

December 9, 2024

The Honorable Cathy McMorris Rodgers Chair Committee on Energy and Commerce U.S. House of Representatives

The Honorable Morgan Griffith
Chair
Committee on Energy and Commerce
Subcommittee on Oversight
and Investigations
U.S. House of Representatives

The Honorable Brett Guthrie
Chair
Committee Energy and Commerce
Subcommittee on Health
U.S. House of Representatives

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Kathy Castor
Ranking Member
Committee on Energy and Commerce
Subcommittee on Oversight
and Investigations
U.S. House of Representatives

The Honorable Anna G. Eshoo Ranking Member Committee on Energy and Commerce Subcommittee on Health U.S. House of Representatives

Dear Chair McMorris Rodgers, Ranking Member Pallone, Chair Griffith, Ranking Member Castor, Chair Guthrie and Ranking Member Eshoo,

We are at a pivotal moment for our nation's organ donation and transplantation system, as more than 100,000 people await the lifesaving gift of transplant. As my organization remains on the front lines of efforts to strengthen the system, I urge you to work with us to ensure patients across the country have access to the transplants they urgently need.

When the National Organ Transplant Act was enacted into law 40 years ago, the government took on the responsibility for overseeing a complex system regulated by multiple agencies concerning organ donation, procurement and transplant. The U.S. Department of Health and Human Services, the Centers for Medicare and Medicaid Services and the Health Resources and Services Administration (HRSA) each have distinct roles and responsibilities over the hospitals, surgeons, transplant centers, organ procurement organizations, histocompatibility labs, and the Organ Procurement

and Transplantation Network (OPTN). For decades, HRSA has awarded the United Network for Organ Sharing the contract to manage our country's OPTN.

UNOS acts at the direction of HRSA to facilitate the OPTN to make decisions about the policies concerning organ allocations and maintenance of the waiting list. But UNOS does not have the authority to mandate changes on its own.

In the two years since I assumed the role of chief executive officer, UNOS has had two critical objectives: effecting change in areas that are within our control and driving needed systemic reforms that cannot be achieved without congressional action. Although much of the donation and transplant system has been outside of the purview of UNOS' service as the OPTN contractor, we are committed to strengthening the system for patients everywhere.

While Congress enacted legislation to reform the management of the OPTN, there is still strong bipartisan interest, heightened media attention, and public support to continue the work that is currently being done to improve the system for patients.

Congress must focus on the implementation of the reforms it has mandated but also do more. UNOS has identified and reduced inefficiencies, primarily through our role as the OPTN contractor. Yet the most significant barriers to a more efficient system can only be addressed through a combination of regulatory and statutory policy changes. As patient advocates and stakeholders continue to demand improvements, ensuring the removal of barriers and making the system more efficient can only benefit the patients the system is designed to serve and work towards the goal of every patient receiving a lifesaving transplant.

UNOS is an indispensable resource for Congress. For 14 consecutive years, the number of life-saving organ transplants has increased, culminating in more than 46,000 successful organ transplants in 2023 – a record that will almost certainly be eclipsed this year. All aspects of the system worked together to make more transplants happen.

UNOS has identified four critical reforms that, if correctly and quickly implemented, would reduce the number of patients who die every day awaiting transplant. UNOS has already begun work on some of these:

• Optimize the Donor Referral Process with Mandated Automated Donor Referrals (ADR). Successful organ transplants depend on information-sharing with organ procurement organizations (OPOs), non-profits that are responsible for recovering organs from deceased donors. This reporting is often undertaken manually by overworked hospital staff. It is antiquated and inefficient. An automated referrals system using electronic health records is being piloted by several OPOs and hospitals. Determining best practices and how to adopt this technology across the country would ensure OPOs are automatically alerted

about every potential organ donor when a dying patient meets predetermined clinical criteria. Studies have found a 49 percent increase in donor referrals and a 333 percent increase in organ donors upon implementation of ADR. Representatives Rob Wittman and Jennifer McClellan have introduced legislation to require a study to determine how to implement this nationally. In reality, the administration could begin this research tomorrow. I hope you will join us and your Virginia colleagues in moving this legislation forward to simplify and improve the donation process.

- Mandated In-Cabin Airline Transportation for Organs. Life-saving organs should never be relegated to airline cargo bays, where they are more prone to be damaged, lost or delayed because of cargo staffing limitations. Thanks to a provision in the bipartisan Federal Aviation Administration Reauthorization of 2024, work on this effort has begun.
- Mandated Organ Tracking for Unaccompanied Organs. There is no federally required national tracking system for organs to prevent them from being lost, delayed in transit, or damaged. A national, centralized, and compulsory system-wide tracking system would give key organ transplant stakeholders maximum visibility into the transportation of life-saving organs, while enabling thorough investigations of lost or delayed organs, which is critical to implementing systemwide improvements. This concept has been discussed for several years but needs action.
- Incentivizing Transplant Hospitals to Accept Hard-to-Place Organs. More kidneys are recovered for transplant every year, in part because organ procurement organizations are increasingly pursuing more medically complex donors. The changes in the health of the donor population, including increased history of hypertension, diabetes and cancer, largely explain the increase in nonuse of these hard-to-place kidneys. Last year, more than 8,000 kidneys were not transplanted, in many cases because they could not be paired in time with a hospital willing to take on the clinical and financial risks that come with accepting organs from more medically complex donors. Kidneys from these donors may have delayed graft function, and patients receiving these kidneys may require dialysis after their transplant until the transplanted kidney starts working. This treatment and monitoring may require longer hospital stays. However, evidence shows that kidneys from more medically complex donors can still result in successful transplant outcomes with appropriate posttransplant care, and that patients will live longer if they receive a transplant – even from a more complex kidney - than if they wait on dialysis. Studies show

that <u>62 percent</u> of kidneys that were not transplanted in the U.S. between 2004-2014 would have been successfully transplanted in France. A policy change to Medicare to compensate transplant hospitals at a higher rate for transplanting more medically complex kidneys would encourage more hospitals to accept these kidneys for their patients, <u>ultimately preventing an estimated 4,000 avoidable deaths annually (14 of the 17 patients who die each day awaiting organ transplants</u>).

UNOS' four decades at the center of the organ donation and transplantation system has provided us with unique insights and expertise. The contracting reforms Congress put in place are just a start. Please work with us to ensure that other significant reforms are established so our system is patient-centric and as effective as it can be to reduce the number of patients on the waiting list and help save more lives.

As you continue to review the transplant system, we hope you and your colleagues will work with us in our efforts to strengthen the system to save more lives.

With kindest regards,

Marrier MBride

Maureen McBride, Ph.D.

Chief Executive Officer

UNOS

cc:

cc: Mary D. Ellison, Ph.D.

Chief External Relations Officer, RETIRED UNOS

CC. Shop

SVP OPO Relations

NORA - Nationwide Organ Recovery Transport Alliance

CC: Elaine Perlman

Flaine Perlman (Nov 12, 2024 11:46 EST)

Executive Director Waitlist Zero

cc:

Brittany k Lyons (Nov 12, 2024 12:06 EST)

Advanced Practice Coordinator
Gift of Life Donor Program

cc: Christopher L. Marsh MD, FACS, FAST

V. P. Surgical Services Scripps Clinic Scripps Clinic & Green Hospital

CC: Kevin M. Chan, MD

Kevin M. Chan, MD (Nov.12, 2024 16:36 FST)

Vice Chair Department of Medicine University of Michigan

cc: <u>John Roberts</u>

Professor of Surgery

University of California San Francisco

cc: <u>Donna Dickt</u>

Executive Director

North American Transplant Coordinators Organization

cc: James J. Wynn, M.D.

Professor of Surgery
University of Mississippi Medical Center

CC: Katherine Giovetsis

Katherine Giovetsis (Nov 19, 2024 11:20 EST)

Chief Executive Officer

American Society for Histocompatibility and Immunogenetics (ASHI)

April E. Roberts

April E. Roberts (Nov 21, 2024 05:20 CST)

MT, ASCP DCI, INC.

CC: Jessica Badders

Jessica Badders (Nov 21, 2024 06:43 EST)

Immunogenetics Strategist NMDP

cc: Jody Jennemann

Technical Coordinator - HLA Lab Barnes-Jewish Hospital CC: Richard Freeman, MD, MHL

Richard Freeman MD MHL (Mry 12, 2024 14:16 EST)

Professor of Surgery and Vice Dean for Academic Affairs Tufts University School of Medicine

CC: <u>Dan M. Meyer, MD</u>

Dan M. Meyer, MD (Nov 12, 2024 21:58 CST)

Chair, Department of Cardiovascular Surgery, Chief of Cardiac Transplant and MCS

Baylor Scott and White Health, Dallas Texas

cc: <u>Susan Gunderson</u>

Susan Gunderson (Nov 13, 2024 08:05 CST)

OPO Executive Retired

CC: Margaret J Schaeffer (Nov 13, 2024 13:24 EST)

Donor Family

NA

CC: George Mazariegos

George Mazariegos (Nov 16, 2024 16:54 GMT+9)

MD, Chief, Pediatric Transplantation
UPMC Children's Hospital of Pittsburgh

Melices Peed (Nov 21, 2024 05:00 CST)

HLA Group Lead

DLO Transplant Immunology Lab

CC: Shivani Patel (Nov 21, 2024 06:39 EST)

HLA laboratory supervisor NJOTSN

Rachel Wahlert
Rachel Wahlert (Nov 21, 2024 07:10 EST)

Histocompatibility Lab Manager Wellstar MCG Health

CC: Mary Libby

Mary Libby 21 2024 07-57 EST)

Laboratory Quality Specialist Allogen Laboratories CC: Runying Tian
Runying Tian (Nov 21, 2024 08:07 EST)

Manager Albany Medical College

CC: Suraya A Berger
Suraya A Berger (Nov 21, 2024 08:13 EST)

Immunogenetics Supervisor
Johns Hopkins University SOM

cc: Tracey Schilling
Tracey Schilling (Nov 21, 2024 08:31 EST)

Clinical Laboratory Specialist JHU Immunogenetics Lab

CC: Kelley MK Hitchman

Kelley MK Hitchman (Nov 21, 2024 07:56 CST)

Histocompatibility & Immunogenetics Laboratory Director TXSR

CC: Eros Qama (Nov 21, 2024 09:29 EST)

Pathology Resident Hospital

CC: Rebecca M Burke

Rebecca M Burke (Nov 21, 2024 08:34 CST)

Administrative Manager

UAB Histocompatibility and Immunogenetics Laboratory, CTI

CC: Roger P Banwart

Roger P Banwart (Nov 21, 2024 08:48 CST)

Histocompatibility Specialist Iowa City VA Hospital

CC: Loren Gragert, PhD

Loren Gragert, PhD (Nov 21, 2024 09:50 CST)

Assistant Professor
Tulane University School of Medicine

cc:

Hua 21, 2024 09:32 EST)

Technical Specialist Massachusetts General Hospital

CC: Leah Pittmon, CHS

Leah Pittmon, CHS (Nov 21, 2024 11:11 CST)

Antibody Lead

Transplant & Genomics Core, Baylor University Medical Center

CC: Leh Chang
Leh Chang (Nov 21, 2024 05:10 PST)

Technical Supervisor Loma Linda University Medical Center

CC: Samantha Sparks-Spires
Samantha Sparks-Spires (Nov 21, 2024 08:21 EST)

Histocompatibility Technician Indiana University School of Medicine

CC: Lori Ellinger

Lori Ellinger (Nov 21, 2024 06:34 MST)

HLA Laboratory Supervisor University of Utah Health

CC: Sidnee Freeman
Sidnee Freeman (Nov 21, 2024 08:08 CST)

Certified Histocompatibility Technologist VUMC

CC: William W. Ward, Ph.D. F(ACHI)
William W. Ward, Ph.D. F(ACHI)

Associate Director, HLA, Department of Transfusion Medicine NIH Clinical Center

CC: Mary Carmelle Philogene
Mary Carmelle Philogene (Nov 21, 2024 09:45 EST)

Histocompatibility Laboratory Director Virginia Commonwealth University

CC:
Trysha Galloway (Nov 21, 2024 06:52 PST)

Donor/Researcher

CC: Sharon Skorupski (Nov 21, 20/4 11:02 EST)

Leader, Senior Technologist Transplant Immunology lab Henry Ford Hospital

CC: Lynden E Gault

Lynden E Gault (Nov 21, 2024 09:25 EST)

Laboratory Medical Technologist
Michigan State University Immunohematology Laboratory

CC: Jane Franco (Nov 21, 2024 11:32 CST)

Histocompatibility Technologist University Health CC: <u>Idoia Gimferrer</u>
Idoia Gimferrer (Nov 21, 2024 09:47 PST)

HLA Laboratory Director BloodworksNW

cc: <u>Karen Heisler</u>

HLA lab supervisor Sanford Health

CC: Valerie Mark (4/21, 7/24 15:39 EST)

National Senior Manager, Advocacy American Liver Foundation

CC: Ann Pole
Ann Pole (Nov 21, 2024 13:54 MST)

H&I Specialist IV, CHS H&I Lab University of Utah Health

Deanna Santana

Deanna Santana (Nov 21, 2024 15:12 PST)

Donor Mom, living donor then a director

El Dorado County Office of Education, Commission for Youth and Families

CC: Shannon Dutterer
Shannon Dutterer (Nov 21, 2024-22-27 EST)

Histocompatibility Technologist Medical College of Georgia

CC: Wietse Mulder
Wietse Mulder (Nov 22, 2024 09:00 GMT+1)

Founder and director TxMiller Foundation

Ira J. Copperman

Ira J. Copperman (Nov 22, 2024 11:28 EST)

Vice-President

Transplant Recipients International Organization

CC: Chris Martin
Chris Martin (Nov 21, 2024 13:14 EST)

Lab supervisor LifeLink Transplantation Immunology Lab

CC: Carly J Amato-Menker

Carly J Amato-Menker (Nov 21, 2024 14:47 EST)

Histocompatibility Director-in-Training Virginia Commonwealth University

CC: John Friedewald, MD

John Friedewald, MD (Nov 21, 2024 14:50 CST)

Medical Director, Kidney Transplantation Northwestern Medicine

CC: Sandra Rosen-Bronson, PhD, F(ACHI)
Sandra Rosen-Bronson, PhD, F(ACHI) (Nov 21, 2024 16:43 EST)

Histocompatibility Lab Director Medstar Georgetown University Hospital

cc: Linda Ohler MSN, RN, CCTC, FAAN, FAST

Retired Associate Director, Transplant Quality Regulatory and Education

New York University Transplant Institute

CC: maken

Melissa Cardenas (Nov 21, 2024 23:27 CST)

Histocompatibility Technologist University Health

CC: الإسلم على

Sharon M. Austria (Nov 21, 2024 20:31 EST)

Specialty Laboratory Technologist Mount Sinai Hospital

cc: lolita Ardiente

Lead Technical Coordinator BloodworksNW CC: Michael S Seely
Michael S Seely (Nov 22, 2024 17:23 PST)

Executive Director (Former retired)
ORUO

cc:

Pachel Marcano (Nov 23, 2024 10:49 EST)

Specialty laboratory technologist Montefiore

CC:

Anh Huynh
Anh Huynh (Nov 25, 2024 10:12 EST)

Account Manager

CareDx

cc: Melissa McQueen

Wellers McQueen (Nov 25, 2024 13:21 MST)

President

Transplant Families

CC:

Rajalingam Raja (Nov 27, 2024 14:23 GMT+11)

Director, Immunogenetics and Transplantation Laboratory

UCSF

cc: MB

HLA Technologist MaineHealth

cc: <u>Dr Randee Bloom</u>

or Randee Bloom (Nov 23, 2024 20:45 EST)

RN, MBA, PhD

Past OPTN/UNOS Board Member

cc: John May

DNA Team lead

IU Health Transplant

CC: Walter Herczyk
Walter Herczyk (Nov 26, 2024 14:53 EST)

Director of Laboratory Services Gift of Life Michigan