11870.
[344] UNOS_1_000011869, at 11870.
[345] UNOS_1_000011869.
[346] UNOS_1_000011885, at 11887.

Full MPSC Concerns

"The letter bothered me. It's something he [the OPO director] could have obtained an affidavit from people that were in the OR that said it was clear, the intent was clear from the professionals involved. Approaching the grieving parent for that shows a lack of judgement and I don't understand how he could perceive that this body was asking for that."

"My concerns with this case going in have not been alleviated because at the end of the day…they have only demonstrated now in my years of experience of talking to them…that when told we want you to do x, y, z and produce documentation they will do it but are never ahead of the game. They never come and say we had this problem and here is how we fixed it. There's nothing proactive, it is all reactive and is basically filling in the blanks of what any reasonable person could interpret from our comments, questions, and requests for information. So we may not have an issue of recurrence of this particular event again, which it the traditional definition of risk of recurrence, but we have a likely recurrence there are other huge holes in their process from an operational standpoint and a quality standpoint. The questions I asked lead me to believe they have changed their policy but they really haven't changed their mindset as to how they're approaching this. There aren't going to be policies or protocols to cover every nuance…but at the end of the day the ability to stop and have a constructive thought process about what might work, what might go wrong and then be able to defend that is not there…I do doubt they have any meaningful QAPI process, that their policies prepare their staff to deal with challenges that they have, and that their administrators on call are properly engaged to say okay, this is how we're going to handle this. There were a lot of good questions that were asked here that they just were not able to process…They need to get the strongest message we feel is appropriate that they have serious operational issues relative to their quality and their policies."

"Just go back the last 12 months. This OPO bypassed a transplant center while allocating a kidney, which required them to withdraw an offer; allocated a kidney for an SLK to somebody that wasn't on the SLK list; and now has this. And they actually have the audacity to say this isn't as bad as a ABO error. This is a process problem, and the list is ten years long. I think with where we go, it would be okay – well, it wouldn't be okay – if this was their first time in front of us, I think you could look to say there's a learning opportunity, but I think they probably failed that part of grade school. I know they're turned over leadership and everything, but we're going to be here 12 months from now talking about another event going oh we didn't see this one coming, but it will be the same OPO."

"They have a systemic issue with quality systems. Our peer review teams looked at that, our peer review teams were concerned about it. We felt like they had fixed it, and here we have how many incidents since they've be released as a Member Not in Good Standing…it's the same cycle over and over again…you need to think very carefully about what message you are sending them, because they will be back."

Notwithstanding a year's long MPSC review and corrective action plan, MPSC staff continued to have concerns with FLMP, including its "professional culture and environment, at both the staff and administrative levels, whereby staff is uncomfortable stopping processes to identify errors."[348] As a result, on May 12, 2021, the Health Resources and Services Administration (HRSA) directed the Organ Procurement and Transplantation Network (OPTN) to conduct an additional onsite peer visit to help inform the MPSC and HRSA's determination of an ongoing risk to patient health and public safety.[349]

Despite FLMP's persistent failures and process violations over a ten-year period, which were only reported following HRSA's directed onsite peer visit, the MPSC only issued FLMP a Letter of Warning for this incident. On the other hand, CMS, which also conducted an independent investigation, found FLMP compliant. At this time, FLMP remains a certified OPO.

[348] UNOS_3_000059364.

APPENDIX M
Indiana Donor Network (INOP)
Re: Trashed Kidneys

On June 12, 2020, Indiana Donor Network (INOP) self-reported an incident to UNOS stating that two kidneys were accidentally thrown in the trash before being packaged for transportation.[350] INOP reported that an, "immediate debrief and [root cause analysis (RCA)] was performed" following the event and that, "the incident occurred because hospital personnel were not familiar with the donation process and assumed the kidneys were left on the back table to be discarded."[351]

On June 16, 2020, UNOS reached out to INOP to inquire about the incident and, on June 30, 2020, INOP sent their response.[352] On July 8, 2020, UNOS sent a follow up letter to INOP notifying them that they would refer this case to the Membership and Professional Standards Committee (MPSC) for the potential violation of Policy "**2.2 OPO Responsibilities** [emphasis included]" which states, "[t]he host OPO is responsible for *all* of the following . . . 10. Preserving, labeling, packaging, and transporting the organs."[353]

In a staff summary prepared for the MPSC, UNOS recommended two options for the MPSC to take:[354]

> **Historical MPSC Actions:** The MPSC would typically close a self-reported case with no action if the member does not have a history of this noncompliance and addressed the issue through its corrective action plan. While the member self-reported this event, the corrective action plan does not appear to adequately address the issue. The MPSC may consider closing the case or issuing a Notice of Noncompliance.

This first recommendation suggests that UNOS and the MPSC have historically looked favorably upon self-reporting and would, "typically close a case with no action."[355] However, three reviewers raise a series of concerns with INOP's RCA and all supported a "Notice of Noncompliance". [356] Reviewer's comments included concerns with INOP's lack of leadership involvement in the RCA, likelihood of reoccurrence, lack of responsibility, and that, "the [corrective action plan] is insufficient in that this event could happen at any hospital, not just the currently involved hospital."[357]

[350] UNOS_3_000007439, at 7440.
[351] UNOS_3_000007439, at 7440.
[352] UNOS_3_000007448.
[353] UNOS_3_000007460, at 7460-61.
[354] UNOS_2_000011591-92.
[355] UNOS_2_000011591-92.
[356] UNOS_2_000011591-92.
[357] UNOS_2_000011591-92.

On November 10, 2020, the MPSC, issued a "Notice of Noncompliance to INOP for violation of policy 2.2 (OPO Responsibilities)."[358]

Additionally, the MPSC requested an informal discussion with INOP, "in order to offer feedback and process improvement suggestions to the OPO."[359] The informal discussion took place on January 21, 2021 and the MPSC reviewed INOP's updated corrective actions at its meeting on February 24, 2021.[360] Based on this review, the MPSC voted to continue monitoring INOP and recommended that INOP take the following actions:[361]

- Develop a chain of custody for all organs
- Conduct a policy review that takes the OPO's growing volumes into consideration
- Develop internal packaging standard operating procedures to promote consistent packaging and mitigate risk of organ discards

It is unclear what the MPSC's final determination of INOP's ensuing response was, and if this case was escalated to the Health Resources and Services Administration (HRSA) or to the UNOS board at any time during the course of the MPSC investigation.

This case calls into question UNOS' ability to educate the transplant community on core functions that, if not properly addressed, "could happen at any hospital, not just the currently involved hospital," resulting in an error that should never happen.[362] To the Committee's knowledge, UNOS has not provided clear guidance on the need to maintain a chain of custody for organs form procurement through to transplant.

[358] UNOS_3_000003581, at 3582.
[359] UNOS_4_000340932.
[360] UNOS_4_000340932.
[361] UNOS_4_000340932.
[362] UNOS_2_000011591-92.

APPENDIX N
Alabama Organ Center (AOC)[363]
Re: Alleged Money Laundering

On February 4, 2011, the United Network for Organ Sharing (UNOS) received a complaint from a whistleblower about improprieties at Alabama Organ Center (AOC).[364] The whistleblower alleged Executive Director Demosthenes Lalisan was participating in a "money laundering" scheme and other financial improprieties, and that AOC was "violat[ing] their own Standard Operating Procedure" resulting in patient safety issues.[365] The complaint goes on to say that Mr. Lalisan paid himself and others "bonuses" anywhere from $8,000 to $20,000 a month with no rationale or explanation of the benefit.[366] In addition, the complaint alleged that in an effort to recover lost revenue, AOC processed several cases that were not cleared by the quality assurance department.[367]

From: [redacted]
Sent: Friday, February 4, 2011 3:06 PM
To: [redacted]@unos.org>
Subject:

There is a high suspicion of money laundering taking place at the AOC. Many employees have expressed their concern. The clinical CPTC's receive a base salary that compensates them for their office time, and a quarterly bonus based on the number of cases worked. This bonus is distributed on the paycheck of the month following the end of the quarter. There is no explanation of benefit on this or formula used to calculate the amount... it just shows up on each coordinator and administrator's check in amounts anywhere from $8,000 - $20,000. The AOC Administrator, Demosthenes Lalisan, gets the largest portion of this bonus (but does not take ANY call). The amount that he pays himself is extremely elaborate. When a coordinator asks for an explanation for the calculation of this bonus, the explanation of how the payment was determined is refused. Each coordinator gets a post-it note at the end of a quarter with the amount of their bonus hand written. It is included on the following check as a lump sum bonus without explanation of how it is calculated. Over the past year, the Administrator of the Alabama Organ Center has managed to pay $2,000,000 in mortgage payments (on three houses), as well as additional lease payments on several luxury vehicles. There is a huge amount of money being distributed within the organization that is not appropriately accounted for. This needs to be investigated. The AOC transplanted fewer organs last year than they had in over 18 years. They violated their own Standard Operating Procedure by sending over 140 tissue charts to RTI for processing without being reviewed by the quality assurance department. This was done in a desperate attempt to recover lost revenue. I hope that you will recognize the seriousness of what is taking place within the organization, and that the issue will be thoroughly investigated. This money has become "blood money" which is being laundered as a result of the proceeds recovered from individuals with the courage to embrace life, despite overwhelming personal tragedy and death of a loved one.

On February 10, 2010, the whistleblower followed up with additional "detailed information" about the complaint.[368] After receiving the complaint, UNOS staff consulted with the MPSC chair and decided to change a scheduled desk review of the OPO to a full, on site

[363] AOC changed its name in February 2019 to Legacy of Hope. *Alabama Organ Center changes name to Legacy of Hope*, UAB.EDU (Feb. 5, 2019), https://www.uab.edu/news/health/item/10146-alabama-organ-center-changes-name-to-legacy-of-hope.
[364] UNOS_3_000015523.
[365] UNOS_3_000015523.
[366] UNOS_3_000015523.
[367] UNOS_3_000015523.
[368] UNOS_3_000015524. The document referenced, "Complaint.docx" in this email, but Committee staff were unable to locate the attachment in the produced records.

review to investigate the allegations of the complaint.[369] The review was conducted in March 2011.[370]

On May 6, 2011, UNOS's Department of Evaluation and Quality (DEQ) sent a letter to AOC notifying them of their plan to review AOC for broader policy violations identified in the whistleblower allegations, but made no mention of the financial improprieties.[371] UNOS sent the letter to Mr. Lalisan, the subject of the complaint, and an individual whom the Federal Bureau of Investigations (FBI) would later charge with healthcare fraud.[372] According to the letter:[373]

> The UNOS Department of Evaluation and Quality received a complaint regarding the operating procedures of Alabama Organ Center. As a result of this complaint and as follow-up to Alabama Organ Center's routine site survey on January 13-14, 2010, DEQ conducted a special on-site survey on March 23-24, 2011. UNOS staff investigated the allegations in the complaint, which involved donors from 2007 through 2010. The site survey portion of the review focused on donors who occurred on or after February 5, 2010. Donors who occurred prior to February 5, 2010 were not included in the site survey report, but are addressed below.
>
> After a detailed review of the information provided by the site survey, the following potential violations of OPTN Policy have been identified:
>
> - Policy **2.2.4** (former OPTN Policy 2.2.3) Donor Evaluation: "Donor evaluation must be performed or coordinated by the Host OPO…"
> - Policy **5.4.1** Internal Labeling Requirements: "The Host OPO is responsible for ensuring that a secure label identifying the specific contents (e.g., liver, right kidney, heart) is attached to the outer bag or rigid container housing the donor organ…"

Staff could not determine if UNOS conducted additional follow up after May 6, 2011.[374]

On August 30, 2011, UNOS sent a letter to AOC after media reports "outlined the recent termination of two executive leaders at [AOC] as a result of 'improper financial relationships with a vendor.'"[375] UNOS requested information from AOC on when they became aware of the allegations and their plan for interim leadership.[376] AOC responded, noting that they were not aware of the issue until August 10, 2011.[377] According to AOC:

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[369] UNOS_3_000016776.
[370] UNOS_3_000016776.
[371] UNOS_3_000015541.
[372] UNOS_3_000015541.
[373] UNOS_3_000015541.
[374] Committee staff identified this case and related files as one of interest to UNOS during its investigation. Committee staff gave UNOS the opportunity to produce additional material or identify documents from the production that would assist the Committee's review. UNOS declined to do so.
[375] UNOS_3_000015552.
[376] UNOS_3_000015552-53.
[377] UNOS_3_000015554-56.

I was informed of a federal investigation of Mr. Dem Lialison, Director of AOC and Mr. Alan Hicks, Associate Director, AOC on Wednesday August 10, 2011. They were being investigated by the Federal Bureau of Investigation (FBI) for allegedly accepting money from a mortuary and crematory company whom we do business with known as Abanks Funeral Home. This is in connection with the AOC's tissue recovery activity not organ recovery activities. The AOC utilized Abanks for transportation of tissue and gift of body donors from our hospitals and for cremation and embalming services that may be required for the tissue and gift of body donors. Both individuals were interviewed by the FBI. Subsequently, both individuals were interviewed by management and both admitted to accepting improper payments from Abanks. Both employees were terminated and the AOC immediately terminated its relationship with Abanks. Our organization has zero tolerance for activities such as this.

Lialison and Hicks later pled guilty to federal fraud charges.[378]

The Committee was unable to identify what, if any, steps UNOS took to investigate the financial improprieties reported to them in March 2011. Instead, it seems UNOS simply rolled the complaint into a broader ongoing review of the OPO for OPTN policy and procedure violations.

[378] Press Release, Dep't of Justice, Former Alabama Organ Center Associate Director Sentenced For Fraud (June 13, 2020), https://www.justice.gov/archive/usao/aln/News/June%202012/June%2013,%202012%20Former%20Alabama%20Organ.html.

United States Senate
Committee on Finance

EXHIBIT LIST

Hearing On

A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network

August 3, 2022

Documents Related to ABO Incompatibility Case 1 (Donor Network West)

A. **1.** UNOS_4_000330241-433 – CADN Case Investigation

2. UNOS_6_000096902-06 – Email re CADN Immediate Action

3. UNOS_6_000096910 – Hyperacute Rejection Case Description

4. UNOS_7_000029172-73 – Emails re HRSA Reportable ABO Event (16)

5. UNOS_E_000026571-73 – Emails re MPSC Request for Additional Information (3)

Documents Related to ABO Incompatibility Case 2 (We Are Sharing Hope)

B. **6.** UNOS_2_000014075-160 – MPSC Summary

7. UNOS_2_000014161-90 – Untitled Staff Summary

8. UNOS_2_000015132-33 – Informal Discussion Summary

9. UNOS_2_000015134-36 – MPSC Informal Discussion Request

10. UNOS_2_000015170-223 – MPSC CAP Update

11. UNOS_2_000015278 – MPSC Outcome

12. UNOS_2_000015300-314 – MPSC Presentation January 28, 2019

13. UNOS_2_000015338-80 – ABO Case Informal Discussion Presentation

14. UNOS_2_000015415-16 – SCOP Informal Discussion Summary and SCOP Accepting Informal Discussion

15. UNOS_2_000015578-631 – SCOP Updated Documentation

16. UNOS_2_000015707-08 – MPSC Resolution Letter

17. UNOS_3_000088960-61 – SCOP ABO Incompatible Tx Communication with SCMU

18. UNOS_3_000088965-66 – HRSA Notification

19. UNOS_3_000088967-69 – Patient Safety Net Portal Submission (1)

20. UNOS_3_000088974-77 – MQ Intake Non-Routine Intake and Triage Form

21. UNOS_3_000088978 – Email re Containment Plan

22. UNOS_3_000088985-87 – Emails between UNOS and HRSA

23. UNOS_3_000089072-80 – Emails re Root Cause Analysis (1)

24. UNOS_6_000067181-82 – Notification of Issue of Noncompliance

25. UNOS_6_000120451 – Emails with Patient Safety Team (2)

26. UNOS_E_000005604 – UNOS Request for Informal Discussion

27. UNOS_E_000020881 – NEOR SCOP Comparison with UNOS Employee Data

28. UNOS_E_000027142 – MPSC Slideshow

Documents Related to Cancer Transmission Case 1 (Life Connection)

C. **29.** UNOS_000046430-48 – Internal Emails at Life Connection

30. UNOS_3_000046449 – Intake Form

31. UNOS_3_000046451-52 – Email Notice to Patient Safety Team

32. UNOS_3_000046456 – UNOS Closure Letter

33. UNOS_3_000086246-49 – Notice of UNOS Inquiry

Documents Related to Cancer Transmission Case 2 (LifeQuest Organ Recovery Services)

D. **34.** UNOS_2_000010025-91 – MPSC Summary

35. UNOS_2_000010558-64 – Not included in RCA

36. UNOS_2_000010569 – Referral to Safety Analyst

37. UNOS_2_000010576-609 – DTAC Late Report Response

38. UNOS_2_000010610-11 – DTAC Late Report Notification

39. UNOS_2_000010612-45 – FLUF Follow Up Information

40. UNOS_2_000010650-51 – DTAC Late Report Inquiry

41. UNOS_4_000284063-64 – Staff Summary

42. UNOS_6_000009263-65 – Emails re DTAC Adjudication (1)

Documents Related to Kidney Death Case (Nevada Donor Network)

E. **43.** UNOS_1_000042009-10 – Patient Safety Net Submission

44. UNOS_1_000042015-16 – UNOS Confirmation of OPTN Submission

45. UNOS_6_000015441-443 – Emails re 2 Kidney Recipients with Tularemia (1)

46. UNOS_6_000015447-449 – Emails re 2 Kidney Recipients with Tularemia (2)

47. UNOS_6_000015454-56 – Emails re 2 Kidney Recipients with Tularemia (3)

Documents Related to Courier Case 1 (Mississippi Organ Recovery Agency)

F. **48.** UNOS_3_000076146-48 – Initial Patient Portal Report

49. UNOS_3_000076149-52 – Intake Form

50. UNOS_3_000076155-57 – UNOS Inquiry Letter

51. UNOS_3_000076166-68 – Closure Letter

52. UNOS_6_000007958 – Senate Inquiry Transportation Issues

Documents Related to Courier Case 2 (Donor Alliance)

G. **53.** UNOS_3_000039003-06 – Patient Safety Net Portal Submission (1)

54. UNOS_3_000039007-11 – Intake Form

55. UNOS_6_000022475-76 – UNOS Emails Re Final Letter (1)

56. UNOS_6_000106060-61 – UNOS Email Stating No Inquiry on this Case

Documents Related to Airline Case 1 (We Are Sharing Hope)

H. **57.** UNOS_3_000086983-84 – Confirmation of OPTN Submission

58. UNOS_3_000086985-88 – Intake Form

59. UNOS_3_000086989-91 – Patient Net Submission

60. UNOS_3_000086992-93 – UNOS Request for Information

61. UNOS_5_000034100 – OPO Case Comments

62. UNOS_6_000007958 – Senate Inquiry Transportation Issues

63. UNOS_6_0000020631 – Internal Emails

Documents Related to Airline Case 2 (We Are Sharing Hope)

I. **64.** UNOS_3_000088813-14 – UNOS Inquiry Letter

65. UNOS_3_000088815-30 – SCOP Response to UNOS and Supporting Documents

66. UNOS_3_000088831-32 – UNOS Response to SCOP

67. UNOS_5_000034100 – OPO Case Comments

68. UNOS_6_000007958 – Senate Inquiry Transportation Issues

Documents Related to Allocation Error Case (LifeGift Organ Donation Center)

J. **69.** UNOS_2_000000019-37 – MPSC Meeting Minutes

70. UNOS_4_000281432-55 – OPO Case Investigations

71. UNOS_4_000281833-54 – MPSC Summary

72. UNOS_6_000009977-78 – Messages re TXGC (1)

73. UNOS_6_000009979-1008 – Messages re TXGC (2)

74. UNOS_6_000010527 – Case Packet Email (1)

75. UNOS_6_000010639-40 – Case Assignment Email

76. UNOS_6_000010679-81 – Messages re TXGC (3)

77. UNOS_6_000010682-86 – Messages re TXGC (4)

78. UNOS_6_000010945 – Case Packet Email (2)

79. UNOS_6_000011142-53 – Messages re TXGC (5

80. UNOS_6_000011204-06 –Messages re TXGC (6)

81. UNOS_6_000011277-78 – Additional Questions to TXGC Email

82. UNOS_000106322-23 – Individual Member Focus Improvement Email

83. UNOS_000118050 – Weekly Meeting Email

84. UNOS_7_000001938 – Messages re TXGC (7)

85. UNOS_E_000020545-46 – HL Examples

Documents Related to Donation after Circulatory Death Case 1 (Indiana Donor Network)

K. **86.** UNOS_3_000001436-46 – CMS Site Survey

87. UNOS_3_000001447-88 – INOP Letter and Corrective Action Plan

88. UNOS_3_000002605-07 – Death Declaration SBAR

89. UNOS_3_000002608-87 – OPO Audit August 2016

90. UNOS_3_000003540-43 – INOP Expedited Review

91. UNOS_3_000003545-54 – INOP Peer Review

92. UNOS_3_000003558-60 – INOP BOD Outcome

93. UNOS_3_000003571 – MPSC Recommendation for Release

94. UNOS_3_000003655-60 – INOP MPSC Interview Summary

95. UNOS_3_000004004-227 – INOP Case Release Packet

96. UNOS_3_000006401-04 – DCD Clinical Pathway Form

97. UNOS_3_000007163 – UNOS Emails Reporting the Complaint

98. UNOS_3_000007164-67 – Intake Form

99. UNOS_3_000073704 – SBAR for the Case

100. UNOS_3_000074107 – Board Compliance Monitoring

101. UNOS_6_000016228 – DonorNet Email

102. UNOS_6_000125944-46 – Emails regarding AOPO Call (1)

103. UNOS_6_000125959-60 – Emails regarding AOPO Call (2)

Documents Related to Donor after Circulatory Death Case 2 (Life Alliance Organ Recovery Agency)

L. **104.** UNOS_1_000011846-50 – Informal Discussion Presentation

105. UNOS_1_000011853-56 – FLMP Informal Discussion Summary

106. UNOS_1_000011869-75 – February 26, 2020 Interview Summary

107. UNOS_1_000011885-89 – March 12, 2020 Letter of Warning

108. UNOS_1_000011967-73 – Peer Visit Request

109. UNOS_1_000012916-19 – Root Cause Analysis

110. UNOS_1_000023933-40 – Staff Summary with Reviewer Comments

111. UNOS_1_000026367-71 – February 28, 2019 FLMP Response to UNOS Inquiry

112. UNOS_1_000026414-16 – February 14, 2019 UNOS Donor Management Inquiry

113. UNOS_1_000026490-509 – March 20, 2019 Donor Letter and Exhibits from FLMP

114. UNOS_1_000026510-579 – MPSC Summary (2)

115. UNOS_2_000005165-89 – MPSC Meeting Minutes

116. UNOS_3_000059364-71 – FLMP Staff Summary Peer Visit

117. UNOS_6_000073311-17 – Correspondence (3)

118. UNOS_7_000000378-85 – April 2021 MPSC FLMP Concerns

119. UNOS_7_000028891-900 – Emails re MPSC Review of Peer Visit and OPO (1)

120. UNOS_7_000028921-27 – CMS Report

Documents Related to Kidney trash Case (Indiana Donor Network)

M. **121.** UNOS_2_000011591-611 – MPSC Summary

122. UNOS_3_000003581-83 – Notice of Noncompliance and Informal Discussion Off

123. UNOS_3_000003592-95 – MPSC Informal Discussion Summary January 21, 2021

124. UNOS_3_000007439-41 – Patient Safety Net Portal Submission

125. UNOS_3_000007442-43 – Incident Handling Triage Form

126. UNOS_3_000007444 – Confirmation of OPTN Submission

127. UNOS_3_000007445-47 – Notice of UNOS Inquiry

128. UNOS_3_000007448-59 – Emails INOP Response

129. UNOS_3_000007460-61 – Notification of Submission to MPSC

130. UNOS_4_000340932-33 – Ongoing Monitoring Staff Summary

Documents Related to Financial Allegations Case (Alabama Organ Center)

N. **131.** UNOS_3_000015523 – OPO Employee Email Report to UNOS

132. UNOS_3_000015524 – Follow Up to OPO Employee Email (1)

133. UNOS_3_000015529-40 – MPSC Summary

134. UNOS_3_000015541-43 – May 6, 2011 UNOS DEQ Notification Letter

135. UNOS_3_000015552-53 – August 30, 2011 Media Inquiry

136. UNOS_3_000015554-56 – September 13, 2011 Media Inquiry Response

137. UNOS_3_000015905-17 – April 8, 2011 On Site Survey Report

138. UNOS_3_000016634-52 – May 6, 2011 Amended Site Report and Closing Letter

139. UNOS_3_000016776-77 – OPO Complaint Summary

140. UNOS_3_000065380 – ALOB Timeframe

Other

O. **141.** No Bates Number Available – SFC Presentation re UNOS Review Process

142. UNOS_2_000003541-68 – DTAC Report

143. No Bates Number Available – USDS Report - Modernizing OPTN January 2021

144. No Bates Number Available – February 10, 2020 UNOS Response to SFC

145. No Bates Number Available – January 31, 2022 SFC IT Security Letter

146. No Bates Number Available – July 11, 2022 McGuireWoods Response to SFC Subpoena

147. No Bates Number Available – March 2, 2022 UNOS Response to SFC IT Security Letter

148. UNOS_6_000026526-29 Kid’s Artwork Emails

149. UNOS_6_000028442-46 Overgrown HOA Emails