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U.S. Senate HELP Committee

"Examining the Future of the U.S. Organ Procurement and Transplantation Network"

Members of the committee, thank you for the opportunity to share this testimony with you on behalf of the Organ Procurement and Transplantation Network (OPTN) Board of Directors.

My name is John Magee. In July of this year, I had the honor of being elected to serve the Transplant Community as the President of the OPTN Board of Directors. In addition to this new role, I am a transplant surgery faculty member at the University of Michigan. I have spent more than 25 years as a surgeon focused on transplantation and organ donation. I chose this path because it embodies the endless potential of humanity and the best of healthcare in the United States.

In addition to my current role with the OPTN, I have served in many leadership positions within my institution. I have also worked with local, regional, and national organizations to advance the care of children and adults, with a specific focus on those needing transplantation. Aside from being a clinician, I am involved in national research efforts and have also committed a great deal of energy over my career to education and training. I have experience partnering with industry, foundations, and federal agencies to effectively work as a team.

The guiding principles for our nation's donation and transplant system are respect for the life and dignity of potential organ donors and transplant candidates. Respect for the autonomy of donor heroes and their families to make their decisions is first and foremost.

The National Organ Transplant Act (NOTA) of 1984 established the OPTN with the sole purpose of creating an infrastructure that would effectively develop and continuously refine policies and processes to respect life, both for transplant candidates and for organ donors. It allows us to serve patients who need transplants as well as the donors and families who help save these patients. It is a public private partnership that is at the epicenter of our transplant system. It is a system with defined roles and responsibilities. Hundreds of volunteer experts across our country are brought together, along with transplant patients, living donors, and donor families, in a partnership with the federal government. It is a unique model in health care delivery, and I believe it is a large part of how we have accomplished all we have in transplantation.

I stepped forward to serve on the new OPTN Board because I am committed to ensuring the OPTN continues to function and constantly improve as Congress intended when it passed NOTA. It is a partnership. And as President of the OPTN Board, I am striving to nurture and advance that partnership. This includes effectively representing the concerns of patients, living donors, donor families, and organ donation and transplant professionals.

The OPTN public-private partnership can be conceptualized as three distinct components, which are the Board and its committees, HRSA, and the OPTN contractors. I am the president of the

OPTN Board of Directors -or the private part of that partnership. The members of the OPTN Board are elected by the voting representatives from its nearly 400 member organizations. The OPTN Board is responsible for the approval and oversight of policies and processes, OPTN membership criteria, and OPTN management and membership policies as defined in NOTA, the Final Rule, and our bylaws. The Board is also responsible for oversight of approximately 20 committees who do much of the core work of the OPTN. The Board and the committees it oversees are all comprised of volunteers. Second, HRSA is entrusted with oversight of the OPTN and represents the public aspect of the partnership. It is our bridge to the federal government. The third component of the OPTN are the contractors who assist the OPTN in accomplishing our common goals. The contractors supply staff and resources to make the system run. While the contractors work with the OPTN Board and committees, they are federal contractors who are selected and managed by HRSA.

Our transplant ecosystem has undergone dramatic growth and transformation that is far beyond the imagination of its founders over 40 years ago. In 2024, there were 16,989 deceased donors in the US. This represents a 98% increase over the last ten years. There were 41,119 recipients of deceased donor organs, a73% increase over the last ten years. And in 2024, 7,031 living donor heroes stepped forward to give the gift of life to patients in need. At the same time, our allocation policies have matured with a focus on fairness and efforts to maximize the precious gift of donation. Technology has advanced, allowing providers to promptly review potential donors and recipients on their smartphone. Advances in deceased organ donation have increased our ability to fulfill the wishes of more individuals who wish to help others in the

event of their death. New approaches in organ perfusion have allowed us to successfully utilize more organs and to share these organs over greater distances in efforts to optimize equity. In total, these advances have allowed us to save thousands of additional lives, and this ability is continuously expanding.

The incredible growth in donation and transplantation, along with all the advances, has required the OPTN to modernize. Recognizing this challenge, in March 2023, HRSA launched the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative to help the OPTN optimally serve the needs of patients and families into the future. Congress acted to support this initiative by passing the "Securing the U.S. Organ Procurement and Transplantation Network Act," which was signed into law in September 2023. This legislation created the ability to fund multiple contracts to support the OPTN and removed the previous \$7 million funding limit for OPTN contracts. Additionally, it established separate boards for the OPTN and the OPTN contractors. As stated at the time by the HRSA Administrator, "individuals on the wait list, organ donors, and their families deserve an OPTN governed by an independent, representative board and supported by best-in-class technology, processes, policy, and people."

I. The Current Progress of the OPTN Modernization Initiative

a. Focus on Patient Safety

Optimizing patient safety for both organ donors and transplant recipients is one of the core pillars of the OPTN Modernization effort. The new OPTN Board has made significant progress in

addressing several HRSA directives. One area of concern has been practices around Donation After Cardiac Death (DCD). While DCD allows patients and families to pursue their wish to donate organs to patients in need, there have been alarming cases reported. We have proposed important refinements focused on safeguarding patients who may be considered for DCD, as well as improving communication with families and hospital staff. I anticipate that, on Friday, the Board will approve the draft policy to go out for public comment. We also created a Board directed workgroup to rapidly reframe the development of formal policy regarding normothermic regional perfusion (NRP), which is a technique used in DCD donors to restore the flow of oxygenated blood following cardiac death to specific regions of the body. While the DCD and NRP policies move through the formal policy development process, we have issued two important safety notices regarding DCD and NRP practices to OPTN members. With respect to transplant recipients, the OPTN is working on approaches to minimize the transmission of Rabies and West Nile virus for donors. In addition to these efforts, HRSA has created a new process to directly and anonymously report allegations of misconduct for investigation. The OPTN Board officers have requested to be included on all patient safety notices that are distributed to members of the Membership and Professional Standards Committee and HRSA to increase transparency.

b. Establishing an Independent OPTN Board of Directors

One area of concern identified in the Modernization Initiative was the lack of independence between the OPTN Board of Directors and the OPTN contractor, and other potential conflicts of interest. This concern has been effectively addressed over the past year. In August of 2024,

HRSA awarded a new OPTN Board Support contract to The American Institutes for Research (AIR) to support the newly incorporated OPTN Board of Directors. In January 2025 HRSA seated a Transitional Nominating Committee to oversee the election of the new OPTN Board of Directors. In order to ensure the new Board's independence from the prior sole OPTN contractor, one requirement for selection to serve on the new Board was that an individual could not have served on the OPTN Board in the last ten years. Nominations were solicited and approximately 300 applications were received from across the country. After a process of screening and interviews, a slate of candidates was created. Elections were held in May and June. The 34 individuals representing the new Board were seated on July 1, 2025.

While the new OPTN Board of Directors is now supported by a new Board Support Contractor, the American Institutes for Research, the majority of the OPTN Committees are currently supported by the long-standing OPTN Operations Contractor. (United Network for Ogans Sharing, (UNOS)) This separation has created multiple challenges including coordination, communication, and visibility. At times it is challenging to efficiently track the status of ongoing work and future aspirations of the various OPTN committees. The OPTN volunteers are working collaboratively with HRSA and the contractors to minimize these challenges.

c. Improving OPTN Operations

As another part of the modernization effort, in September 2024 HRSA launched OPTN discovery task orders to provide insights regarding the current state of OPTN operations across five key areas including:

- Approaches to improving patient safety across the multiple entities in the OPTN.
- Approaches to supporting modernization of the OPTN Information Technology (IT)
 system that is critical to all OPTN functions.
- Approaches to improving the process of OPTN policy development, including enhancing transparency and public engagement.
- Approaches to improving communications from the OPTN, within the OPTN and,
 importantly, with patients and families.
- Approaches to improving OPTN financial management including budget development,
 management systems, and processes.

Insights from four of these task orders were shared with the public in September 2025 and approaches to advancing these improvement opportunities are being considered. With respect to the fifth task, the Board and the transplant community are also eager to engage in planning the modernization of the OPTN IT infrastructure, pending guidance from HRSA. The OPTN IT system serves a critical role in listing patients for transplant, evaluating potential donors, generating match runs in accordance with established policy, evaluating the effectiveness of and compliance to allocation policy, and monitoring and investigating patient safety. The IT system also needs to ensure flexibility to accommodate new changes in policy in a rapid and cost-effective manner.

From the outset, the organ transplant community, including patients, living donors, donor families, and transplant professionals enthusiastically embraced the need to conduct self-study

when this initiative was launched. The OPTN Board looks forward to working collaboratively with HRSA to review the findings and recommendations. While we understand some in the organ transplant community had concerns about the process by which these reviews take place, we remain committed to working alongside HRSA to improve OPTN operations in a patient-centric manner.

d. Moving to a Multi-Contractor Model

As an additional effort to strengthen the future of the OPTN, in November 2024 HRSA issued additional contract awards to further build HRSA's capacity for OPTN modernization efforts, including:

- Improving Organ Transplantation Logistics and Transportation
- Evaluating Organ Allocation Policy
- OPTN IT Modernization Strategy Implementation
- Program Management, Data Partnerships, and Analysis

The OPTN Board and the entire transplant system look forward to learning more about this work and effectively partnering with all involved in these initiatives.

e. Updating OPTN Finances

Changes have also been made to the financial system within the OPTN. In March 2025, Congress passed the 2025 Full-Year Continuing Appropriations and Extensions Act (Sec. 1904 in P.L. 1968), which granted HHS explicit legal authority to directly collect and distribute registration fees

from OPTN member institutions. These patient registration fees, which are paid by transplant programs when a patient is listed, account for approximately 90% of the funds historically available for supporting OPTN operations. Previously these fees were collected by the OPTN Operations Contractor (UNOS). The potential advantages of the patient registration fees going directly to HRSA include the ability to direct funds to different OPTN contractors more effectively in the new multi-vendor environment. Under the new model, the OPTN Board maintains the ability to recommend the OPTN registration fee amount to the Secretary. Additionally, the OPTN has the ability to review, approve and prioritize OPTN policy projects within the allocated policy implementation budget. The OPTN Board is actively evaluating how best to improve its financial oversight functions in light of the new multi-contractor model and multiple competing priorities.

This year the Board of Directors again voted to increase the registration fee, and this action was formally approved by the Secretary of HHS. This marks the first increase in four years. This increase was needed to meet the costs associated with OPTN priorities which are taking place under HRSA's directives. These include development of policies and oversight mechanisms to reduce allocations out of sequence, revising the donation after circulatory death policy, establishing policies related to normothermic regional perfusion, directive regarding data collection and enhancing the security and stability of the current OPTN IT system. These directives address critical issues, and the Board is committed to ensuring they are effectively addressed. These directives require a significant portion of the annual budget and will be prioritized until they are resolved.

II. Next Steps with OPTN Modernization

The new OPTN Board has embraced the efforts around OPTN Modernization. We have worked through challenges associated with integrating an entirely new Board that had not previously worked together, and working alongside a new Board Support Contractor. These initiatives are being incorporated at the same time that the OPTN works to ensure our current system works safely for donors and transplant patients today.

The critical work around DCD and NRP mentioned previously will be completed. The Board has also formed a new workgroup with three distinct teams to address the critical issues around allocation out of sequence, which is defined as whenever a deceased donor organ is allocated outside of the OPTN-designed match run. The Board is also currently addressing several other HRSA directives and advancing select policy proposals that have been in development. We have also worked with the Lung Transplant Committee to make and formally approve critical adjustments to the lung allocation policy, making significant headway in just two months. I look forward to updating all interested parties about our progress over the next few months.

As these components of the modernization initiative move forward, I believe there are several areas of interest to our community.

a. Effective integration of multiple vendors within the OPTN and ensuring transparency and trust.

New vendors and new systems are necessary for modernization and are welcomed by the community. They are critical for our future. We must also recognize the need for deliberate planning and the active management of any issues that may arise. Everyone's roles and responsibilities must be clearly delineated. Some questions that I'm considering are: How will the new vendors interact with the Board? Is there a role for community input regarding the qualifications and specifications desired in new contractors? What are the specific task orders? What is our role in evaluating the performance of new contractors?

Given the experience with the integration of the Board Support Contractor (AIR) into the overall organ transplantation system over the past year, the organ transplant community is concerned about the potential impact on these transitions. We look forward to learning more and working collaboratively with pre-existing vendors, new vendors, and HRSA to optimize the system.

b. Continued access to OPTN Data by investigators across the transplant community.

Data collected through the OPTN has been used for decades by the OPTN contractor and the Scientific Registry of Transplant Recipients (SRTR) contractor (also overseen by HRSA) to monitor the performance of the system, monitor individual transplant programs and Organ Procurement Organizations (OPO's), to develop policy, and to monitor the impact of policy changes.

Additionally, upon request, this data has been provided to the government, insurance providers, OPTN committees, and researchers. As part of the modernization efforts, HRSA is expanding

internal data management and analysis capabilities. There has also been an effort to centralize the data in a single system to create a uniform data set for future analyses. It is critical that the organ transplant community maintains ready access to the raw data. Transparency and access to this data are critical to maintain trust in the system. External investigators must be able to conduct independent analyses and investigators must be able to submit their work for peer review and publication.

c. <u>Effective collaboration, integration, and alignment across the organ donation and</u> transplantation ecosystem

The OPTN Board and committees are only one part of the OPTN. And the OPTN is only one part of the transplant ecosystem. While there are statutory and regulatory constraints on actions the OPTN Board can take and limitations related to potential conflicts of interest must be respected, we believe in fostering open discussion and collaboration to advance the system. Potential stakeholders include patient advocacy groups, professional societies, donor hospitals, and other federal agencies—all have significant expertise, perspectives, and data that may help improve the overall system. The presence of multiple entities also creates the potential for misalignment of metrics and incentives. The system will optimally serve patients when there is clear alignment. We also need to ensure the specific roles and responsibilities of the multiple entities are clearly communicated The OPTN Board is actively exploring new was to foster collaboration, integration, and alignment.

III. Conclusion

Through the OPTN, our country has created a system that has saved more than one million lives, shown substantial growth, and continues to serve as a model of best practices for the world.

The entire donation and transplantation community are stewards of our guiding principles, and it is our collective responsibility to acknowledge areas of improvement and necessary change.

This is our path towards ensuring that our system continues to increase the number of patients that benefit from transplantation.

It is worthwhile to restate that the private part of the OPTN partnership, specifically the OPTN Board and OPTN committees, consist entirely of volunteers. From July 1, 2023, to June 1, 2024, the OPTN consisted of 459 individual volunteers from across the United States filling 599 positions. A conservative estimate of the number of hours these volunteers contributed to the OPTN that year is 42,000 hours. These committed volunteers include organ donation and transplant professionals, patients, living donors, and donor families. Aside from the effort contributed, the breadth of expertise and lived experiences is irreplaceable. The potential risks associated with the OPTN not effectively partnering with the volunteers who represent the donation and transplantation community are the loss of effective stakeholder input, decreased financial transparency, potential politicization of transplant policy, and government centralization. The partnership that is the OPTN is precious and fragile.

Our system, while remarkable, needs to accelerate ongoing targeted improvements to effectively address systemic challenges. We must constantly respect our values and ethics as

sacred as we address these issues as a community. As we move forward to better our system, we must be mindful that our patients need us to do so carefully and with constant awareness of what is at stake. Disruption and unintended effects can risk lives. Our collective goal is to constantly improve the system without losing or dismantling the principles upon which it was built. We must constantly continue to embrace transparency, accountability, and oversight.

I look forward to working alongside each of you and I extend my gratitude to the members of this Committee for the opportunity.

Thank you.