

PATTY MURRAY, WASHINGTON
ROBERT P. CASEY, JR., PENNSYLVANIA
TAMMY BALDWIN, WISCONSIN
CHRISTOPHER MURPHY, CONNECTICUT
TIM KAINE, VIRGINIA
MARGARET WOOD HASSAN, NEW HAMPSHIRE
TINA SMITH, MINNESOTA
BEN RAY LUJÁN, NEW MEXICO
JOHN W. HICKENLOOPER, COLORADO
EDWARD J. MARKEY, MASSACHUSETTS

BILL CASSIDY, LOUISIANA
RAND PAUL, KENTUCKY
SUSAN M. COLLINS, MAINE
LISA MURKOWSKI, ALASKA
MIKE BRAUN, INDIANA
ROGER MARSHALL, KANSAS
MITT ROMNEY, UTAH
TOMMY TUBERVILLE, ALABAMA
MARKWAYNE MULLIN, OKLAHOMA
TED BUDD, NORTH CAROLINA

United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

WARREN GUNNELS, MAJORITY STAFF DIRECTOR
AMANDA LINCOLN, REPUBLICAN STAFF DIRECTOR

www.help.senate.gov

September 10, 2024

VIA ELECTRONIC TRANSMISSION

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

Dear Administrator Johnson:

In 2023, 46,632 organ transplants were performed, marking the eleventh consecutive year with a record number of transplant procedures.¹ This was made possible by the generosity of more than 23,000 donors.² Despite this progress, however, over 103,000 men, women, and children are currently on the national transplant waiting list.³ The Organ Procurement and Transplantation Network (OPTN) has historically faced numerous challenges, including lost or damaged organs, cybersecurity incidents affecting patient information, and antiquated technology infrastructure.⁴ As the agency tasked with overseeing the OPTN, the Health Resources and Services Administration (HRSA) must ensure that the OPTN improves its efficiency so that more patients can receive the gift of a lifesaving organ.

Last year, Congress passed the Securing the U.S. Organ Procurement and Transplantation Network Act, a bill that I co-sponsored to modernize the OPTN in response to complaints raised against the United Network for Organ Sharing (UNOS), the non-profit entity HRSA contracts with to manage the OPTN.⁵ As part of this legislation, Congress gave HRSA the authority to award multiple contracts to support the operations and functions of the OPTN in order increase competition and make improvements to the OPTN's management.

¹ *Continued increase in organ donation drives new records in 2023; New milestones exceeded*, HEALTH RESOURCES & SERVICES ADMINISTRATION (Jan. 10, 2024), <https://optn.transplant.hrsa.gov/news/continued-increase-in-organ-donation-drives-new-records-in-2023-new-milestones-exceeded/#:~:text=There%20were%2046%2C632%20organ%20transplants,organ%20transplants%20from%20deceased%20donors.>

² *Id.*

³ *Organ Donation Statistics*, HEALTH RESOURCES & SERVICES ADMINISTRATION (Mar. 29, 2024), <https://www.organdonor.gov/learn/organ-donation-statistics>.

⁴ SENATE COMMITTEE ON FINANCE, STAFF MEMO ON ORGANIZATION FAILURES OF THE UNITED STATES ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (Aug. 3, 2022), [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).

⁵ *H.R. 2544, Securing the U.S. Organ Procurement and Transplantation Network Act*, 118th Cong. (P.L. 118-14).

Despite this mandate from Congress, HRSA has been slow to implement these much-needed reforms. In fact, it just recently issued final requests for proposals (RFPs) to support multiple contract awards related to board of directors' support and operations in May and formally incorporated an independent board of directors in June.⁶ Additionally, HRSA has yet to release details about steps to improve the OPTN's IT infrastructure through the forthcoming Next Gen contract solicitations. These steps to modernize the OPTN are essential to transition to a functioning system given the past challenges the OPTN has faced.⁷ As the Ranking Member of the Senate Committee on Health, Education, Labor, and Pensions, HRSA's lack of urgency implementing these important reforms is very concerning. To that end, I ask that you answer the following questions on a question-by-question basis by **September 24, 2024**:

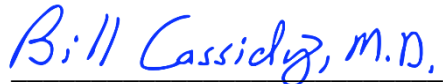
1. In June, HRSA announced that it had implemented a new board of directors for the OPTN. When does the OPTN intend to nominate new board members?
2. In July, HRSA announced that it would be holding a special election for new board members later this fall. What informed HRSA's decision to hold a special election for the new board members?
 - a. Did HRSA consider an appointments process for the new OPTN board members?
3. What policies and procedures will HRSA implement for the special election of the OPTN board?
4. What steps is the OPTN taking to ensure both future and current board members do not have any conflicts of interest?
5. How does HRSA intend to fill management positions within the OPTN, including the executive director role? Will HRSA directly appoint OPTN executive and management roles or will future openings be made publicly available?
6. What steps is the OPTN taking to ensure future management positions within OPTN do not have any conflicts of interest?
7. HRSA has stated that it intends to release solicitations for proposals related to its Next Gen Contracts to modernize the OPTN. When does HRSA expect to release those proposals?

⁶ HRSA's Progress on Transforming the Organ Transplant System to Better Serve Patients and Families, HEALTH RESOURCES & SERVICES ADMINISTRATION (Jun. 6, 2024), <https://www.hrsa.gov/optn-modernization>; HRSA's Latest Steps to Transform the Organ Transplant System to Better Serve Patients and Families, HEALTH RESOURCES & SERVICES ADMINISTRATION (May 2, 2024), <https://www.hrsa.gov/optn-modernization/may-2024>.

⁷ Joseph Menn and Lenny Bernstein, *Thousands of lives depend on a transplant network in need of 'vast restructuring'*, THE WASHINGTON POST (Jul. 31, 2022), <https://www.washingtonpost.com/health/2022/07/31/unos-transplants-kidneys-hearts-technology/>.

8. How regularly does HRSA receive organ procurement data from the OPTN?
 - a. What information is included as part of those transmissions?
 - b. How is this data formatted?
 - c. Does HRSA need specific software or tools to access this data?
9. What ownership or control rights does HRSA assert over organ procurement data collected through the OPTN?
10. Does HRSA have any requirements to delete historical data in its contract with the current OPTN should it not extend that contract?
11. What steps does HRSA have in place to ensure there is no disruption in services if transitioning between information technology (IT) systems?
12. What IT functions has HRSA identified as needing improvement as part of any future technical system?
13. Is HRSA considering the ability of multiple vendors to service OPTN's IT infrastructure? If so, please explain. If not, why not?
14. HRSA assesses a registration fee on entities who list organ candidates on the OPTN network. How is HRSA monitoring that process and does it anticipate any fee changes as part of its broader modernization efforts?

Respectfully,



Bill Cassidy, M.D.

Ranking Member

U.S. Senate Committee on Health,
Education, Labor, and Pensions