

**Congress of the United States**  
**Washington, DC 20515**

November 29, 2022

The Honorable Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, M.D. 21244

Carole Johnson  
Administrator  
Health Resources and Services Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Secretary Becerra, Administrator Brooks-LaSure, and Administrator Johnson:

Every American, regardless of race, ethnicity, or geographic location, deserves equal access to organ donation and transplantation. According to the Health Resources and Services Administration, there are approximately 106,000 people on the organ waiting list, most of whom need kidneys. Approximately 6,000 Americans die each year while awaiting organ transplants. That is, on average, 17 people pass away each day while waiting for organs, a number that does not include patients who die after being removed from the waiting list —having been considered too sick to transplant —or patients who never make it onto the organ waiting list at all due to systemic inequities.<sup>1</sup> This problem is even more severe for people of color and residents of rural areas. An analysis of recent data from the Centers for Medicare and Medicaid Services (CMS) shows that organ donation success rates vary widely for people of color.<sup>2</sup> Because same-ethnicity matches are more likely to occur, the failure of federal organ donation contractors to serve Black Americans further harms Black patients on the organ waiting list.<sup>3</sup> Additionally, the COVID-19 pandemic resulted in an increased need for organ transplants, while exacerbating existing inequities.<sup>4</sup>

After the National Organ Transplant Act (NOTA) was enacted in 1984, the Secretary of Health and Human Services (HHS) established the Organ Procurement and Transplantation Network (OPTN), a nationwide, computerized system for matching patients with organs.<sup>5</sup> NOTA also established a mechanism for nationwide organ donation facilitated by HHS-certified organ procurement organizations

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<sup>1</sup> “Organ Donation Statistics.” Health Resources and Services Administration, <https://www.organdonor.gov/learn/organ-donation-statistics>.

<sup>2</sup> Fernandez, Marisa. “Organ Donation Recovery Rates Worse For People Of Color, Data Show.” Axios, 9 Nov. 2021, <https://www.axios.com/2021/11/09/organ-donation-recovery-worse-people-of-color>.

<sup>3</sup> Ibid.

<sup>4</sup> Aleccia, JoNel. “Covid Spawns ‘Completely New Category’ Of Organ Transplants.” Kaiser Health News, 13 Apr. 2021, <https://khn.org/news/article/covid-spawns-new-category-of-organ-transplants/>.

(OPOs). Currently, there are 391 members of the OPTN, including 252 transplant centers and 57 OPOs. The first OPTN contract was awarded to the United Network for Organ Sharing (UNOS) in 1986, and UNOS has received all seven subsequent OPTN contracts.<sup>6</sup>

According to a report endorsed by all five former Chief Technology Officers of HHS, the federal government and taxpayers could save up to \$40 billion over 10 years through a number of suggested improvements to the OPTN and OPOs.<sup>7</sup> Experts estimate that 28,000 more organ transplants could take place each year if the government's contractors were held accountable through modernizing the system and improving oversight.<sup>8</sup> Currently, the failure to recover more organs has resulted in greater need for dialysis and the treatment of end-stage renal disease, which account for \$36 billion in Medicare costs annually.<sup>9</sup> Kaiser Health News reports that organs recovered often do not get transplanted due to UNOS errors, stating, "a startling number of lifesaving organs are lost or delayed while being shipped on commercial flights, the delays often rendering them unusable."<sup>10</sup> Additionally, extensive research has shown that patients of color receive organ transplants at disproportionately lower rates and after longer waiting times than other patients.<sup>11</sup> For example, one study found that health care providers were less likely to perceive Black families that wanted to donate and OPOs were more likely to not have spoken to Black families.<sup>12</sup>

In 2020, the Senate Finance Committee began probing UNOS and subsequently subpoenaed them in February 2021.<sup>13</sup> On August 3, 2022, the Senate Finance Committee held a hearing and released a report titled "A System in Need of Repair: Addressing Organizational Failures in the U.S. Organ Procurement and Transplantation Network." The report concluded that, "[f]rom the top down, the U.S. transplant network is not working, putting Americans' lives at risk."<sup>14</sup> Based on information collected in 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."<sup>15</sup>

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<sup>5</sup> "History And NOTA – OPTN." Organ Procurement and Transplantation Network, <https://optn.transplant.hrsa.gov/about/history-nota/>.

<sup>6</sup> "About The OPTN - OPTN." Organ Procurement and Transplantation Network, <https://optn.transplant.hrsa.gov/about/>.

<sup>7</sup> "The Costly Effects of an Outdated Organ Donation System." Bloomworks, <https://bloomworks.digital/organdonationreform/>.

<sup>8</sup> Ibid.

<sup>9</sup> Ibid.

<sup>10</sup> Aleccia, JoNel. "How Lifesaving Organs For Transplant Go Missing In Transit." Kaiser Health News, 10 Feb. 2020, <https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/>.

<sup>11</sup> "The Costly Effects of an Outdated Organ Donation System." Bloomworks, <https://bloomworks.digital/organdonationreform/inequity/>

<sup>12</sup> Siminoff, Laura A, et al. "Comparison of black and white families' experiences and perceptions regarding organ donation requests." *Critical Care Medicine*, vol. 31, 2003, pp.146-151. National Center for Biotechnology Information, <https://pubmed.ncbi.nlm.nih.gov/12545008/>.

<sup>13</sup> "Grassley, Wyden Subpoena The United Network For Organ Sharing As Part Of Continued Investigation Into U.S. Organ Transplant System." The United States Senate Committee on Finance. 4 Feb. 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>.

<sup>14</sup> "Committee Hearing Memo—A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network." The United States Senate Committee on Finance, 3 Aug. 2022, <https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Memo.pdf>.

<sup>15</sup> Ibid.

The report also found that, between 2010 and 2020, “104 complaints were submitted to UNOS regarding ‘testing procedure’ errors.” These complaints—some of which involved fatal patient safety lapses— included 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.<sup>16</sup> These findings are all the more alarming given that OPOs currently have no meaningful clinical requirements to manage donors, affecting both donor care as well as recipient safety. The Senate Finance Committee concluded that “[t]he lack of oversight of OPOs by UNOS causes avoidable failures in organ procurement and transplantation resulting in risks to patient safety.”<sup>17</sup>

The conditions of participation for OPOs were amended in 2020 and reaffirmed in 2021 with the publication of a new rule, 85 FR 77898.<sup>18</sup> This rule became effective July 31, 2022 and changes the metrics by which OPOs are evaluated. OPOs are subject to recertification every four years so that they will be evaluated based on the new metrics and face decertification for failure to perform. The new measurements include a donation rate measure and a transplant rate measure, among other things. Because they compare the number of organs donated and transplanted to the overall number of deaths consistent with organ donation according to data already held by the Centers for Disease Control and Prevention, these new measurements move CMS to objective standards in patients’ interests. In accordance with the new regulation, OPOs that fail to meet performance measures may be decertified or engage in competition for their donation service area with higher-performing OPOs.

While we commend the steps that have already been taken to address this crisis, the timeline for enforcement of these performance metrics is lengthy. We encourage CMS to take measures to oversee and improve OPO performance in the interim given the lives at stake and equity implications. Furthermore, while improving OPO performance and the availability of transplantable organs is critical, CMS has also noted inequities in who gets placed on the waiting list, writing that “Black Americans are almost four times more likely, and Latinos are 1.3 times more likely, to have kidney failure compared to White Americans. Despite the higher risk, data shows that Black and Latino patients on dialysis are less likely to be placed on the transplant waitlist and have a lower likelihood of transplantation.”<sup>19</sup> Therefore, waitlist management and organ acceptance criteria must also be addressed for the sake of patients and health care equity. We must ensure that the U.S. organ procurement and transplantation system functions at its optimal level to prevent any missed opportunity for organ donation. No American should die while waiting for a transplant, especially while thousands of lifesaving organs go unrecovered.<sup>20</sup>

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<sup>16</sup> Ibid.

<sup>17</sup> Ibid.

<sup>18</sup> “Medicare And Medicaid Programs; Organ Procurement Organizations Conditions For Coverage: Revisions To The Outcome Measure Requirements For Organ Procurement Organizations”. Federal Register, 2 Dec. 2020, <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicare-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>

<sup>19</sup> “HHS Seeks Public Comments to Advance Equity and Reduce Disparities in Organ Transplantation, Improve Life-Saving Donations, and Dialysis Facility Quality of Care.” Centers for Medicare & Medicaid Services, 1 Dec. 2021, <https://www.cms.gov/newsroom/press-releases/hhs-seeks-public-comments-advance-equity-and-reduce-disparities-organ-transplantation-improve-life>.

<sup>20</sup> “Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final rule.” Centers for Medicare & Medicaid Services, <https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf>.

Moreover, according to a confidential government review obtained by *The Washington Post*, the mechanics of the entire OPTN must be overhauled.<sup>21</sup> The review, conducted by the White House's U.S. Digital Service, cited outdated software, frequent system failures, programming errors, and excessive reliance on manual data entry as reasons for this conclusion. The U.S. Digital Service suggested that the government "break up the current monopoly" of the organ procurement transplantation network in its evaluation.<sup>22</sup> It advocated for distancing the network's technology contract from the OPTN's policy duties, such as determining how to balance factors affecting transplant eligibility. The U.S. Digital Service review noted that, "the organizational structure of the software that matches donors with patients is so clunky that even a single change in priority policy can take a full year to be reflected in the code."<sup>23</sup> Inefficiencies in the technology and processes responsible for organ matching at the OPTN are all the more concerning given new data showing national kidney discard rates have reached 25%, meaning one in four kidneys donated does not make it to a recipient.<sup>24</sup>

The monopoly dominance of UNOS has allowed for a system that lacks accountability and incentives to improve operations. Inefficiencies within such a critical component of our health care system have cost American lives. In response to increased scrutiny from Congress and HHS, OPOs have increased their lobbying expenditures by 500% since 2017, and some have attempted to obstruct the investigation into them.<sup>25</sup> They have purposefully blocked efforts to gather information, with the likely goal of concealing their behavior from Congress and the American people. This industry urgently needs monitoring and accountability. As part of the ongoing efforts to address these concerns within the entire transplant system, we ask for your Administration to outline:

1. Which steps you plan to take to ensure that UNOS does not maintain a monopoly over our nation's transplant system, following the recommendations from the Senate Finance Committee; and
2. Which actions you will take to open OPO process data for evidence of effective and equitable performance, and to hold failing OPOs accountable before 2026, given that any delay costs lives and constitutes an urgent health care equity issue.

We appreciate your prompt attention to this request and look forward to your response.

Sincerely,

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<sup>21</sup> Bernstein, Lenny, and Joseph Menn. "Thousands of Lives Depend on a Transplant Network in Need of 'Vast Restructuring'." *The Washington Post*, 3 Aug. 2022, <https://www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology>.

<sup>22</sup> Ibid.

<sup>23</sup> Ibid.

<sup>24</sup> Robinson, Amanda, et al. Eliminate Use of DSA and Region from Kidney Allocation One Year Post-Implementation Monitoring Report. Organ Procurement and Transplantation Network, 1 Jul. 2022, [https://optn.transplant.hrsa.gov/media/p20c3ada/data\\_report\\_kidney\\_full\\_20220624\\_1.pdf](https://optn.transplant.hrsa.gov/media/p20c3ada/data_report_kidney_full_20220624_1.pdf).

<sup>25</sup> Zagorin, Adam. "America's Transformative New Organ Donation Rule Goes into Effect over Objections from Monopolistic Contractors." Project On Government Oversight, 5 Apr. 2021, <https://www.pogo.org/investigation/2021/04/americas-transformative-new-organ-donation-rule-goes-into-effect-over-objections-from-monopolistic-contractors>.



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Cory A. Booker  
United States Senator



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Mondaire Jones  
Member of Congress



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Benjamin L. Cardin  
United States Senator



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Elizabeth Warren  
United States Senator



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Jamaal Bowman, Ed.D.  
Member of Congress



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Ro Khanna  
Member of Congress



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Donald M. Payne, Jr.  
Member of Congress



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Sheila Jackson Lee  
Member of Congress



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Katie Porter  
Member of Congress



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Troy Carter  
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Barbara Lee  
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Ayanna Pressley  
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André Carson  
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Ritchie Torres  
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Al Green  
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