UNOS
UNITED NETWORK FOR ORGAN SHARING

Saving lives together

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Testimony of

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FULL COMMITTEE HEARING

Chairman Wyden, Ranking Member Crapo, and members of the committee, thank you for inviting me to discuss our nation's organ transplant system and the role of United Network for Organ Sharing, or UNOS. I am Brian Shepard, the CEO of UNOS, the non-profit organization which holds the federal contract to serve as the U.S. organ donation and transplantation network.

I look forward to having a conversation with you about our nation's diverse and thriving organ transplant system that just marked its 9th consecutive record-setting year of lifesaving transplants.

In 1984, Congress passed the National Organ Transplant Act (NOTA) to address the nation's critical organ donation shortage and improve organ matching and placement. The law called for an Organ Procurement and Transplantation Network (OPTN) to maintain a national registry for organ matching, and specified that the network would be a private, nonprofit entity.

UNOS is proud to have been awarded the OPTN contract successively since 1986. Each contract rebid is based on a competitive process. We welcome this competitive process, and it has been our honor to serve the nation for over three decades.

From UNOS' inception as a mission-based non-profit and since we began serving as the federal contractor, we have never once taken this privilege lightly; UNOS staff, volunteers—including transplant professionals, recipients, and donor families—and others dedicate their time and expertise every day to saving lives and improving the system. Our work focuses on three main areas: developing equitable allocation policies that ensure the fair distribution of organs; maintaining the national waitlist with safe, secure and modern technology; and continuing to improve overall performance.

But we do not exist in a vacuum; we convene a community of 40,000 organ donation and transplant professionals and work in concert with our federal partners.

The OPTN contract is awarded and managed by the Health Resource Services Administration (HRSA). The Centers for Medicare and Medicaid Services (CMS), meanwhile, covers the cost for many of the nation's lifesaving transplants and related services. Through its reimbursement programs, CMS regulates transplant hospitals, and is also charged with certifying and overseeing organ procurement organizations (OPOs).

Together, UNOS, HRSA and CMS each play important roles in ensuring both the integrity and continuity of the complex national system on which so many rely. UNOS strives to align its efforts with those of HRSA and CMS so that we all work in concert as we fulfill our respective roles, while recognizing that there will always be room for improvement.

OPTN Background

The OPTN, as described in the statute, is a membership organization. We count amongst our members physicians, patients, transplant hospitals, organ procurement professionals, living donors, donor families, professional organizations, advocates, and volunteers, all of whom make the system what it is. And that is by design.

When Congress developed the framework for the OPTN, it did so knowing that it was entrusting physicians and patients with the responsibility to make critical, medically complex policy

decisions based on firsthand experience, shared values, and their ongoing participation in the organ donation and transplant process. We still agree with that prescient decision.

That is the community UNOS is so proud to represent – a community dedicated to the equitable distribution of organs no matter who you are or where you live to save as many lives as possible through transplant.

With this commitment to equity underpinning everything we do, we have seen rapid and remarkable changes in the past few years alone; changes that have expanded equitable access to transplants for candidates on the waitlist, increased priority for the sickest patients on the waitlist, addressed disparities by increasing transplants for historically marginalized communities, and so much more.

However, while access to a transplant once a patient has been added to the waitlist is largely equitable, there are systemic shortcomings within the larger U.S. healthcare system that make getting *added* to the waitlist inequitable. We must confront this issue as a nation and we are committed to addressing it within our purview as the OPTN.

Ours is a complex system; one that is dedicated to continuously improving, monitoring and adapting; one that involves thousands of people coming together every single day across the country in order to save lives.

It is a system Congress set in motion nearly forty years ago, and which, thanks to the decisions and expertise of those who laid the foundation, allows us to best serve patients in need of a transplant.

Ongoing Successes

UNOS works to save lives every day, and the numbers bear out our successes in both improving the system and identifying new areas for enhancement.

In 2021, for instance, the national system made global history: for the first time in a single year, the United States surpassed 41,000 lifesaving transplants. That same year, the system also saw record numbers of liver, heart and lung transplants. These exciting milestones are the result of year-over-year increases in organ transplants for the past decade and occurred in the midst of worldwide pandemic.

Additionally, post-implementation monitoring reports show the positive impact of recent modifications to kidney and liver allocation policies. According to the one-year monitoring report analyzing changes to kidney allocation (the most transplanted organ), we saw an ongoing increase in kidney transplants nationally, especially for historically marginalized communities, patients on dialysis, and others. This includes increases of:

- 23 percent for Black patients
- 29 percent for Hispanic patients
- 20 percent for Asian patients
- 36 percent for patients with long wait-times on dialysis
- 63 percent for pediatric patients.

Meanwhile, the two-year monitoring report for changes to liver allocation policy continued to show increases, with national rates increasing by 4.3 percent, including for the sickest patients, historically marginalized communities, and others.

Again, these successes have taken place in the midst of the global pandemic that imperiled access to health care. Deceased donor transplant rates dipped in March of 2020, but quickly rebounded to pre-pandemic levels by April 2020. This was the result of the collective effort of physicians, professionals and others on the front lines.

It should also be noted that these successes are not stand-alone achievements, but instead the product of years of ongoing policy development, inclusive debate, rigorous discussion, monitoring, and a commitment to continuous improvement.

While the votes to enact these policies were not unanimous, the changes were enthusiastically supported by a vast majority of Board members. Additionally, our policy development process has now been reviewed by HHS and the General Accounting Office, as well as multiple courts, and these policies are now in effect and benefitting patients across the country.

Unfortunately, an ongoing misconception is that our nation's success in donation and transplant is due to the ongoing and tragic opioid crisis and to the prevalence of gun violence.

The national increase in transplants predates the beginning of the opioid crisis and the recent rise in violent crime. Additionally, both policy changes and technological advancements have played a role in increasing transplants. Yet there is another, more important point to be made here.

Every death is tragic. However, regardless of the manner in which a potential donor dies, the Organ Procurement Organization (OPO) is still there to counsel the family, surgeons are still there to recover the selfless donor's organs, and the transplant hospital is still there to give the gift of life to a grateful recipient.

As previously mentioned, we have seen dramatic increases in the number of transplants taking place over the past decade. We are also focused intently, not just on the number of transplants, but the equitable distribution of lifesaving organs.

The OPTN Minority Affairs Committee (MAC) has been looking at these issues for years, resulting in the policies that have helped drive increases in transplants for patients of color.

Just recently, following the efforts of a diverse workgroup made up of both patients and physicians, the OPTN Board passed a new rule requiring that all transplant hospitals must use race-neutral measures of kidney function.

Role of UNOS

With the creation of the OPTN, Congress designed a system to address the nation's critical organ donation shortage and improve organ matching and placement. To accomplish this, Congress did not create a centralized, government-run process to determine policies impacting these life-saving actions. Instead, Congress believed that patients and physicians should lead the way. This was the correct decision then, and remains the best choice today.

Thanks to congressional foresight, we now have an OPTN with a board and committees populated by patients, physicians, living donors, donor families and patient advocates who help make policy through rigorous debate and based on their unique experiences. There are currently 26 OPTN Committees, including committees dedicated to specific organ transplant types, technology, minority affairs, patient affairs, policy oversight, safety, and others.

These experiences are essential to making difficult, complex, and often emotional policy decisions that impact the lives of thousands across the country.

So much of the ongoing discussion of our shared successes, collaborative efforts, and everything this diverse and thriving national community has accomplished is muddled by a basic misunderstanding of UNOS' role in our complex national system.

Some think of UNOS as a regulator, with codified regulatory authority and congressionally mandated powers to oversee and penalize those not in compliance.

However, based on the law Congress enacted, UNOS, in its role as the OPTN, is not a regulator.

Regulatory authority of the nation's organ donation and transplant system rests with CMS, and the delineation of our different roles is clear, established in both statute and policy, and essential to our ongoing collaboration and alignment.

Our particular role is multifaceted, complex and essential:

- UNOS members work alongside each other as partners in improvement
- We operate a rigorous peer review process which includes site-visits, reviews, helping to develop plans of action, offering educational opportunities, and other limited oversight functions
- We built, monitor and continuously improve the IT infrastructure that makes it possible to match donor organs with recipients in need of a transplant
- We develop, implement, and monitor equitable organ allocation policies
- We serve as both a convener of the transplant community and as an advocate on behalf of the nation's organ donation and transplant system

Membership and Professional Standards Committee (MPSC)

The Membership and Professional Standards Committee (MPSC) is an operational committee of the OPTN. In this role, the committee maintains OPTN membership criteria, monitors OPTN member compliance with this criteria, as well as compliance with OPTN bylaws, policies, and the OPTN Final Rule. As needed, the MPSC takes action or makes recommendations for further action to the OPTN Board of Directors.

The MPSC also identifies opportunities for individual member improvement and opportunities for transplant community education, all in an ongoing effort to improve patient safety and safeguard the integrity of the transplant system.

The MPSC is made up of volunteers who reflect the transplant community at large, including physicians with expertise in each organ transplant type and OPO volunteers. Health Resources Services Administration (HRSA) representatives also participate as ex officio members.

Integral to UNOS' success in supporting continuous improvement among members and the community at large is the MPSC's confidential medical peer-review process – a vital process required by the OPTN Final Rule and the federal contract that allows the OPTN to review member performance, conduct investigations, and fact-find within a confidential setting.

Confidential peer-review is a common practice across the U.S. healthcare system. This was driven in large part by a landmark Institute of Medicine (IOM) report from 2000, which emphasized the

importance of confidential peer-review to boost performance, ensure patient safety and encourage continuous improvement.

This report led to a national sea-change and spurred the adoption of confidential peer-review across the healthcare landscape. HHS incorporated this approach into the Final Rule in 2000 and this critical tool was included into the OPTN contract soon after.

The "peer review" component is essential. Clinicians and professionals on the MPSC represent all the primary disciplines involved in transplantation. This expertise makes it possible to view member actions within the proper context, including what should have been known and what actions should have been taken under any given circumstance.

Confidentiality is equally important, as it increases the possibility that OPTN members are more likely to come forward to report issues that occur at their organization. Without willing members able to provide critical information, the committee would not be able to fully assess a given event, and suggest needed improvements. Removing confidentially protections would imperil the process and may have a chilling effect on those who might otherwise report troubling behavior.

The protection afforded by confidential medical peer-review also includes the opinions, statements and deliberations of MPSC committee volunteers themselves, ensuring their participation in the process without fear of professional reprisal or litigation.

A range of actions are available if, after investigation and deliberation, the MPSC finds a member has not followed OPTN requirements. Some of those sanctions are not public, such as notices of noncompliance or letters of warning. However, if the MPSC recommends that the OPTN Board of Directors take an "adverse action," which includes placing a member on probation or declaring a member not in good standing, and the Board acts on the recommendation, these designations are made public.

The Board may also decide a member's non-compliance with OPTN requirements risks patient health or public safety, or that the member consistently fail to improve while under an adverse action. In these cases, the Board must make an official referral to the U.S. Secretary of HHS.

This complex but essential process helps ensure the nation's organ donation and transplant system holds itself to the highest standards, drives member improvement and makes it possible to work with our community partners to address issues and arrive at workable, patient-centered solutions, all with appropriate governmental oversight.

The MPSC works collaboratively with every member in our community as a partner in improvement, and its rigorous process ensures prompt responses and swift action if necessary.

National Academies of Sciences, Engineering, and Mathematics (NASEM) Report

UNOS has continued to pursue efforts to improve the nation's organ donation and transplant system, increase equity, expand access, increase patient opportunities for involvement, and save even more lives.

NASEM's February 2022 report addressed many of these issues. We were pleased that their in-depth analysis recognized many of our ongoing efforts, which aligned with their recommendations and reflect work already underway within and across our community, in many instances led by, in collaboration with or made possible by the support of UNOS.

These include:

- Enhancing current educational offerings for patients,
- Emphasizing shared-decision making between patients and physicians,
- Establishing new patient-centric transplant program performance metrics that go into effect this year
- Adjusting payment policies to incentivize the utilization of harder to place organs
- Increasing transparency and accountability by launching a new list of codes for transplant programs to use when they refuse an order offer

And other efforts outlined in more detail below.

Equity

The NASEM report emphasized the importance of increasing equity in access to the national waitlist, regardless of where the patient lives or who they are. We agree, and have been dedicated to this proposition since our inception, both as a condition of our own organizational values and as a condition of the law which first established the OPTN.

One recent example is the development of the "Continuous Distribution" framework, an approach the NASEM committee vigorously supported. The Continuous Distribution policy will erase hard boundaries, ensuring that no single attribute will determine if a patient gets a transplant. Importantly, this framework is also designed to be augmented over time, allowing for ongoing feedback from a wide range of stakeholders and giving patients an important seat at the table.

As mentioned earlier in this statement, the OPTN Board of Directors voted in June on an equity-based proposal to prohibit the use of race-based estimation of kidney health in OPTN policy.

Systemic Improvements

The NASEM Committee also made several recommendations for the OPTN and the donation and transplant community overall to improve the system. One of these was the development and adoption of national performance metrics, which we fully support. Other tools we currently offer to the public and policymakers to monitor ongoing progress are the OPTN Metrics Dashboard and the OPTN Equity Dashboard. Both can be found on the OPTN website.

NASEM also made recommendations for maximizing organ use. In its capacity as the OPTN, UNOS already has developed, tested and now offers the Kidney Offer Filters tool to transplant hospitals, which is in keeping with this NASEM recommendation. Our innovative tool, first available in January of 2022, allows kidney transplant programs to preemptively screen out offers they are unlikely to accept, reducing administrative burden, accelerating organ placement and making it easier for OPOs to find best-fit candidates quicker. We also must continue to reduce differences in practices from hospital to hospital and do our part to make sure everyone understands the organ offer review and acceptance process.

As a part of overall system improvement, NASEM also recommended that the U.S. Department of Health and Human Services (HHS) conduct an evaluation of the OPTN IT system within one-to-two years. UNOS welcomes this evaluation; as of this writing, one has not been conducted.

Beyond and before NASEM's recommendations, UNOS has always undertaken efforts to continuously improve the national system, bolster performance and support others within our community.

While the above efforts, projects and tools are in no way a comprehensive list of ongoing work, they do represent an accurate picture of UNOS, as a federal contractor, responding to the needs of patients, physicians, and the organ donation and transplant community at large.

Transportation

Transportation is essential to the success of the organ donation and transplant system. Unless a recovered organ happens to be accepted by a candidate in the same hospital where the organ was recovered, the organ must necessarily be transported from the donor hospital to the transplant hospital. The vast majority of organ shipment logistics are determined between the OPO and the transplant hospital on the ground, although the OPO may request OPTN assistance in rare cases. Additionally, the OPTN has multiple policies in place that address the safety of organs in transport, particularly regarding packaging, labeling, and ultimately verifying successful delivery to the patient who accepted the organ.

Additionally, except for kidneys, most organs (hearts, lungs, livers, etc.) are transported in the company of the transplant physician who will be conducting the surgery. Disruptions are rare, but can still have a direct and serious impact on a patient in need of an organ.

Like many things within this national system, transporting an organ is extremely complex. Something as simple as a courier taking a wrong turn can delay the delivery of an organ.

That is why we have engaged in several collaborations with the community to improve the transport of organs through the development and adoption of innovative, evidence-based products to ensure patient safety.

The UNOS organ tracking service, for example, is now in use by 15 OPOs across the country and allows users to oversee organ shipments in real time. The tool provides OPOs with real-time location data, package updates and maps with easy-to-read visualizations. It also fully integrates with existing tools and systems, all in an effort to improve performance, speed, and patient outcomes.

We have also conducted a successful pilot of a UNOS Travel App, which will allow OPOs to select the best options for transporting organs. Once fully operational, the app will allow OPOs to view and select the most efficient options for shipping lifesaving organs on commercial flights. While these are all important innovations, we continue to pursue efforts to further improve the transport of donor organs.

IT Infrastructure

Our focus on continuous improvement also includes constantly enhancing our safe, secure and efficient IT infrastructure; a modernized system that we built, maintain, and enhance to ensure the highest performance on behalf of all those who have come to rely on it.

Our system is audited by both federal authorities and third-party cybersecurity firms. We regularly meet and exceed both their standards and our rigorous federal contract obligations. Additionally, the OPTN's Network Operations Oversight Committee (NOOC) assists the OPTN Board in overseeing a variety of essential IT functions, including organ matching and data collection.

We have spent years developing and improving our infrastructure, building and incorporating technological innovations, partnering with industry leaders, and leveraging Cybersecurity and Infrastructure Security Agency (CISA) resources to ensure robust performance and security on behalf of the communities we serve. This is why, despite more than 3 million hacking attempts each day, our system has remained safe and secure.

Our modern infrastructure was designed to make the nation's complex allocation policies possible; an effective, one-of-a-kind approach that weds robust technological capabilities with in-depth policy knowledge and has maintained, outside of periodic scheduled maintenance, a system uptime of 99.99%.

While the votes to enact these policies were not unanimous, the changes were enthusiastically supported by a vast majority of Board members. Additionally, our policy development process has now been reviewed by HHS and the General Accounting Office, as well as multiple courts, and these policies are now in effect and benefitting patients across the country.

Our IT developers and business analysts are experts in both technology and transplant and donation; it requires this kind of unique background to successfully and thoughtfully integrate effective technology and lifesaving policy.

A Shared Vision for the Future

Our vision for the U.S. donation and transplant system is straightforward: being able to provide a lifesaving transplant for everyone who needs one. There is still much work to do, but in collaboration with our community partners, physicians, patients, OPOs, hospitals, policymakers, advocacy organizations, volunteers and others, we are making this vision a reality. From transportation to technology, from equity to system-wide improvements, by building on the successes of our national system and our community's ongoing efforts on all fronts, we can come together around these shared goals. It is challenging and sometimes controversial; we welcome constructive debates. But when we come together, our work can literally change someone's life.

This collaborative, ambitious vision is transforming the system as we know it, building an even stronger national system we can be proud to call our own.

I would like to thank Chairman Wyden, Ranking member Crapo, and the entire Senate Committee on Finance once again for inviting me to discuss the status of donation and transplant today and what we can accomplish when we work together to further improve this lifesaving system. I look forward to your questions.