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

Prepared Testimony to the U.S. Senate
Committee on Health, Education, Labor and Pensions

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Chairman Cassidy, Ranking Member Sanders, Members of the Committee, I am grateful for the opportunity to testify today about urgently needed reforms to the U.S. organ transplant system to better serve patients and their families. My name is Seth Karp, and I am a liver transplant surgeon, System Surgeon-in-Chief, and Chair of the Section of Surgical Sciences at Vanderbilt University Medical Center. In addition to my clinical practice at one of the largest transplant centers and donor hospitals in the country, I have undertaken and published research on the transplant system. I previously served on the Board of Directors for the Organ Procurement and Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS) when those bodies functioned as one and the same.

I'd like to thank the Senators present for the legislative and oversight work Congress has undertaken on organ transplantation in recent years. I believe this work has begun to meaningfully improve our system and saved lives. However, there is still important work to do to realize the promise of the Securing the U.S. Organ Procurement and Transplantation Network Act in 2023,[1] and the faster the work is completed the more lives will be saved. I have confidence in the current leadership team at HRSA, people like Administrator Engels, Suma Nair, Dr. Ray Lynch and Brianna Doby, dedicated professionals committed to patients. Meaningful bipartisan oversight hearings on both sides of the Capitol have also

helped shed a light on the need for systematic reforms and where gaps in accountability and patient care continue.

I want to briefly tell you about a patient waiting for a liver transplant who represents the tens of thousands of patients depending on reform of our system: Jill Chance has consented to have her story shared. She is a 48-year-old woman whose priority score for liver transplant does not reflect the severity of her illness. She is in and out of the hospital with infections in her liver, and lives with drains coming out of her abdomen. She is looking forward to a liver transplant so she can spend time with her four grandchildren and meet the fifth who is on the way.

In the system's current state, too many people are still unnecessarily dying. As I previously testified before Congress,[2] an efficient and accountable system can provide enough organs for every person removed from a heart, liver, or lung transplant waiting list because they died or became too sick for a transplant. Such a system will dramatically decrease the time on the waiting list for a kidney transplant, eliminating suffering and saving lives. Essential and urgent reforms fit into three categories.

Category 1: **Structural Reform and Oversight of the OPTN**

The structure of the relationship between the government and the OPTN contractors must fundamentally change. In the past, the contractors wielded complete control over the system, with disastrous consequences. The Committee is well aware of allegations of the OPTN's failure to ensure organ procurement organizations protect donor patients, and recover sufficient organs for those in need.[3] Insufficient oversight of out of sequence allocation allowed skipping of patients waiting for life-saving organs,[4] and errors in lung allocation meant that the sickest patients were incorrectly bypassed.[5] Retaliation against whistle blowers continues to be a major concern.[6]

I am also deeply troubled by reports that the U.S. Digital Service characterized the legacy OPTN contractor as hostile and threatening when being encouraged to be more transparent and accountable. The Committee may not be aware that the staff of OPTN members routinely refuse to share data with researchers, and when they do, often require that the data be published anonymously. This is done to shield the organization from analysis and accountability. The Committee may also

not be aware of the difficulty in obtaining methods and approaches necessary from contractors to recreate published data. More recently, the OPTN implemented policies that have led to increased organ discards, costing patients' lives, and likely hundreds millions of dollars of additional cost - much of it born by Medicare.[7,8,9] OPTN contractors, both the new organization that supports the OPTN Board, and UNOS, which still serves as the operations contractor for the OPTN, reviews the success of the OPTN's own policies, leading to a conflict of interest which biases these organizations to look favorably on the outcomes of their own changes.

The conceptual framework to modernize the OPTN must recognize these failures, and change how services are overseen, structured, delivered. Currently, between the primary OPTN contractor, UNOS, and the Scientific Registry of Transplant Recipients, nearly all aspects of the system are controlled. This includes policing its own members, collecting, accessing, analyzing and reviewing data, and determining process and policy. The contractor has used this control to effectively limit governmental oversight. To remedy the situation, the following reforms should be put into place.

- HRSA must be empowered to directly collect OPTN fees to provide stronger oversight of the activity of the contractor.
- Reporting of misconduct of OPTN members must be made directly to HRSA, not OPTN or its contractors.
- HHS must ensure there are consequences for stakeholders that fail patients, including decertification, when appropriate. HRSA's own documentation of the failures at the Kentucky-based OPO[10], as well as Congressional investigations by your colleagues in three separate committees, suggest that there are other cases like the Miami OPO out there. The new structure must be able to quickly find and act on these situations, including replacing OPOs when necessary.
- HHS must own transplant data and make it publicly available. In our modern world, data is accountability.
- HHS must also own the technology and systems developed by the contractor essential to run the system. The ability of a contractor to hold the system hostage, or restrict access to the data, systems, and analysis must end - and it must end now.

- Many functions currently performed by the OPTN should be managed by the federal government, including patient safety.

These changes can be the backbone of a system that creates and sustains a culture of accountability and performance. This cannot be a one-time exercise but rather be part of a sustainable structure carried forward on a system level.

Category 2: **Standardizing Policy, Supporting Innovation, and Engaging Experts**

HRSA should be empowered to provide greater leadership than it has historically, informed by consultation with transplant stakeholders. There is a need to standardize best practices, promote innovation, and bring in external experts across the transplant system.

A recent example is donation after circulatory death (DCD). In these cases, organs are procured when a patient is pronounced dead after cessation of cardiac and circulatory function. Technological advances have vastly increased the number of successful donations using this method, and saved thousands of lives. Without DCD donation, many individuals living today after a successful transplant would never have received an organ and not have survived. Unfortunately, lack of standardization for how these organs are recovered has led to confusion both for transplant professionals and the public. HRSA should exert greater control over standardizing the approach to these patients, ensuring clear, sensible policy is enacted, disseminating the rules, and ensuring transplant professionals are appropriately educated.

The need to promote innovation is similarly urgent. There has never been a more exciting time in transplantation. Vanderbilt is one of the largest transplant centers in the U.S. predominantly based on development and rapid adoption of new technology.[11,12,13] Innovators like my colleagues Ash Shah and Kelly Schlendorf are refining techniques that have resulted in many more organs for transplant. Unfortunately, there is no effective central mechanism for promoting adoption of new technology across the national transplant system. HRSA should establish mechanisms for evaluating new technology and ensuring life-saving advances are quickly disseminated across the system.

In the Securing the U.S. Organ Procurement and Transplantation Network Act, Congress recognized that over the last 40 years since the National Organ Transplant Act was passed, the transplant system has gotten too complex for one contractor to manage. Yet more than two years after the law's passage, UNOS, the legacy OPTN contractor, is still responsible for a multitude of tasks including logistics, technology, cybersecurity, supporting policymaking, modelling, and finance. Each of these domains is a distinct field, requiring enormous content knowledge and expertise. To address this, each of these areas needs consideration of a separate contractor or subcontractor, to be actively overseen by HRSA, with input from those both inside and outside of transplant. Critical aspects of the system, including patient safety, are essential for public trust and need to be overseen directly by HRSA.

As the OPTN contract is restructured, it is imperative that the application and bidding process be as fair as possible - and encourages interest from experts that might have been discouraged from even applying in the past. I urge you to make previously successful applications available to the public, so interested parties have the best chance to prepare a competitive bid. I ask that you provide ample time for applicants to prepare these complex applications.

Category 3: **Donation Data Availability and OPO Accountability**

System-wide reform is limited if data is not freely available to the public to ensure accountability for individual OPOs. As I wrote with coauthors in an editorial in the *Journal of the Americal Medical Association Surgery,* what cannot be measured cannot be fixed.[14] HHS must ensure that data for all steps in the donation process, including whether potential donors are correctly referred by a hospital to an OPO, the response of the OPO, how the patient and family are approached, the results of the discussion, and the placement of organs, are recorded for study. HRSA's proposed initiative for data collection regarding patients referred to OPOs for evaluation is a novel and ground-breaking approach for two reasons. The first is that this desperately needed data will now be collected, and the second is that the data will be directly accessible. It is my hope that HHS will continue to make critical data directly available without constraints.

Study after study, beginning in 2003, demonstrated the number of potential donors in the system is between 2 and 4 times the number of actual donors.[15,16,17]

Previous performance metrics for the OPOs were self-reported and widely understood to be inaccurate. CMS has made great strides in establishing new metrics based on work led by David Goldberg.[18] These metrics must be enforced in the upcoming 2026 certification cycle, with failing OPOs replaced. In advance of the certification cycle, CMS must close the research pancreas loophole, whereby OPOs were able to receive credit for organs not transplanted into a patient.

One final comment, having been involved in the transplant of a man with Down syndrome who is leading a remarkable life after multi-organ transplant, I am strongly in favor of the Charlotte Woodward Organ Transplant Discrimination Prevention Act to help prevent discrimination in transplantation, and ensure each center can make the appropriate decision for each patient.

In summary, I have three recommendations:

1) HHS must restructure the relationship between the government and the contractors operating the nation's transplant system. HHS should directly collect fees, create a mechanism to receive system complaints outside of the contractor, and directly address egregious patient safety violations by decertifying organizations. HHS must own transplant data and make it broadly available to identify failures and needed solutions that can save lives. HHS must own the technology required to run the transplant system.

2) HRSA should be more involved in directing policy. HRSA must require standardization of policies and procedures, for example for DCD and technology implementation, and be able to consult and engage experts in each of the fields that impact our transplant system to rapidly maximize the number of donors. New contracts must be bid out competitively and fairly, and the government must retain the ability to hold contractors accountable and quickly replace contractors who fail to serve the public or interfere with government oversight.

3) HHS must mandate data reporting for all aspects of the donation process. OPO performance must be measured and performance standards enforced through the OPO Final Rule. Poorly performing OPOs should be decertified. The research pancreas loophole must be closed.

On behalf of our patients, I urge Congress and Administration to implement these reforms as quickly as possible. Because as I testified in 2021, and as transplant candidate Jill Chance understands, time matters in transplantation.

Thank you for your important work on this topic, and for the opportunity to speak today. I welcome any questions you may have.

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