

MIKE CRAPO, IDAHO, CHAIRMAN  
CHUCK GRASSLEY, IOWA  
JOHN CORNYN, TEXAS  
JOHN THUNE, SOUTH DAKOTA  
TIM SCOTT, SOUTH CAROLINA  
BILL CASSIDY, LOUISIANA  
JAMES LANKFORD, OKLAHOMA  
STEVE DAINES, MONTANA  
TODD YOUNG, INDIANA  
JOHN BARRASSO, WYOMING  
RON JOHNSON, WISCONSIN  
THOM TILLIS, NORTH CAROLINA  
MARSHA BLACKBURN, TENNESSEE  
ROGER MARSHALL, KANSAS  
RON WYDEN, OREGON  
MARIA CANTWELL, WASHINGTON  
MICHAEL F. BENNET, COLORADO  
MARK R. WARNER, VIRGINIA  
SHELDON WHITEHOUSE, RHODE ISLAND  
MAGGIE HASSAN, NEW HAMPSHIRE  
CATHERINE CORTEZ MASTO, NEVADA  
ELIZABETH WARREN, MASSACHUSETTS  
BERNARD SANDERS, VERMONT  
TINA SMITH, MINNESOTA  
BEN RAY LUJÁN, NEW MEXICO  
RAPHAEL G. WARNOCK, GEORGIA  
PETER WELCH, VERMONT

United States Senate  
COMMITTEE ON FINANCE  
WASHINGTON, DC 20510-6200

GREGG RICHARD, STAFF DIRECTOR  
JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

February 26, 2025

The Honorable Robert F. Kennedy Jr.  
Secretary  
The Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

Secretary Kennedy:

As you begin your service as the Secretary of Health and Human Services (HHS), we write to bring to your attention the critical importance of the continued implementation of improvements to the nation's organ donation and transplantation system.

In August 2022, the Senate Finance Committee held a hearing titled, "A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network,"<sup>1</sup> and released a bipartisan memorandum that concluded "[f]rom the top down, the U.S. transplant network is not working, putting Americans' lives at risk."<sup>2</sup>

These findings resulted in the passage of the bipartisan *Securing the U.S. OPTN Act* in 2023, which provides the Health Resources and Services Administration (HRSA) with statutory authority to improve management and government oversight of the U.S. organ transplantation system.<sup>3</sup> The legislation also gave HRSA the authority to expand competition for contracts to operate the Organ Procurement and Transplantation Network (OPTN) in order to break up the monopoly the United Network for Organ Sharing (UNOS) has held since 1984.<sup>4</sup> As a result of this legislation, HRSA created the OPTN Modernization Initiative and progress is underway to address the shortcomings and threats to patient safety inherent in the system. A continued, concerted effort is needed to address the serious concerns outlined below and noted in prior communications with HHS. The dire need for implementation of the Congressionally mandated modernization and robust, effective, oversight of the U.S. transplant system is readily apparent now and has been for many years. As our investigations and public reporting have uncovered, UNOS has been found lacking in their duties to operate the U.S. transplant system. The *Securing*

<sup>1</sup> United States Committee on Finance, Full Committee Hearing, *A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network*, August 3, 2022, at <https://www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network>.

<sup>2</sup> *Id.*

<sup>3</sup> *Securing the U.S. Organ Procurement and Transplantation Network Act*, 42 U.S.C. 201, <https://www.congress.gov/118/plaws/publ14/PLAW-118publ14.pdf>.

<sup>4</sup> *Id.*

*the U.S. OPTN Act* gave HRSA the authority to award the OPTN contract to different and or multiple nonprofit and for-profit contractors, effectively breaking up the monopoly hold UNOS has had on the transplant system for decades.

In order for the Congressional intent of the bipartisan legislation to be carried out, and UNOS to be removed as the sole contractor, which our oversight has shown is necessary, HHS and HRSA must continue implementing critical reforms. Implementation of the modernization effort requires HRSA be sufficiently staffed with the necessary capacity and expertise to address the serious and ongoing concerns raised by the Finance Committee. As recently as last month, in a response to a Question for the Record posed by a member of the Finance Committee as part of your confirmation hearing before the Finance Committee, you committed to ensure proper staffing at HHS and its sub-agencies to ensure the success of the OPTN Modernization Initiative.

It is imperative that you uphold this commitment. On February 11, 2025, the White House issued an Executive Order which, on its face, will shrink the size of HRSA's existing staff and make the hiring of new staff who are necessary to implement key aspects of the modernization effort much more difficult, if not impossible.<sup>5</sup> This Executive Order tasks agency heads with preparing for "large-scale reductions in force", particularly for employees not engaged in activity mandated by statute.<sup>6</sup> We share the concern raised in a letter to you by the National Kidney Foundation that indiscriminate lay-offs of probationary employees initiated by HHS on Friday, February 14, 2025 has already resulted in the termination of key personnel hired to implement OPTN modernization initiatives.<sup>7</sup> As discussed above, this modernization effort was put into law following an active bipartisan investigation, hearing, and legislation, thus as the Secretary of HHS you have a duty to fulfill your commitment and ensure that HRSA has adequate staffing to pursue its legislative mandate.

Right now, 17 people in the U.S. die each day while waiting for an organ transplant. Modernization of the transplantation system cannot be delayed.

The following steps in the path toward modernization have already begun. To allow those efforts to pause or cease altogether would calcify the issues within the organ transplant system which spurred this effort in the first place, and would amount to a failure to implement federal law.

### **Contracting**

HRSA has begun movement to a new contract structure that will adequately provide support for the organ donation and transplantation system while ensuring safe transplant patient and organ donor care to replace the monopoly contract structure that was in place since 1986 and resulted in a complacent and ineffective system. In a letter dated May 2, 2024 the Finance Committee

---

<sup>5</sup> The White House, Executive Order, *Implementing the President's "Department of Government Efficiency" Workforce Optimization Initiative*, Feb. 11, 2025, at <https://www.whitehouse.gov/presidential-actions/2025/02/implementing-the-presidents-department-of-government-efficiency-workforce-optimization-initiative/>.

<sup>6</sup> *Id.* at Section (3)(c).

<sup>7</sup> Letter from the National Kidney Foundation to Senators Grassley and Wyden, Feb. 18, 2025, at [https://www.kidney.org/sites/default/files/2025-02/2025-02-18\\_sfc-letter\\_hrsa\\_final.pdf](https://www.kidney.org/sites/default/files/2025-02/2025-02-18_sfc-letter_hrsa_final.pdf); STAT, *Trump Administration to Fire Thousands at Health Agencies*, Feb. 14, 2025, at <https://www.statnews.com/2025/02/14/federal-employee-layoffs-at-hhs-cdc-on-first-day-robert-kennedy-health-secretary/>; see also National Kidney Foundation, *NKF Statement on Mass Staff Terminations at HHS*, Feb. 18, 2025, at <https://www.kidney.org/press-room/nkf-statement-mass-staff-terminations-hhs>.

encouraged HRSA “to consider which [OPTN] functions fall outside of the purview of the OPTN Board of Directors and would be better structured in relation to other contracts facilitating other OPTN functions, such as compliance and IT functions.”<sup>8</sup> Adequate contract oversight and subject matter expertise within HHS is absolutely necessary as HRSA proceeds through this complex process. For HRSA to be able to solicit new contracts and break up the monopoly, as Congress expressly put into law, it will require the availability of experts for retention or hiring.

## **Technology**

Our investigation found that the technology at the heart of the U.S. organ donation and transplantation system was seriously deficient. This IT system, which facilitates critical data collection and communication necessary to match donor organs to those waiting organ transplantation in a safe and efficient way compliant with statutory and regulatory requirements, has been maintained as a Contractor Owned, Contractor Operated system by UNOS under contract with HHS. Our August 2022 report found that the “archaic IT system results in delays in placing organs, organs being discarded, and inaccurate data being used to place organs”.<sup>9</sup>

We understand that HHS has brought in experts in IT development and procurement to provide oversight of critical IT security shortcomings and failings of the OPTN IT system. It is critical that HHS maintain this unique expertise as HHS moves to ensure the best technology available is implemented to support OPTN functions. Without the maintenance of the new staff who were brought in as technology experts for the express purpose of implementing these critical IT reforms, UNOS will be the only actor capable of operating the IT system. This would contravene the findings of the Finance Committee and the will of Congress.

## **Data**

Similarly, collection of adequate data and HHS oversight and analysis of the data is critically necessary for the OPTN system to function safely in the future. We note and appreciate that HRSA directed the OPTN to begin collecting additional data in the following areas:

- Information from transplant centers about when individuals are first referred to them for an organ transplant, as well as the results of their transplant evaluation and selection as a transplant candidate.
- Information from organ procurement organizations on all ventilated patients referred to them from hospitals in their donation service area, regardless of whether such individuals progress to organ donation.<sup>10</sup>

This data collection is critical to ensure adequate information is available to provide oversight of Organ Procurement Organizations (OPOs) and transplant center performance. In a letter to CMS

---

<sup>8</sup> Letter from the U.S. Senate Committee on Finance to Carole Johnson, Administrator of Health Resources and Services Administration, May 2, 2024, at [https://www.finance.senate.gov/imo/media/doc/050324\\_wyden\\_grassley\\_to\\_hrsa\\_optn\\_rfp.pdf](https://www.finance.senate.gov/imo/media/doc/050324_wyden_grassley_to_hrsa_optn_rfp.pdf).

<sup>9</sup> Memorandum, *A System in Need of Repair: Addressing Organizational Failures of the U.S.’s Organ Procurement and Transplantation Network*, Aug. 3, 2022, at [https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20\(FOR%20RELEASE\)%20on%20website.pdf](https://www.finance.senate.gov/imo/media/doc/UNOS%20Hearing%20Confidential%20Memo%20(FOR%20RELEASE)%20on%20website.pdf).

<sup>10</sup> Organ Procurement & Transplantation Network, *HRSA Directive to Expand OPTN Data Collection*, Feb. 7, 2024, at <https://optn.transplant.hrsa.gov/news/hrsa-directive-to-expand-optn-data-collection/>.

in April 2022, the Finance Committee noted that the absence of this data collection “reduces transparency and allows for continued underperformance, failures, and missed opportunities for improvement.”<sup>11</sup> We applaud HHS for moving forward to require these data. We understand that HHS has significantly increased its staff and expertise to provide oversight of the system and the data needs to provide adequate oversight. We implore you to maintain this expertise to ensure safe and efficient operation of the OPTN.

### **Board Oversight/Conflict of Interest**

On May 2, 2024, bipartisan members of the Finance Committee wrote to HRSA to make explicitly clear that HHS oversight of the OPTN is not only accomplished through oversight of contract awards made by HHS, but also through regulatory oversight of the OPTN Board by HHS.<sup>12</sup> The letter specifically states the OPTN Board, “will not be independent from regulatory oversight, and that this regulatory oversight, along with HRSA’s oversight of the contractors supporting the OPTN Board and carrying out other OPTN functions, is intended to ensure all OPTN activity is consistent with legal and regulatory requirements.”<sup>13</sup> The Finance Committee members also emphasized that the OPTN Board’s responsibilities in relation to the OPTN contracts are to be defined by HHS and “stem solely from the designation provided by HHS.”<sup>14</sup> Of course, none of this limits Congressional oversight of all matters relating to the new law.

We note that HRSA has moved to establish a new OPTN Board structure with the OPTN Board independent from the governing board of any OPTN contractor. This structure is intended to provide adequate expertise from transplant professionals free of conflicts of interest. We noted in the May 2, 2024, letter to HRSA that the OPTN Board is to act only within the terms of the designation provided by HHS for the Board to serve as the OPTN Board and that “their authority to establish membership criteria and medical criteria stems solely from the designation provided by HHS”.<sup>15</sup> Once again, it is critically important that HHS maintain adequate expertise of federal staff to facilitate HHS oversight of the OPTN Board.

We urge you to seriously consider the efforts that have already been undertaken and the consequences on the organ transplant system and the American people should those efforts falter due to ill-informed lay-offs. Without proper staffing at HRSA, the modernization effort will be severely stymied and the efforts of years of bipartisan investigation and legislation will be thwarted. We urge you to keep your commitment to ensure staffing levels adequate to follow and implement the law. Please respond to the questions below no later than March 5, 2025.

---

<sup>11</sup> Letter from U.S. Senate Committee on Finance to Xavier Becerra, Secretary of Health and Human Services & Chiquita Brooks-LaSure, Administrator of Center for Medicare and Medicaid Services, April 7, 2022, at <https://www.finance.senate.gov/imo/media/doc/040722%20Wyden%20Grassley%20Young%20Transplant%20System%20RFI%20letter.pdf>.

<sup>12</sup> Letter from the U.S. Senate Committee on Finance to Carole Johnson, Administrator of Health Resources and Services Administration, May 2, 2024, at [https://www.finance.senate.gov/imo/media/doc/050324\\_wyden\\_grassley\\_to\\_hrsa\\_optn\\_rfp.pdf](https://www.finance.senate.gov/imo/media/doc/050324_wyden_grassley_to_hrsa_optn_rfp.pdf).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

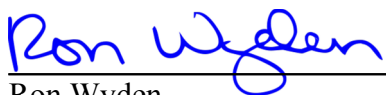
<sup>15</sup> *Id.*

**Questions:**

1. How many HRSA staff are dedicated to implementing improvements in the U.S. organ donation and transplantation system? Please specify how many of these are dedicated to improvements in each of the following areas: 1) Technology, 2) Data and Analysis, 3) Patient Safety and Policy Development Oversight, 4) Contracting.
2. How many HRSA staff dedicated to implementing improvements in the U.S. organ donation and transplantation system have been terminated or otherwise placed on leave since the beginning of the Trump Administration? How many of these staff have been terminated or otherwise placed on leave since the beginning of your term as HHS Secretary? For both please specify how many these staff were assigned to the following issue areas: 1) Technology, 2) Data and Analysis, 3) Patient Safety and Policy Development Oversight, 4) Contracting.
3. How does HHS intend to provide adequate staffing and relevant experience and expertise to ensure continued improvements to the nation's organ donation and transplantation system in keeping with the intent of the *Securing the U.S. OPTN Act* in 2023?
4. What is your estimation on when the Congressionally mandated modernization process will be completed?

It is the responsibility of Congress and the Administration to ensure that the U.S. organ procurement and transplantation system operates as an efficient, modern structure that provides lifesaving, equitable care to tens of thousands of Americans every year. This cannot be done if the agency responsible for modernizing the system is burdened by understaffing.

Sincerely,



Ron Wyden  
United States Senator  
Ranking Member, Committee  
on Finance



Bernard Sanders  
United States Senator  
Ranking Member, Committee  
on Health, Education, Labor,  
and Pensions