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Chairman Joyce, Ranking Member Clarke, and Members of the Subcommittee,

Thank you for the opportunity to testify on behalf of the Health Resources and Services Administration (HRSA), an agency within the U.S. Department of Health and Human Services (Department). HRSA's Organ Donation and Transplantation programs seek to extend and enhance the lives of individuals with end-stage organ failure for whom an organ transplant is the most appropriate therapeutic treatment. We thank Congress for its attention and leadership on strengthening the tools available to support this mission. I am honored to speak before this Subcommittee about oversight of the system.

Background

The Organ Procurement and Transplantation Network (OPTN) is a public-private partnership established by the National Organ Transplant Act (NOTA) (P.L. 98-507) to: (1) develop, monitor and enforce OPTN organ allocation policies and membership standards; and (2) to maintain the national waitlist and IT system that matches donated organs and those waiting for a transplant. OPTN members include transplant hospitals, organ procurement organizations (OPOs), histocompatibility labs, public organizations, individuals, and medical and scientific organizations.

Through delegated authority from the Secretary, HRSA has an oversight role as to the OPTN, OPTN members, and the HHS contractors supporting the OPTN, which permits HRSA to monitor OPTN operations and direct the OPTN to undertake actions that protect public health and patient safety. The Centers for Medicare & Medicaid Services (CMS), has responsibility for

establishing standards for OPOs and transplant hospitals to participate in Medicare and Medicaid, and for conducting surveys to assess for compliance with these standards.

Modernization

As stated above, the OPTN was established after Congress passed NOTA in 1984. As the organ procurement and transplant system has evolved and expanded, NOTA's requirements for the OPTN proved to be restrictive in application. Due to limitations written in the statute, only one non-profit entity held the contract to support OPTN operations, and the same entity, the United Network for Organ Sharing (UNOS), held that contract for the past 40 years. Consequently, the Board of Directors responsible for OPTN governance was the same as the corporate Board of the sole OPTN contractor, which created a potential conflict of interest. Furthermore, the statute restricted HRSA's ability to fund the OPTN contract above 7 million dollars—to oversee a network that deals in billions of dollars.

In 2023, Congress passed the Securing the U.S. Organ Procurement and Transplantation Network Act (Act) (P.L. 118-14), reforming the decades-old statute and enabling HRSA to fundamentally transform the OPTN system and make multiple awards to access best-in-class vendors for the different system functions. At around the same time, HRSA launched the OPTN Modernization Initiative, which was designed to re-center the OPTN system on the health and safety of the patient. With the changes to the structure of the OPTN and its contractors and the new support provided by the unanimous passage of this Act, we have been able to make meaningful changes in a short period.

In 2024, armed with new funding resources and statutory authorities, HRSA pushed several firsts in the history of the program. To start, to ensure that the same entity did not serve as both the OPTN Board and OPTN contractor, HRSA issued multiple solicitations to support robust and innovative competition in the management of the OPTN. HRSA established clear criteria to mitigate conflicts of interest with any OPTN contractors and strengthen accountability by establishing a separate organization to serve as the OPTN Board of Directors, independent of any OPTN contractors. This spring, HRSA oversaw the special election of a new Board by the transplant community, using a candidate pool that was cleared of conflicts of interest inherent in the old system. This year's election saw strong voter participation, with more than 83 percent turnout, reflecting a high level of engagement from across the organ procurement and transplantation community. The newly elected Board represents a significant step toward strengthening governance and accountability within the OPTN and is designed to reduce potential conflicts of interest and better reflect the voices of those most impacted by the system. The new Board includes patients, healthcare providers, and representatives from transplant hospitals, organ procurement organizations and histocompatibility labs, in alignment with the requirements of the OPTN Final Rule. The new Board was seated on July 1, 2025.

In tandem with the seating of an independent and unconflicted board, the OPTN Modernization Initiative is focused on improving Board support and transition operations to allow the orderly adoption of changes needed to support patients and families. HRSA also engaged the United States Digital Service to evaluate and advise on modernizing the OPTN IT system. Last fall, HRSA issued the first-ever multiple vendor awards to support the OPTN operations. These five initial awardees are tasked with research and discovery work of the OPTN system. That

information will help to inform the changes that are needed for a modernized IT system, improved processes, and streamlined operations. However, this is only the first phase of these efforts. We are now looking forward to developing and implementing our Next Gen IT approach to improve the IT system, functionality, and security of the OPTN.

While we continue to leverage increased appropriations provided by Congress to implement the OPTN Modernization Initiative's reforms as swiftly and responsibly as possible, we are also working to ensure a smooth transition to this new multi-vendor environment. Upwards of 80 percent of the total OPTN operating costs for supporting OPTN operations, such as technology and the work of the committee investigating patient safety complaints, are derived from registration fees paid by transplant centers for each patient the transplant centers add to the transplant wait list. At the very least, this resulted in a perceived bias, as the OPTN contractor controlling the finances and OPTN operations also oversaw the policymaking committees and investigations of OPTN members. Furthermore, this historical practice of a single vendor collecting these registration fees was not a sustainable long-term strategy. The Full Year Continuing Appropriations and Extensions Act, 2025 (P.L. 119 – 4) temporarily authorizes the Department to directly collect and spend the fees to support modernization. HRSA is working to stand up this system to enhance our oversight of OPTN finances and improve the integrity of the OPTN network and we look forward to working with Congress to make this authority permanent.

The changes described are the beginning stages in a multiyear OPTN Modernization Initiative which will allow for more efficient, reliable and transparent governance of the procurement and

transplant system. All of these efforts are in support of HRSA's central goal, to improve patient safety and outcomes. Despite the 48,000 transplants performed last year, there are over 100,000 patients on the wait list. This sobering number is often quoted as evidence of the need to do more in transplant, and yet it fails to fully account for the total number of patients and families whose lives are touched by the OPTN and its members. There are millions of Americans with chronic disease, of whom a large fraction will be referred to transplant centers for consideration of getting a precious spot on the waitlist. In addition, there are 170 million Americans who have made the noble decision to identify as potential organ donors in the event they suffer a terminal event. Each year, over a million such individuals are referred to OPOs from within hospitals, entering into the procurement side of the OPTN's purview. Each of these groups – pre-waitlist and pre-donor – was historically excluded from consideration by the OPTN in policy making and review. Over the last year, HRSA has undertaken an effort to expand OPTN data collection to fully capture the outcomes and experiences of all patients for whom OPTN members provide procurement or transplant expertise. HRSA aims to foster an environment where providers, patients, and families feel safe to report concerns, ensure timely and thorough investigations, and implement corrective actions as warranted.

Patient Safety

Historically, HRSA did not receive complete, consistent, and, at times, accurate information regarding patient safety complaints and concerns raised by OPTN members and other stakeholders. Passage of the Securing the OPTN Act enabled HRSA to begin its modernization efforts to separate OPTN Board functions from OPTN contractor functions. Congress also provided the Agency with additional resources to hire more technical and substantive expertise.

These investments allowed us to build robust internal data analysis capability, enabling HRSA to analyze OPTN data for better oversight and policy compliance purposes. HRSA has now established a new process where patient safety complaints come directly to HRSA to triage to the appropriate entities for further investigation, as needed.

However, that was not the case for the issue we are discussing today regarding reports of alleged misconduct by Kentucky Organ Donor Affiliates (KYDA) (since renamed Network for Hope), an OPO providing care to patients across Kentucky, and in counties in Ohio and in West Virginia. HRSA first learned of this alleged misconduct following the September 2024 House Energy and Commerce Oversight and Investigations Subcommittee Hearing, "A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation." At that time, this Subcommittee shared a letter alleging that, in 2021, a patient had been inaccurately pronounced dead and was improperly pursued as an organ donor by KYDA. According to the letter, the patient, who was a victim of a drug overdose, showed clear signs of life at multiple points, but KYDA senior staff directed that organ procurement proceed. The incident reporter further claimed that the operation was halted only after the procuring surgeon refused to participate in the organ recovery. The incident reporter claimed that the patient was later discharged from the hospital.

The Subcommittee shared the allegations on September 11, 2024. On September 12, 2024, the OPTN's Membership and Professional Standards Committee (MPSC) sent KYDA a detailed request for materials relevant to the allegation. KYDA responded on September 20 with a single page letter that claimed they were "satisfied and confident" in the care provided to the patient

without providing any materials requested by the MPSC. In response, the MPSC moved to close the investigation on September 24, 2024. HRSA noted that KYDA had not adequately addressed questions raised by MPSC, and on October 1, 2024, directed the OPTN to reopen the investigation. Based on materials subsequently provided by KYDA, HRSA directed the OPTN on October 18, 2024, to broaden the scope of their review to all patients since 2021 who had been entered into the donation after circulatory death (DCD) pathway but from whom no organs had been recovered.

As HRSA was directing the OPTN to conduct this review of KYDA practices, an industry trade group, the Association of Organ Procurement Organizations (AOPO), publicized an open letter characterizing the ongoing effort to improve patient safety through enhanced oversight as a "misinformation conspiracy campaign," and concluded "[i]t is time for it to stop."[1] Among the signatories to this letter were more than 20 UNOS staff signing with their corporate affiliation, including the Chief Executive Officer, Chief Legal Officer and General Counsel, Special Counsel for Contract Operations, and the Director of Member Quality and Contract Operations. Additional signers included two members of OPTN Board of Directors and a member of the MPSC. These signatures raised serious concerns about the objectivity of the OPTN leadership and contractor.

HRSA proceeded with parallel investigative processes. HRSA directed the OPTN and UNOS to proceed with reviewing materials received responsive to HRSA's October 18 direction, and, on

[1] Open letter from stakeholders following September 11, 2024, Hearing in House Energy and Commerce Subcommittee on Oversight and Investigations, https://aopo.org/wp-content/uploads/Donation-Transplant-Community-Open-Letter-on-Misinformation-1.pdf, 27 Sep 2024.

November 20, 2024, HRSA requested clarification from contractor staff on a plan to mitigate the potential conflicts of interest as identified given the above-referenced industry letter. HRSA supplemented its direction on December 6, 2024, with an additional requirement for the OPTN's investigation into KYDA to exclude any individual who signed the industry letter. Finally, in response to further anonymous reporting of a concerning case from December 2024, on January 8, 2025, HRSA directed that KYDA supply, and the OPTN review, patient records from attempted DCD procurements through the end of calendar year 2024.

On March 4, 2025, the OPTN concluded its investigation and identified no major concerns or patterns. In contrast, in HRSA's March 24, 2025, memo and subsequent May 28, 2025, letter to the OPTN, we found that KYDA has engaged in a pattern of concerning DCD practices that expose patients to risk of preventable harm and potentially unsafe conditions. In addition, HRSA found that KYDA failed to accurately report relevant data to the OPTN. Findings also suggest that the OPTN did not adequately recognize and respond to poor patient care and practices in this instance. HRSA responded by directing the OPTN to develop and implement a monitoring plan for KYDA and to take remedial actions to improve practices and OPTN policies.

Corrective Actions

All OPOs are OPTN members required to comply with OPTN policies, bylaws, and OPTN obligations, including the adherence to state and federal laws and regulations. The OPTN Final Rule[2] authorizes the Department to conduct special reviews and evaluations that the Secretary deems necessary to carry out the Department's responsibilities under the Public Health Service

[2] 42 CFR 121.10

Act. Following HRSA's review of KYDA, HRSA issued a corrective action plan. The corrective action plan directs the OPTN to develop and implement a 12-month monitoring plan of KYDA to address the concerns HRSA identified in its review and evaluation. In order to assist KYDA in urgently increasing the reliability, completeness, and timing of neurologic assessment and re-assessments of patients who may donate their organs, HRSA required that the monitoring plan provide a set of practice improvement steps to ensure the reliability and safety of the procurement process for patients in the KYDA donor service area.

HRSA's directed review of KYDA and resulting corrective action plan is the first of its kind, but HRSA directing the OPTN to undertake policymaking to ensure safety and fairness is not novel. As part of the corrective action plan, HRSA directed the OPTN to develop, submit for public comment, and implement new policies to create safeguards for patients and families receiving care from OPOs. HRSA will closely monitor progress with these actions.

Conclusion

Organ procurement and transplantation creates a unique health care dynamic and opportunity in that it requires the participation of more than one patient and their family. It requires trust in the system, a trust that 170 million Americans have been willing to give by registering as potential organ donors.

Historically, the system has shown the ability to respond when presented with the need to do so. We have seen OPOs expand their practices and increase the number of organs available for transplant in recent years after the adoption of objective metrics for performance. Similarly, as

HRSA stood up its ability to directly receive complaints relating to the OPTN and OPTN members, we have received positive feedback from providers who are able to see issues of concern, share best practices, and make improvements to their processes to improve delivery of care.

Finally, the Trump Administration is committed to efficient use of financial resources. Since passage of the Securing the U.S. Organ Procurement and Transplantation Network Act, HRSA continues to work with Congress to address what resources are needed to support implementation. We are grateful to the members of this Committee who recognize that more than 80 percent of OPTN operations, including patient safety investigations, are supported by patient waitlist registration fees paid by transplant centers to the current OPTN operations vendor. The temporary authority granted in the Full Year Continuing Appropriations and Extensions Act of 2025 (P.L. 119 – 4) for the Department to collect and spend these fees allows us to take initial steps to set up a more transparent system whereby we can develop the best framework for investigating misconduct allegations and holding OPTN members accountable.

We look forward to continuing to work with Congress to meet our shared goals of ensuring the OPTN operates fairly, efficiently, and safely, which will earn the public's trust, and connect the 170 million Americans who have registered to donate their organs with the 100,000 Americans awaiting an organ transplant.