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# THE COST OF INACTION AND THE URGENT NEED TO REFORM THE U.S. TRANSPLANT SYSTEM

## HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH CARE

OF THE

## COMMITTEE ON FINANCE
## UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

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COMMUNICATIONS

# THE COST OF INACTION AND THE URGENT NEED TO REFORM THE U.S. TRANSPLANT SYSTEM

**THURSDAY, JULY 20, 2023**

U.S. SENATE,
SUBCOMMITTEE ON HEALTH CARE,
COMMITTEE ON FINANCE,
*Washington, DC.*

The hearing was convened, pursuant to notice, at 10:03 a.m., in Room SD–215, Dirksen Senate Office Building, Hon. Benjamin L. Cardin (chairman of the subcommittee) presiding.

Present: Senators Wyden, Cortez Masto, Warren, Grassley, Lankford, Young, and Blackburn.

Also present: Democratic staff: Martha P. Cramer, Staff Director for the Subcommittee on Health Care of the Senate Committee on Finance and Health Policy Advisor for Senator Cardin; Michelle Galdamez, Legislative Aide for Senator Cardin; and Carolyn A. Perlmutter, Legislative Aide for Senator Cardin. Republican staff: Beth Nelson, Health Policy Director for Senator Young.

## OPENING STATEMENT OF HON. BENJAMIN L. CARDIN, A U.S. SENATOR FROM MARYLAND, CHAIRMAN, SUBCOMMITTEE ON HEALTH CARE, COMMITTEE ON FINANCE

Senator CARDIN. Good morning. The Subcommittee on Health Care of the Senate Finance Committee will come to order. I first want to thank Senator Wyden and Senator Crapo for their help in allowing us to move forward with this hearing today in regards to transplants. I also want to acknowledge Senator Young not only for his taking on the responsibilities for this hearing, but also his leadership on this issue. And we thank Senator Daines for his cooperation in allowing the subcommittee to proceed with today's hearing.

Lastly, I want to thank Senator Grassley, who has been the real champion on this issue for many, many years. He will be joining us. He is at the Judiciary Committee right now, and he will be joining us shortly, and at that time he will be recognized for his opening statement.

In the United States, the need for organs is far greater than those available. There are about 104,000 adults and children on the national transplant wait list, and every 10 minutes another person is added to it. In 2020, the Senate Committee on Finance did an investigation into the system and documented significant failures.

Today, we discuss the path forward to a better system. My constituents in Maryland have access to two excellent transplant cen-

ters in our State. Maryland also has a Tier 1 Organ Procurement Organization, OPO, that is taking innovative action to some of the most underserved areas like Baltimore City, to encourage organ donation. This OPO has been among the top ten performers nationwide. Access to transplants in Maryland is far from perfect. Despite the high-performance transplant ecosystem, due to the nature of the underlying issues with the current transplant network, 148 people died while on transplant waiting lists in Maryland last year. That is unacceptable. Other States are not so lucky. Marylanders and people across the Nation deserve better.

Nationally, 17 people die each day waiting for an organ transplant. OPOs are ranked Tier 1, Tier 2, Tier 3 depending on performance levels, Tier 3 being the lowest. According to the Centers for Medicare and Medicaid Services in a 2023 performance review, 24 OPOs, or 42 percent, have been classified in Tier 3.

Senators Wyden, Grassley, Young, and I have been leading the Senate Finance Committee's investigation into the organ transplant system for over 3 years, and each new line of inquiry has exposed more and more failures, which are often borne by the sickest patients in the Nation.

Specifically, our committee has uncovered transportation and testing failures that have put patients' lives at risk; outdated information technology underlying the network; a lack of oversight by the current Organ Procurement and Transplantation Network, OPTN, contractor, the United Network for Organ Sharing (UNOS); and misuse of Medicare funds.

These disparities impact people throughout the country, including those who are low-income, the uninsured, members of racial and ethnic minorities, people with disabilities, and rural populations. Even more concerning, the U.S. Digital Service has found that UNOS is incapable of modernizing the OPTN IT infrastructure. The stakes of neglecting the needs of underserved communities could not be higher.

During the last administration, CMS put out an OPO final rule, which will establish a performance tiering system that triggers decertification, competition, and potential DSA reassignment. HRSA has taken critical steps to modernize the OPTN, but statutory changes are necessary to ensure that HRSA is able to work with the better-equipped organizations to ensure the OPTN is operating in an efficient and safe manner.

When lives are at stake, Congress cannot accept logistics or poor administration as excuses. Last week we held a roundtable with senior officials from the Center on Medicare and Medicaid Services and HRSA. It was a productive conversation, where we discussed efforts to modernize the organ transplant system and increase transparency and accountability.

Currently, we have a system that works well for some, as some of our witnesses will discuss today. But that is insufficient. Where an individual lives or their ability to afford travel to get care should not determine access to lifesaving organs.

Today, we have the opportunity to hear from patients and professionals who are working on key reforms. Our committee will continue to address the biggest challenges facing our Nation, including

the transplant system. We demand better, and we will not stop until we make it so.

With that, let me recognize Senator Young.

[The prepared statement of Senator Cardin appears in the appendix.]

## OPENING STATEMENT OF HON. TODD YOUNG, A U.S. SENATOR FROM INDIANA

Senator YOUNG. Thank you, Chairman Cardin, for your leadership on this issue. I see Senator Wyden here, who has shown exemplary leadership as it relates to this issue as well. Senator Grassley, one of the real champions, as indicated, will be joining us a bit later, as I understand.

Every day, 17 people die while on organ transplant waiting lists, and another 13 are removed from the waiting list because they have become too sick to receive a transplant. In total, there are more than 100,000 Americans on the organ transplant waiting list today, including nearly 1,200 in my home State of Indiana.

These are not just statistics. These are lives. Organ donation is a personal issue for me. My friend, Dave Gunny McFarland from Jeffersonville, IN, died because his heart transplant never came. We served together in the United States Marine Corps, and I have gotten to know Gunny's wife Jennifer over the years.

She has made it her mission to raise awareness about the transplant process, and to help prevent others from facing a similar fate. Because the organ transplant system is so complex, most people do not know how it works, or if patients are being protected.

Now, I began looking into this issue right after being elected to the House of Representatives in 2010. In the early 2010s, I explored ways to try and incentivize some innovation in this space. I had a silly idea to try and create a prize concept to coax people into innovating in the kidney space. The bureaucrats told me it would go nowhere.

I began working on organ procurement oversight and reform in 2018. I told *The Washington Post* then, "We can't continue to allow thousands of Americans to die each year waiting for lifesaving organs that we know are available, if only this system were being managed by competent individuals operating in the light of day."

I was proud to help champion performance measures for Organ Procurement Organizations, which the Centers for Medicare and Medicaid Services adopted and finalized in 2020, and I joined my colleagues Chairman Wyden, former Chairman Grassley, and Senator Cardin in launching an investigation that same year.

I welcomed the announcement earlier this year that HRSA will break up the Organ Procurement and Transplantation Network monopoly, and I joined my colleagues to colead the Securing the U.S. Organ Procurement and Transplantation Network Act, bipartisan legislation that gives HRSA the tools to implement commonsense reforms to act in patients' interests.

But there is still much work to be done, and our friends and neighbors are still dying every day. It does not have to be this way. A functional organ donation system could facilitate tens of thousands more organ transplants every year.

Americans deserve to know what the organ donation and transplantation system and their government are doing to increase organ donation and transplantation, as well as to ensure patient safety. HHS and Congress must treat organ donation reform with the urgency it deserves.

Lives are being lost, and we cannot stand by while some of our most vulnerable neighbors die on the organ waiting list, waiting for a call that never comes. We need strict enforcement of the OPO rule, reform of the OPTN, and to ensure the entire organ and transplantation system operates in the best interest of patients.

We have taken initial steps, but we cannot stop there. I look forward to hearing from our witnesses and learning from their experiences and expertise of living and working within the organ donation and transplant system on a daily basis.

I will not stop working on this issue until we increase the availability of organs for patients in need and eliminate the inefficiencies occurring in our organ donation system.

Thank you.

Senator CARDIN. Thank you, Senator Young. The Senate Finance Committee, under the leadership of Senator Wyden, has been the moving factor in the investigations done that uncovered so many of the mistakes and abuses that we have in the current system. Senator Wyden has been our leader and captain on this issue.

Senator Wyden?

## OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you, Chairman Cardin. And I just want to note that one aspect of our service on the Finance Committee is, we have always considered this the committee where you see the NBA all-stars in the health-care arena. And certainly, Chairman Cardin has been continuing that.

I am sitting in the seat this morning that was occupied for many years by Senator Rockefeller, who was a great champion and would be with us all the way in terms of cleaning up these abuses that my colleagues have just mentioned.

I also especially want to thank our Republican colleagues, Senator Grassley and Senator Young. This has been in the best tradition of the Senate Finance Committee, with all these all-stars we have in health-care policy working in a bipartisan way, and I appreciate it.

I am going to be very brief. We have a terrific panel of witnesses, and I am going to have to be in and out. I'll just start by updating members and the public about our work, and particularly moving forward with the Health Resources and Services Administration to implement their modernization of OPTN, the organ procurement network.

We are pleased with the bipartisan support that the bill has gotten, and it has been good to see that UNOS is not opposing the legislation. I can report to my colleagues and people who are following this, I have had a number of productive conversations with Chairman Sanders on this, and I want everybody to understand, because I am not going to be able to be here for the whole discussion.

This committee, on a bipartisan basis—as witnessed by my colleagues here—we are going to be pulling out all the stops to get the Senate to act on this issue as soon as possible. The reason we are is because—both of my colleagues just mentioned it. I think Senator Young used the word "urgency."

I cannot sum it up better than that, other than maybe a capital "U," because this is a matter of life and death for too many Americans. There is not a moment to lose, friends, with respect to getting this bill passed. And HRSA, the Health Resources agency, is on track to begin the contract process this fall. We are just going to be working here to complement their effort.

Now, last week we hosted a meeting with officials from HRSA and the Centers for Medicare and Medicaid Services to discuss the administration's efforts to modernize the network, connect more Americans with lifesaving organs, and particularly bring more accountability and competition to the contracting process.

And three of us, Senator Grassley and others who attended, we got the message loud and clear that the agencies want to show a new emphasis on accountability and coordination. That was very welcome.

A couple of other points, and one is, this hearing is going to give us another chance to clear up some of the confusion about what the legislation sets out to do and the rumors. And if you listen to the rumors, I am telling you, they are trying to basically run a kind of incumbent protection program and smear this bill.

And Senator Grassley and I in particular, at this session, asked questions with respect to our legislation and these so-called rumors that the three of us are going to want to privatize the system. I mean, if you listen to these rumors, it would be like Congresspeople are trying to sell organs on the side.

It was outrageous, the kind of stuff that we were hearing. And here is what we were told by HRSA, the Health Resources agency. "No, the system is not being privatized, period." In fact, HRSA notes that our bill will, for the first time, mandate an independent board of directors to oversee OPTN, separate from the contract holder.

Second, I asked HRSA to explain the boundaries that are actually in place for a for-profit organization. How is it going to work if they get a contract as part of OPTN? They said that for-profit organizations would be held to strict Federal standards for contractors. Let me quote again, "limits on profits and fees and comprehensive oversight, both before and after the contract award."

HRSA also made clear they intend for the section of the contract concerning support for the independent OPTN board of directors to be awarded to a nonprofit organization. So, to all those people who are trying to spread these false and ugly rumors about what this bill does, shame on you.

We are going to blow the whistle and make sure that the American people know the facts. These colleagues will be here this morning. I will be in and out. We are working in a bipartisan way. And by the way, special credit to Senator Grassley, who with me is the cochair of the Whistleblowers Caucus. We know a little bit about people speaking out if there are abuses. That is not the case here.

So, I will just wrap up by saying, "Here is what is on offer. We want to make sure that our country has the best-in-class organ transplantation system in the world."

And we found critical failures, looking in a bipartisan way, from the current contract holder, especially when it comes to matters such as information technology and logistics. So the bill was written from top to bottom to ensure competition for technical functions like those that will help the OPTN perform to the highest level possible.

Thanks to my colleagues, and I have spoken to both of them in recent days, and everybody understands. This is priority business for the Senate Finance Committee, and there is not going to be an ounce of partisanship here. We are going to stay at it until we get this done, because the American people deserve it. It is long overdue.

Senator Grassley, before you came—and I do not want to make this a bouquet-tossing contest—I was talking about the fact that you have been bulldogging this every step of the way, and I really was grateful last week when we had the session to go through the legislation, that we could all be together.

We appreciated your words, blowing the whistle on these outrageous rumors that have been spread by some people who do not really want change, that somehow this would privatize things. So, thanks for all your good work, and you will see it in the record that we are just so appreciative of your leading this for so many years.

Senator GRASSLEY. Can I respond by saying that I owe you a big "thank you," because we were finishing so much stuff I started a long time ago. You were there helping me with every letter and every move we made on it. So——

Senator WYDEN. We are in it together, for the public.

Senator GRASSLEY. Yes.

Senator WYDEN. Thank you, Mr. Chairman.

Senator CARDIN. Well, thank you, Senator Wyden. And thank you for your commitment to keep this on track to get done. It is very, very bipartisan. Senator Young and I have already commented about Senator Grassley's leadership on this issue. We have been mentored by Senator Grassley in regards to the need for this committee's oversight on programs that we enact, and he has taught us well.

Senator Grassley, thank you for your leadership on this issue. You are recognized.

## OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA

Senator GRASSLEY. Okay. Well, thank you, Chairman Cardin. Today, we are here to visit about the urgent need to reform the transplant system, and the deadly cost to patients and generous donor families due to decades of inaction.

In 2005, I started the investigation of the deadly failures of UNOS and the monopoly tasked with managing the U.S. organ donation system. Since then, more than 200,000 patients have needlessly died on the organ waiting list. There is a reason that I call UNOS "the fox guarding the hen house."

For nearly 2 decades, UNOS has concealed serious problems about the Nation's Organ Procurement Organizations, known as OPOs, instead of working to uncover and correct the corruption. This human tragedy is even more horrific because many of these deaths were preventable. They were the result of a corrupt, unaccountable monopoly that operates more like a cartel than a public servant.

Our bipartisan investigation was started when I was chairman of the committee, and I already referred to Chairman Wyden's efforts in this working with me. We uncovered kidneys lost in airports, technology systems that regularly go down, and the cover-up of patient deaths. It uncovered a history of misinformation and lobbying against accountability and transparency for the local OPOs it's supposed to oversee.

We also are aware of ongoing threats to whistleblowers and patient advocates. Instead of amending its bylaws to protect these brave individuals, UNOS has continued its longstanding practice of intimidation and retaliation. This is unacceptable.

Tens of thousands of organs go to waste every year, exploiting generous donor families, while organ procurement executives travel on luxury private jets to five-star resorts. Investigative reporting has revealed anticompetitive behavior designed to block new entities from the competitive bidding process for new contracts, entities that have the technology and skill desperately needed to save our lives.

Our Nation's organ procurement system is a deadly failure. In recent years, UNOS has attempted to disguise its failures by misrepresenting alleged record increases in organ donations. Unfortunately, these increases are the results of public health tragedies, including the opioid epidemic, which has ravaged our rural communities.

It's time that we put an end to UNOS's attempts to use the Nation's drug crisis to juice up its members, to try and show the system is working. Simply put, the system is not working. For too long, UNOS has run a system that benefits the executives who run it, collecting taxpayer-funded perks and paychecks. It has been more than 20 years since *Forbes* called UNOS, quote, "the Federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly," end of quote.

Our bipartisan investigation was clear. UNOS failed our fellow Americans, and disproportionately so with respect to older people or to people of color and rural residents. The solution is also clear. Congress must pass our bipartisan bill, S. 1668. Patient lives are at stake.

I yield. Thank you, Mr. Chairman.

Senator CARDIN. And, Senator Grassley, thank you for your statement. More importantly, thank you for your leadership.

In response to Senator Wyden, our topic, I think, very much underscores the point that you made: the cost of inaction and the urgent need to reform the U.S. transplant system.

We have an excellent panel who have experienced firsthand the challenges in our transplantation system. So we are very pleased to have all of our witnesses here today to help us in this regard.

Your entire statements will be made part of our record, and you will be permitted to proceed as you wish.

I am going to introduce the five of you in the order in which you will be speaking, and I will start with Miss LaQuayia Goldring, who is from Bardstown, KY. She is a premedical graduate from the University of Louisville. She is a previous kidney transplant recipient and current kidney transplant candidate.

She received the Lisa Allgood Excellence in Kidney Disease Education award from the National Kidney Foundation, awarded to those focused on improving the care and outcome for those affected, as well as communicating risk factors and implementing outreach efforts. Her first publication appeared in *STAT News,* highlighting the failures of our U.S. organ donation system and Black and Brown individuals seeking transplants.

She will be followed by Ms. Molly McCarthy, a three-time kidney transplant recipient. She grew up in northwest Illinois and received her first transplant in 1991 at the University of Iowa, her second at the University of Wisconsin, and her third at the University of Washington.

She is in her fifth year as a volunteer with the OPTN Patient Affairs Committee, serving for the last 3 years as vice chair of the committee.

Our third witness is Mr. Matthew Wadsworth. He is the president and CEO of Life Connection of Ohio, which serves families and saves lives through organ donation in northwest and west-central Ohio. Before taking the reins of Life Connection of Ohio, he served as the vice president of clinical affairs at Nevada Donor Network. Under his leadership, Nevada Donor Network doubled its performance within 3 years.

And next, we will hear from Dr. Ray Lynch, who is a professor of surgery and public health sciences and the director of transplantation quality and outcomes at Penn State Health's Milton S. Hershey Medical Center.

He is a transplant surgeon whose research focuses on improving access to organ procurement and transplantation care. His work has formed the basis for objective metrics for assessing the effectiveness of Organ Procurement Organizations.

Our fifth witness is Ms. Donna Cryer, who is the founder and chief executive officer of Global Liver Institute, the largest patient-led liver health nonprofit. She has channeled her experience as a patient with inflammatory bowel disease with a 28-year liver transplant into professional advocacy across her career in law, policy, consulting, public relations, clinical trial recruitment, and nonprofit management.

She has been awarded the Distinguished Advocacy Award by the American Association for the Study of Liver Diseases, and the Founder Award from Global Genes, among many of the accolades for her pioneering patient advocacy.

So we will start with Ms. Goldring.

**STATEMENT OF LaQUAYIA GOLDRING, KIDNEY TRANSPLANT RECIPIENT AND KIDNEY TRANSPLANT CANDIDATE, LOUISVILLE, KY**

Ms. GOLDRING. Hello, and good morning, Chairman Cardin, Ranking Member Young, and members. Thank you for this opportunity to testify before you today. My name is LaQuayia Goldring. I am currently dependent upon the U.S. organ donation system to save my life while I await a second kidney transplant. In the meantime, the system is continuing to fail me badly.

As a toddler, at the age of three I was diagnosed with a rare kidney cancer that took the function of my left kidney, and when I was 17 I went back into complete renal failure, and I received a first kidney transplant at that time. Unfortunately, in 2015, I went back into kidney failure. And at that time, I was not ready for another transplant, but I did not have a choice but to go back on dialysis. I have been waiting 9 agonizing years for a transplant, dependent upon a dialysis machine 5 days a week just to be able to live.

I was told that I would receive a kidney transplant within 3 to 5 years, but yet I am still waiting. I am undergoing monthly surgeries just to be able to get my dialysis access to work, so that I can continue to live until I get a transplant.

The UNOS wait list is not like 1 to 100, where everybody thinks you get a number. I am never notified on where I stand on the list or when I will get the call. I have to depend on an algorithm to make the decision of what my fate will be.

Every day that I am waiting, I am closer to becoming one of the 30 Americans who die waiting for an organ transplant. I know this all too well, because that is why I have had to take matters into my own hands and start searching for a living kidney donor by starting a social media campaign.

I have lost multiple family members and friends to organ failures, and I have seen more funerals than success stories, and I do not want to be the next. The reason it is so hard for me to get a transplant is because the government contractors running the organ donation system are failing and corrupt.

I grew up in rural Kentucky, where the organ procurement systems, the OPOs, are now failing like many in our country, where over 20,000 organs every year are not recovered and instead they go lost or they are wasted. More than one in four kidneys are thrown in the trash as generous families have offered to donate.

It is even worse for people who are labeled minority, or people who are Brown and Black. Our kidney functions are wrongly calculated based on race, and it delays our access to transplant. OPOs are less likely to show up for us when it is time to get authorization for you to be a donor. The treatment that we get is less urgent and less caring, and they are less compassionate toward us.

I know this firsthand, as my grandmother was an organ donor, and we had to personally reach out to the OPO just to show up. These failures lie at the feet of the monopoly UNOS. Patients like me go completely forgotten in a system that is failing us every day as more and more of us continue to die.

Just a few weeks ago, a donor family had reached out to me to be a directed kidney donor, meaning they chose me specifically for

a kidney transplant. But unfortunately, due to the errors in the UNOS technology, I was listed as inactive—and this was a clerical error. All that they told me was this was a clerical error and they could not figure out why I was inactive. But when it came down to it, I am active on the transplant list.

This was not a one-off event. UNOS technology is unsecure and unreliable, and it crashes hourly. During that time, transplant candidates are not getting phone calls. While kidneys continue to go lost, lives continue to be lost in the process. Every time this happens, patients like me continue to die.

You cannot even imagine how this feels every time I lose a family member because of UNOS's failures. Every time I lose a friend or every time I look in the mirror I see that I am standing with one foot in the grave and one foot hoping to be able to live to see another day, waiting on a call that may never come.

As the email from the OPO CEO board member once said, justifying the policy proposal that systematically hurt minorities based on where we live, that we are dumb expletives for living in the South and rural America, as though we can choose where we live as we wait for a transplant.

But this is never the case. While they are using taxpayer dollars to get specific trips, large salaries, going on golf tournaments and vacations in beach houses, patients who look like me are getting coffins. But there are never any consequences for them, because the government has never held them accountable.

The government has completely failed me, as well as many of us sitting here today. The only solution to replacing failing OPOs is to get rid of UNOS—not tomorrow, not 2 years from now, but today. My fate lies in the hands of the Senate. My fate, like many other Americans, lies in the hands of you and all your constituents, and I am just asking that you all stand behind this legislation as we move forth, and that all of Congress stands together to pass this new legislation, so more lives can be saved and less will be put in coffins.

Thank you.

[The prepared statement of Ms. Goldring appears in the appendix.]

Senator CARDIN. Ms. Goldring, thank you very much for your testimony. You have heard us mention the numbers that are out there, but there is nothing like seeing the individual who is impacted by that. Each number is a person. So, I thank you for sharing your story with us. It is powerful.

Ms. GOLDRING. Thank you, sir.

Senator CARDIN. Ms. McCarthy?

**STATEMENT OF MOLLY J. McCARTHY, VICE CHAIR AND REGION 6 PATIENT AFFAIRS COMMITTEE REPRESENTATIVE, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN), AND 3-TIME KIDNEY TRANSPLANT RECIPIENT, REDMOND, WA**

Ms. MCCARTHY. Good morning, Chairperson Cardin, Ranking Member Young, and the members of the committee. I am grateful for the opportunity to speak with you today. My name is Molly McCarthy, and I am an exceedingly grateful three-time kidney

transplant recipient, after having had my first transplant 32 years ago.

I am one of the fortunate ones. I have made it, despite the broken and corrupt system that we have been saddled with, and I am all too aware that many patients are not as fortunate. I received two living donations, one from my mom and the other from my dad, an option that so many patients just do not have.

Eleven years ago, I received my third transplant from a generous, deceased donor, and while I am very healthy now, I am acutely aware that I may need another transplant in the future, and whether that happens is dependent on what Congress does now.

I am here today to plead with you to please pass S. 1668. The reason why is as simple as it is heartbreaking. The Federal monopoly contractor managing the organ donation system, UNOS, is an unmitigated failure, and its leadership spends more time attacking critics than it does taking steps to fix the system. I have seen this firsthand in my 5 years as a patient volunteer with the OPTN, and 3 years ago I stepped into the role of vice chair of the Patient Affairs Committee, or PAC.

I thought this would be a great opportunity for me to demonstrate my gratitude by representing and advocating for the patient voice to be included in national policy. I could not have been more wrong. What I have observed is that UNOS at best treats patients as props; at worst, it outright lies to us and then uses us as a shield against much-needed oversight and reform.

UNOS knows enough not to lie to Congress, so it lies to its patients instead, and then launders those lies through us. It is no wonder to me that *Forbes* called UNOS a cartel in 1999.

For the last year, much of my work with PAC has consisted of writing to congressional offices to fact-check UNOS misinformation, which I would like to take the opportunity to do today. For example, UNOS leadership has created a systematic effort to misrepresent the facts, regularly celebrating recent increases in organ donations as evidence of their success and a well-working system.

The reality, however, is that this growth is driven entirely by the opioid epidemic, skyrocketing gun deaths, as well as other increases in suicides and fatal car accidents. All UNOS is celebrating are national tragedies, not evidence of a well-run system. Arguably worse, people who speak out have been bullied, threatened, and retaliated against. I personally have been warned by the UNOS board that it is unhappy with my criticism, and that there may be consequences if I continue to speak out.

I am a three-time patient. How do they say that to me? Further, I have been called by a board member, telling me to stop focusing on system outage and down time of the UNOS tech system. He told me that having down time was not a big deal at all. The donors are dead anyway.

That comment speaks volumes to me about the lack of empathy and respect UNOS has for donor families. UNOS has failed to oversee OPOs. As a patient, I cannot fathom why any Tier 3 OPO is allowed to operate. Our lives depend on this business, and CMS must immediately replace failing OPOs with the successful OPOs that are getting the job done.

There is no shortage of evidence that this system is broken. What I hope to convey today is that the problems are far worse than publicly known, and the rot goes far deeper. While we may never know the true toll of the gross negligence and abuse of the government's own organ contractors, we at least know the solutions.

CMS needs to move urgently to open data for OPOs. They must replace these failing OPOs without caving to industry pressure to weaken standards, and close the dangerous pancreas loophole that allows OPOs to pad their numbers, misrepresent their results, and jeopardize patient lives.

Two, Congress needs to break up the UNOS monopoly by passing S. 1668, ensuring that HHS uses its authority to replace UNOS as its contractor. Before my last transplant, my family and I waited 6 agonizing years, and watching your hearing last August, we realized that potentially years of that wait were unnecessary.

Patients deserve an effective, safe, transparent, and equitable organ donation system. Speaking as a patient, and after having had an inside glimpse into the culture and operating model, I have zero confidence that we will ever see improvement if UNOS has any role whatsoever in the transplant system.

Thank you.

[The prepared statement of Ms. McCarthy appears in the appendix.]

Senator CARDIN. Well, Ms. McCarthy, thank you for your courage to come forward and to share with us the information that you have observed.

Mr. Wadsworth?

**STATEMENT OF MATTHEW D. WADSWORTH, PRESIDENT AND CEO, LIFE CONNECTION OF OHIO, KETTERING, OH**

Mr. WADSWORTH. Chairman Cardin, Ranking Member Young, and members of the committee, my name is Matthew Wadsworth, and I serve as the president and CEO of Life Connection of Ohio, the Organ Procurement Organization responsible for facilitating organ donations in northwest and west-central Ohio.

My job is to help as many patients as possible receive lifesaving transplants. Most days, I try to do that through continually improving practice at our OPO. But to effect meaningful change at scale, we need Federal policy reforms. The current system is broken.

OPOs have geographic monopolies, which has made too many sluggish and complacent at the expense of patients' lives. There are absolutely no guard rails in place to ensure that OPOs are adequately serving patients, and many of them are not. And yet the Centers for Medicare and Medicaid Services has never once decertified an OPO for performance failures.

In recent years, it appears things may finally be starting to change. CMS finalized two regulations in 2020 to hold OPOs accountable for the first time in 40 years. Three years later, CMS still has not taken the steps to provide OPOs with any guidance on how the rules will be enforced, or any indication that it will support meaningful competition to ensure that patients are only served by the best OPOs.

Furthermore, CMS has remained silent on waivers filed by hospitals that want to work with higher-performing OPOs now, instead of waiting until 2026. Additionally, CMS has not taken any apparent steps to close a dangerous loophole in the rule, which gives OPOs credit for recovery of pancreata that are never transplanted, pancreata labeled for research, which many OPOs have begun to flagrantly exploit—evidenced by over a 400-percent increase in the number of pancreata placed for research under this new rule.

This means that OPOs that are failing at their central task—recovering organs for transplant—can avoid accountability by simply recovering one organ and labeling it "research." The fact that executives in our industry lack the moral compass not to exploit this loophole is perverse. I am deeply appreciative of this committee for investigating this particular abuse.

This should be proof positive of a perhaps self-evident notion. OPOs respond to their incentive structure. Unfortunately, those incentives are currently entirely misaligned with what patients need. This is not only regulatory but financial. The OPO industry, including OPO boards, are often rife with financial conflicts of interest, which means OPOs all too often spend taxpayer resources on special interest projects, rather than investing in organ recovery.

Another issue that deserves urgent attention is the lack of safety guard rails. There is not even a standardized process for declaring brain death across the country. The reality is that the quality of care a donor patient and a donor family receives depends on where in the country that person dies.

The fact the organ procurement system has been so broken for 40 years speaks directly to the complete abandonment of patients by the organization at the top of the system, UNOS. Even now, more than 3 years into this committee's investigation of UNOS's failures, UNOS has transitioned from an organization that's inept, possibly incompetent, to one that takes an active role in preventing patients from being transplanted.

Take for example recent reporting in *The Washington Post* that UNOS is proposing changes to its terms of service, to disallow external organizations from conducting data-driven research into the most effective ways to place organs for transplantation, even as our organ discard rates skyrocket.

UNOS only appears to be doing this to interfere with the business of a potential competitor for its contract, showing that, once again, the system has been held hostage by a terrible actor, one which values its own contract far above the lives of patients whom we are meant to serve.

This is a perfect microcosm of the problem. At every turn, UNOS stifles innovation and hides its deadly failures, all to keep its monopoly contract. There are three things the Department of Health and Human Services needs to do immediately to ensure that patients receive safe and high-quality organ procurement care.

One, prepare to enforce the OPO rule without weakening or delaying it, including closing the pancreas for research loophole, publishing guidance for how the rule is going to be enforced, and requiring the publication of OPO process data. Two, break up the OPTN contract and allow for competition. Patients need to be

served by the best in areas such as technology, logistics, data analytics, business development, and process improvement. And three, eliminate board and financial conflicts that exist in our industry that prevent OPOs and any OPTN contractors from investing their dollars in areas that grow donation and transplantation.

I commend this committee for introducing legislation to finally break up this monopoly, and I stand ready to work with you in any way possible to ensure that this bill passes. It is the only way this industry will be able to save more patients' lives.

Thank you.

[The prepared statement of Mr. Wadsworth appears in the appendix.]

Senator CARDIN. Thank you very much for your testimony, particularly as it relates to accountability and competition. We appreciate it very much.

Dr. Lynch?

**STATEMENT OF RAYMOND J. LYNCH, M.D., M.S., FACS, PROFESSOR OF SURGERY AND PUBLIC HEALTH DIRECTOR, TRANSPLANTATION QUALITY AND OUTCOMES, THE PENNSYLVANIA STATE COLLEGE OF MEDICINE, HERSHEY, PA**

Dr. LYNCH. Chairman Cardin, Ranking Member Young, and members of the committee, my name is Raymond Lynch. I am a liver and kidney transplant surgeon and a professor of surgery and public health at Penn State Health and Penn State College of Medicine in Hershey, PA. Thank you for the opportunity to speak today.

In my career, I have had the privilege of recovering organs from more than 200 generous deceased donor patients. I have performed hundreds of organ transplants, and I am the principal investigator on an NIH-funded study to enhance organ procurement care for United States veterans.

I am here because Congress has the ability to take action to save my patients' lives. I ask the committee to take concrete steps to make organ procurement and transplant safer and more effective for all patients by supporting legislation that permits authentic competition for the OPTN contract, allowing specialized, highly skilled organizations the opportunity to move our transplant system into the 21st century; by ensuring that CMS and HRSA collect and report data on how OPO workers provide clinical care; and by ensuring that CMS enforces the current OPO performance threshold without delay or dilution.

I want to differentiate between organ donation, which is the altruistic decision of the donor patient and their family, and organ procurement, which is the clinical care provided by OPO staff. This is what turns the gift of donation into the usable organs for transplant.

Organ procurement is a clinical specialty. It is the last medical care that many patients will ever receive. It is reimbursed by the Federal Government, and it is administered by OPOs that are each the only provider in the territory to which they hold Federal contracts.

Right now, patient care delivered by OPOs is some of the least visible in American health care. I cannot tell you how many pa-

tients were evaluated by OPO workers in the U.S. in 2022. I cannot tell you how many patients were examined, or how many families were given information about donation, or how many times an OPO worker even showed up to a hospital to do this clinical duty.

This lack of information about what OPO providers actually do for patients is the root cause of the variability in rates of organ procurement around the country. My research has shown that what we call OPO performance is a measurable restriction on the supply of organs that results in the unnecessary deaths of patients with organ failure. For example, if the lowest-performing OPOs from around the country had just reached the national median over a recent 7-year period, there would have been 4,957 more organ donors, yielding an estimated 11,707 additional organs for transplant.

Because many OPOs operate in a low-quality data environment and without appropriate oversight, almost 5,000 patients did not get adequate organ procurement care, and nearly 12,000 other patients did not receive lifesaving transplants. Patients like Ms. Goldring, Ms. McCarthy, and Ms. Cryer carry the burden of the failures in the system.

OPO clinical work is currently not visible, it is not benchmarkable, and it is not able to be adequately evaluated, analyzed, or compared. However, much of the hidden data about how OPOs provide care to patients is known to one entity, and that entity is UNOS.

The front-line OPO providers who administer procurement care are some of the most dedicated and hardworking in medicine. Instead of offering these workers assistance, UNOS has instead advocated for a deadly status quo, where fearmongering takes the place of action to address quality of care.

Even worse, UNOS claims recent increases in organ donors as a measure of its own success. I have published peer-reviewed research that reveals the primary driver of the large portion of these increases to be the opioid epidemic. Between 2009 and 2018, 94.6 percent of the increase in the number of donors came from patients who died from a drug-related cause.

This does not lessen the value of these donor patients' gifts, but it does make the appropriation of their tragic deaths as a success story for government contractors a lot harder to stomach. UNOS is not capable of managing a safe, effective, and innovative transplant system.

I know many of us have served to the best of our ability on UNOS committees. I emphasize I direct my critical comments to UNOS leadership and their network of cronies. In spite of our best efforts, UNOS's incompetence prevents patients from becoming organ donors or receiving transplants.

We need a new network of highly skilled specialist organizations, each attending to areas of expertise in the management of the OPTN contract. I ask you to listen to patients, to researchers, and to front-line health-care workers at OPOs, transplant centers, and community hospitals. I ask you to remove this burden from the patients and put a new OPTN contractor to work. My patients' lives depend on it.

Thank you.

[The prepared statement of Dr. Lynch appears in the appendix.]

Senator CARDIN. Dr. Lynch, again I thank you for your willingness to come forward with this information. It is very helpful to us.

Ms. Cryer?

**STATEMENT OF DONNA R. CRYER, J.D., FOUNDER AND CEO, GLOBAL LIVER INSTITUTE, WASHINGTON, DC**

Ms. CRYER. Thank you, Mr. Chairman, Ranking Member, and committee members, for your bipartisan support and commitment to saving the lives of the more than 100,000 Americans waiting today for an organ transplant, by passing legislation to break up the deadly Federal organ transplantation monopoly.

My name is Donna Cryer, and I am the CEO of the Global Liver Institute. I founded this organization to ensure that other patients and their families would have the same lifesaving opportunity I had, because we know too many do not.

It seems I have waited decades to give this testimony, and I know only by the grace of God am I alive to give it. Since my own lifesaving liver transplant nearly 3 decades ago, I have worked in the organ donation and transplantation field and seen the system from all angles: as a patient, as a lawyer, as a nonprofit executive, as a Federal Government appointee, and having served in several roles as a UNOS staffer and volunteer.

And so, I know that the fault for thousands of unnecessary deaths and so much dysfunction lies squarely with the United Network for Organ Sharing, the Federal organ donation and transplantation monopoly contractor which has held this contract since 1986. I applaud this committee's investigation for helping us, all of us here and so many others around the country, to pull back the curtain finally and show every American citizen the corruption that lies beneath this.

My first role at UNOS was as a patient affairs specialist, which gave me views into policy, education, communications. I even drafted the board minutes, so I know about the conversations that were going on. Years later, as a member of UNOS's Membership and Professional Standards Committee, or MPSC, I was charged with reviewing patient safety lapses and generating remediation plans.

I hoped this was finally a place where I could make a difference. But as the Senate Finance Committee's investigation has revealed, UNOS executives joke that "it's like putting your kids' art work up at home. You value it because of how it was created, not whether it's well done."

This is consistent with my firsthand experience. The joke, I guess, is that UNOS knowingly leaves patients unsafe and unprotected. I fail to see the humor.

What I experienced firsthand was that at MPSC, decisions were made by a small cabal of industry insiders protecting each other, routinely ignoring or excusing aberrant and dangerous behaviors. The patient in me was traumatized. The lawyer in me was wondering at what point would HHS staff in the room do what they were supposed to do, and oversee the overseers. When would they step in and act? They never did.

We can change that today. UNOS has been well aware for decades of severe, often fatal risks to patients and has worked far harder to cover them up than to fix them. There is no reason to

believe UNOS has changed since then. Many of the same executives are not only still there, but they have been promoted.

For example, the current CEO, Maureen McBride, has been there since 1995. How is that a change agenda? We have the opportunity today though to create a different future for patients and families. Transplantation is often painted as complex, but a very few simple steps would make the system significantly safer and equitable, and would elevate the quality of organs available.

Congress needs to pass the Securing the U.S. Organ Procurement and Transplantation Network Act, period. Secondly, there are acts that CMS can take, long-awaited acts that they can take. Some examples are simply to enforce regulations, to hold OPOs accountable for their performance, and to do so without caving to industry lobbying pressure to weaken these standards in any way.

Openly publish OPTN process data; require that all staff interacting with patients have some baseline clinical training or licensure—that should not be too much to ask for; and require that adverse patient events are publicly reported.

Innovation and reform will never come from the same people paid lavishly to perpetuate the status quo. They will push back as they always do, and arguments will be made that change is disruptive. But I assure you that nothing is more disruptive than dying.

At my sickest point, doctors stood outside the ICU and told my mother that I only had 7 days to live. Right now, 210 people are estimated to die in the next 7 days. They will not be saved by empty promises that reforms will come years down the line. They need you, Senators, to act today.

Thank you.

[The prepared statement of Ms. Cryer appears in the appendix.]

Senator CARDIN. Well, thank you, Ms. Cryer, for your testimony, and laying it on the line with us. The five of you have presented very powerful testimony, and there is consensus among the five of you of what we need to do.

It really does reinforce our initial thoughts on legislation that we filed that would open up competition. Your assessment that the OPOs are not being held accountable, too many on Tier 3—one is too many, and as a result we do not have the outreach and procurement that we should have in our communities, which is costing people's lives.

The inability of UNOS to modernize—you are not alone on that. The United States Digital Service found that UNOS is incapable of modernization. And then the lack of transparency: we do not have the data; we do not have the information. Ms. Goldring, the fact that you cannot get adequate information as to where you are on a list is unacceptable. The anxiety of that issue alone, and the pain it causes you and how it affects your health, is something that cannot be tolerated moving forward.

So normally I have a lot of questions I want to ask; I want to ask a couple. But you have really reinforced, I think, our views of the need for our legislation, but more importantly also the need for accountability.

CMS needs to enforce the rule that was adopted that would hold OPOs accountable, and decertifications if they do not meet the test, and opening up competition that all of you have talked about being

so important that we have. All of that is just so important, and of course without the data, we get——

Our investigation showed that there were transportation delays, that the IT was down for a period of time. And if you are down for a couple of hours, that is, if I understand it—maybe I will ask Dr. Lynch this about the timing, how important it is to get immediate time information here.

So if you delay, if IT is down, or the transportation—you cannot track where the organ is—what impact does that have on a successful transplant?

Dr. LYNCH. Life and death.

Senator CARDIN. That is a pretty direct answer, and that has happened over and over again. Or organs not properly sampled from the point of view of disease. What impact does that have?

Dr. LYNCH. Potentially life and death, Senator.

Senator CARDIN. Yes, and these are mistakes that are routinely being made—too often. We have been told that the error rates on transportation are higher than we have on the private companies where you can just go to the neighborhood and you can track your packages better than you can track organs in this country.

I guess I will ask a question on transparency. You have all talked about it, but that is an area that I find incredible, that you cannot get the data and information about a lot of this because it is just not available. Is that what I am hearing?

Mr. WADSWORTH. I will answer that. Speaking to the recent reporting in *The Washington Post*—I mean, UNOS is obstructive to it. The idea that we would not use this data, aggregate it and use it to drive process improvement, to save patients' lives, I cannot understand that. We have the ability to do it. Let us analyze it so we can do better.

Senator CARDIN. And then, the IT modernization. We all have modernized our IT except for this area. I do not understand why there has not been the progress made. You have, Mr. Wadsworth, made specific recommendations, and we made note about that, and all of you have.

I can tell you that we will be working on a dual track. One, legislation, but two, also accountability and enforcement by HHS, which we—that is the reason why we had our roundtable discussion last week with HRSA and HHS, CMS: to make it clear that we expect enforcement.

HRSA is responsible to make sure that we have accountability, and we do not have accountability in the current system, that is clear. It is the general consensus that UNOS has failed. We recognize that, and that has to be first and foremost.

Secondly, we do need independent boards, and I know they are moving forward on that point, and we do not want to have conflicting boards. Third, transparency, and fourth, competition, and then accountability for those that are not performing.

Senator Young?

Senator YOUNG. Well, thank you for your riveting testimony, especially to our patients, but really to everyone. I thank you. This is very helpful in generating additional attention towards this issue and helping us effect change.

You know, since I got involved in this issue, I was told time and time again from UNOS, from HHS, from other interested parties, that somehow management principles did not apply. They could not be applied to this endeavor of procuring organs and matching them up with individuals for lifesaving treatments. This was different.

It turns out that the basic management principle "if you cannot measure it, you cannot manage it" also applies to this setting. What is different is UNOS has had a monopoly, and we do not allow monopolistic behavior in other areas. But we have allowed it far too long in this area. We have seen it manifest itself in lost lives, anxious individuals, and incredible professionals who are trying to do the best they can within the system.

Dr. Lynch, you have really broken a lot of ground in measuring what we can, right, and indicating what needs to be measured more effectively. I thought it was really compelling when you were talking about this clinical practice that is so opaque.

It seems to me there is an incredible opportunity, if we can get this legislation passed, to shine some light on that practice and to begin measuring, and therefore more effectively managing, this entire enterprise. So I see the possibilities here, and I am excited about those.

Dr. Lynch, there seems to be overwhelming evidence that there are significantly more organs available for donation today than are actually procured. Has UNOS or OPTN made any meaningful attempts to increase the number of organs that are procured?

Dr. LYNCH. No, Senator, UNOS did not make any comment on the final rule that went into effect in November of 2020 until April of this year.

Senator YOUNG. We can remedy that.

Mr. Wadsworth, I was looking at you when I was discussing these individuals who have done yeoman's work within the parameters you are given, within this ecosystem, to try and make improvements. You have done it at Life Connection of Ohio, and in some of your previous work.

What were the most critical changes you implemented that have led to improvements? Can these changes be replicated or shared with other OPOs? And then, where I am leading with this is, does anyone give you a venue to share those practices, and shouldn't that perhaps be the role of the OPTN?

Mr. WADSWORTH. We actually used a lot of Dr. Lynch's work in our analysis of Life Connection when we first got there, and what we did was, we built structures to capture what the data said the potential was.

So yes, this absolutely can be replicated. We have done it twice. We did it in 3 years in Nevada, and we did it in 2 in Life Connection, with our amazing team there. So yes, it can be replicated, for sure.

Senator YOUNG. And what role should the OPTN be playing in helping to facilitate some of this sharing of best practices?

Mr. WADSWORTH. Yes. So to your second question, no, I do not have a venue, and it is probably because I am looked at as a little bit of pariah, given the House testimony in 2021, in saying the things that probably should have been said a long time ago. And I am sure I will get some backlash here for this.

But no, I do not have a venue. But one thing we talked about internally is, our organization will share any practice, anything we do, with any organization that asks, and we do not need credit for it. Just save someone's life. But no one ever asks. It is crazy to me.

Senator YOUNG. Okay. I will have some more questions, Mr. Chairman.

Senator CARDIN. Senator Blackburn?

Senator BLACKBURN. Mr. Chairman, thank you so much, and I want to thank each of you for being here. We had an insightful roundtable last week as we started looking at this issue, and to Tennesseans, this is an important issue, getting this right. Mr. Wadsworth and Dr. Lynch, I so enjoyed my few moments of conversation with you all.

Dr. Lynch, I think I want to come to you first. And when we look at OPTN and look at the Securing Organ Procurement Act, the bill would strip the nonprofit requirement for the manager of the Organ Procurement and Transplantation Network, which would open the door for profiting from organ procurement and donation.

And to me, this is something that I think many people really fear, especially people who are on a wait list. So, what I would like for you to do is to address that, and address those concerns, and why or why not you think the Act has it right.

Dr. LYNCH. Thank you, Senator. I think it is unfortunate that people would be afraid of that, because it needs to be changed. Many of the patients that you reference are wait-listed at for-profit hospitals.

For-profit is a part of American health care, and I can tell you that our not-for-profit entity, UNOS, does not work and there are for-profit hospitals and for-profit transplant centers that do work. So, patients do not need to be afraid of that. They do need to be afraid of the status quo.

Senator BLACKBURN. Okay; thank you for that.

Mr. Wadsworth, we have talked about the OPOs and what they could or could not do to follow HRSA's guidance on modernization, and you have talked a little bit about that. So, when it comes to leveraging some of the modernization efforts and trying to enhance transparency, competition, and overall efficiency in the system, what do you see as the most vital steps that should be taken so that we are moving toward that goal?

Mr. WADSWORTH. For me, I think it is mostly around the data analytics, the business development of the organizations, to be structured in a way that they can capture the most potential possible for the patients that they serve. And then also, utilization of technology, the application of it.

Senator BLACKBURN. And then address the issue of patient privacy, as you look at data and how some of that data is captured and shared, and then how that moves into research. What is the importance of anonymity and privacy for those patients?

Mr. WADSWORTH. It is always going to be important to protect patient data, and it is personal. But there are ways to look at the data that blinds that, and it is still going to drive process improvement without having concerns of sharing something that should not be shared.

Senator BLACKBURN. Okay.

Ms. McCarthy, did you want to weigh in on that?

Ms. MCCARTHY. I absolutely agree. Obviously, we need protection of our personal data, but right now everybody hides behind that, or UNOS hides behind that, as reason not to share information with us. In the context of wait list accuracy, our PAC several months ago made a request for data around how many people are actually on the waiting list and whether it is accurate, knowing that 40 percent are inactive.

We were told as recently as last week that we will not be able to see any future movement on that for no less than 8 months, despite it being anonymized data. We were just completely told that we could not do it, despite coming in with the spirit and tooling to be able to find some opportunities to improve.

Senator BLACKBURN. All right.

Dr. Lynch, anything to add on that topic?

Dr. LYNCH. So, the responsible use of patient data is a key part of health-care research, and it is something that happens in other fields. This is something where we do take on the public trust to do that, but it is a recognized way to move forward. Saying that it is a stumbling block or an absolute "no" is simply false.

Senator BLACKBURN. And do you fault UNOS in that regard?

Dr. LYNCH. I do.

Senator BLACKBURN. Okay. Thank you all.

Thank you, Mr. Chairman.

Senator CARDIN. Thank you.

You know, the lack of transparency here in data makes it difficult for us to understand all of the challenges that we have. But I take a look at the waiting list and the numbers that come off the waiting list with an organ, and the percentages in the non-Hispanic, minority racial communities versus the rest, it is a much, much lower chance of getting an organ.

And I tried to find out why that is the case, whether it is the ineptness of the OPOs that are in those regions, or whether it is UNOS's issues. But I know that there is disparity here, and we need to do something about it.

Ms. Goldring, you have experienced, and currently experience, the frustrations of being on a wait list and not being able to procure an organ transplant. Can you just share with us some of the experiences that you have had in regards to being on that wait list?

Ms. GOLDRING. Yes, Senator. In regards to being on a wait list, I have gotten to a point where I sit by the phone and wait and just wait basically. Every day you are waiting for that chance to be able to get that one call, and it never comes.

And so we are stuck battling the State when it comes to insurance. As somebody waiting on one transplant list, you want to be able to secure an organ in another State. Well, if I want to go to another transplant site outside of the State of Kentucky, I am stuck dealing with the medical side of trying to figure out how can I qualify to go to the next team, in response to not having the protections against insurance discrimination.

On top of the failures of UNOS not calculating my GFR correctly, it delayed my process of being listed a whole year sooner for transplant. So, I am stuck on dialysis until I actually get that transplant, and then in the process of going to see various transplant

teams and working with the OPO in my State, I have managed to talk to them about discrimination while still being discriminated against.

When I ask the same question, why are Black and Brown people or just anybody who looks like me not being transplanted, they have no answer other than, "Well, we need more Black donors." My response is, "Why don't we see you in the hospitals actually securing organs for us?"

When it comes down to it, organ donation is not about your skin tone. Organ donation is about an individual looking for another chance at life, and that is all I am asking for, a chance at living.

Senator CARDIN. Ms. Cryer, do you have any views as to why it is a much lower-percentage chance for a racial minority to be able to have a transplant?

Ms. CRYER. Yes, and it really does come down to UNOS not doing its job of overseeing the Organ Procurement Organizations. We know from many studies that Black and Brown communities donate organs in the same percentage they are of the population.

So it is not a problem of willingness to donate. It is a problem, as Ms. Goldring was starting to discuss, about UNOS and OPOs—not ensuring that OPOs go out into the communities and develop relationships far before that horrible decision is needed to be made to donate the organs of a family member.

Also, this underscores the importance of the transparency of data. If we do not have granular data that shows those specific disparities, whether it is racial and ethnic or rural and urban, we really cannot solve the problem and continue to improve.

Senator CARDIN. Ms. McCarthy, do you have any view on this?

Ms. MCCARTHY. This is a topic that has been near and dear to the heart of our PAC for quite some time. And more than a year in advance of any movement on the eGFR calculation being racially biased, we raised this time and again with the UNOS leadership as something that was disadvantaging Black patients.

We were ignored. We were told to stop talking about it and bringing it up, that it was a far too complicated topic for them to address. Basically, we were dismissed, although now, as a result of some of the movement forward, there is now a class-action lawsuit by 27,000 Black Americans to actually, hopefully, make right that which has been obviously a disadvantage for them.

Senator CARDIN. Do either of the two of you want to comment on this? I would be glad to hear from you.

Dr. LYNCH. So this is a multilayer problem for which we do need interventions at every layer. What we know from within the transplant community is that UNOS has failed to help us with data, and this is why it is so important for CMS and HRSA to require the recovery of data that is already being collected at centers and OPOs on processes that go from before the wait list decision, or from before somebody becomes an organ donor patient.

So data will help us to address the parts of it that we can address within transplant.

Senator CARDIN. Absolutely.

Senator Cortez Masto?

Senator CORTEZ MASTO. Thank you. And thank you to the chairman and ranking member. Such an important issue. So, I appre-

ciate your work here and the panelists for being here. And, Ms. Goldring, I want to thank you for being here today as well and sharing your story with our subcommittee.

I think we all agree it is critical that we understand your experience, the experience of many across this country, and really try to fix or at least address what we are hearing are some of the concerns.

Let me follow up on Senator Cardin's questions around transparency. Unfortunately, as we all know, we have a tremendous lack of transparency when it comes to the U.S. transplant system, and even when information is made available—and I hear this in my State—it is difficult to find and hard to understand. This fosters mistrust and reinforces the complexity of navigating the transplant network, a system that should be, I believe and I think many of us believe, as transparent as possible.

Dr. Lynch, what role does increased transparency play in impacting the quality and outcomes of the transplant system? How can transparency help make sure the United States transplant system is really more equitable, as you were talking about?

Dr. LYNCH. I think we have a tremendous opportunity right now, Senator. I think this legislation is going to be central to that. Getting specialist organizations that will help us to build trust within the community and for our patients is going to be a part of it.

And then getting that, what we call "process data" to understand how we are delivering care to various sociodemographic groups, the various geographic areas, all that is going to be central to how we help the patients with organ failure, how we respect the decision to become an organ donor patient for those people who have passed away, and how we make the best and most efficient use of all the resources we have.

Senator CORTEZ MASTO. Thank you.

And let me just ask the panel in general: in recent years, some Organ Procurement Organizations have implemented new practices really to the success of their region becoming high-performing OPOs. However, I recognize that many are failing to meet some of our most important measures of performance, and quite frankly that is why we need to move forward with these much-needed changes.

But—and this is open to the panelists. From your perspective, is there a balance to consider here? Do you believe we should be working on maintaining and promoting the success of Tier 1 OPOs while moving forward with broader reform? And, Ms. Cryer, you can start. Thank you.

Ms. CRYER. Nothing that we are contemplating today would disrupt or disallow those who are performing well from continuing to perform well. All it means is that we will have more OPOs that are operating at that level. As Mr. Wadsworth is a perfect example, leadership matters.

And it is so important to the point that you made about equity as well, to ensure that every American, wherever they are in the country, has the same chance at a lifesaving transplant, and the same respect for their donation as well, no matter where they live. And we cannot do that without the legislation and the changes we are asking for today.

Senator CORTEZ MASTO. Thank you.

And I noticed, Mr. Wadsworth, you had mentioned the improvements of an OPO in Nevada as well, and I am curious about your comments.

Mr. WADSWORTH. Thank you. If you look at the data and you watch, you can see who is treading and who is taking it seriously. If you remove the pancreata for research loophole, you can see whose improvement is genuine. Now, I do not think giving anybody more time means their behavior is going to change. They are who they are.

I think in other evidence—and I do not think it is a coincidence that a lot of CEOs retired the moment this rule was announced, because it got hard, right? That is just a lack of leadership in our industry. When stuff gets hard, you lead your organization through it and you help patients. You do not exit stage left to leave someone else holding the bag.

So I do not think behaviors are going to change. The easy way to make your procurement organization look better was to take advantage of this pancreata for research loophole. And as I said in my opening testimony, that is absolutely perverse, that someone would actually do that and be in a position of leadership and their board not act on that.

That is extremely troubling. We should not have given them an opportunity to move tiers because they can do it, and then exploit it even further on a larger population base.

Senator CORTEZ MASTO. Thank you.

Ms. McCarthy, did you have anything to add?

Ms. MCCARTHY. As I said in my opening statement as well, as a patient, I cannot fathom why we have any of these Tier 3 OPOs that are being allowed to exist. For me, I would like to see them closed down immediately, transfer the responsibility to high-performing OPOs that also happen to have high-performing leadership, and make those changes now. I think that is the only way we are going to start to see some material impact to patients.

Senator CORTEZ MASTO. Thank you. Thank you again for being here. I so appreciate it.

Senator CARDIN. Senator Young?

Senator YOUNG. Thank you.

I just want to rejoin something you said earlier, Ms. Goldring. I have to tell you, I am stunned to hear your comments that you randomly discovered that you were listed as inactive on an organ waiting list. It is horrifying. It ought to send chills down the spine of anyone who is watching this hearing. You were blocked by our U.S. Government contractee from receiving lifesaving organs.

This, if anything, highlights to me the urgent need for reform. In the wake of this horrible discovery, are you aware if there was any attempt from UNOS to notify you that your status had changed to inactive?

Ms. GOLDRING. Senator, to answer your question, no. UNOS never particularly contacted me nor the hospital to say what the actual problem was that happened, and I was never apologized to. And so, I ended up having to talk to the actual family who wanted to donate to me, to apologize——

Senator YOUNG. They said it was a clerical error—I am sorry for interrupting—a clerical error?

Ms. GOLDRING. Yes, sir.

Senator YOUNG. Clerical errors happen. Was anyone held accountable?

Ms. GOLDRING. No, sir. And all that I was told is, "Well, sometimes this may happen, but we will do what we can going forward to make sure it does not happen to another patient," and that is all I was told about the situation. That was from an executive director of an OPO.

Senator YOUNG. This goes back to basic business principles. When there are really important tasks to be done, there are mechanisms that can be put in place administratively to highly minimize the number of clerical errors that could occur, for example.

Ms. McCarthy, is there any formal policy about when and how to notify patients of this important status change, from active to inactive?

Ms. MCCARTHY. To the best of my knowledge, there is a policy that we are to be told of any changes in our status by U.S. mail letter. Speaking as a patient who has been on the list three times, and many patients that I have talked to as well, none of us have any recollection whatsoever of actually receiving any of those letters.

As recently as last August, our PAC spent 4 hours doing a design thinking workshop around how we could solve this problem using technology. I asked as recently as last week what the outcome of that was. I was told by the UNOS leadership that they are not allowed to tell me, but that I am going to really, really like it. But as I have done more digging, there is absolutely no movement forward in that.

Senator YOUNG. I mean, this—so your PAC has come up with all sorts of ways to avoid this, right?

Ms. MCCARTHY. Countless. We have proposed, yes——

Senator YOUNG. And with the highest degree of respect, you are not probably populated with NASA engineers and, well, maybe you are. But nonetheless, I bet I could sit down and probably come up with some guard rails here.

But it is not my job. Today, it is the job of UNOS. And if we have our druthers, if this panel has its druthers, and anyone watching this proceeding has their druthers, UNOS will not be doing this for very long.

Ms. MCCARTHY. God willing.

Senator YOUNG. I have about a minute left, and I want to make use of our time together. So, Dr. Lynch, what does CMS need to do to appropriately enforce the 2020 OPO rule?

Dr. LYNCH. They need to move forward with this as quickly as possible, not dilute it, not delay it, not risk-adjust it to make it less effective.

Senator YOUNG. What do OPOs need from CMS in order to improve performance for Tier 2 and Tier 3 OPOs?

Dr. LYNCH. So, they need honesty. They needed that 2 years ago when UNOS had the ability to give that to them. It is really important to reiterate—and this is an answer to Senator Cortez Masto

as well—there is no requirement under the CMS regulation that any OPO go out of business, that it be decertified.

The OPOs are being judged against what is being currently performed by their peers, and so this is something that they can achieve if they look and see what is happening to their next-door neighbor.

Senator YOUNG. Thank you. We've got some work to do up here and within this body, and we owe that to all of you, to keep pressing hard.

Mr. Chairman?

Senator CARDIN. Well, just to follow up—Senator Cortez Masto, do you have any additional questions?

[No response.]

Senator CARDIN. Just to follow up on Senator Young's point, you responded, Dr. Lynch, to enforce the rule, and we agree with you. That means there should be considerations of decertification if they are not performing at a level that is acceptable.

But you also have to have the services available in a community, so you need to have competition. You need to have the ability to not just decertify, but to make sure there is access to transplant services in the community. So, we do not want CMS to hide behind that issue and say they are never going to enforce this rule, and I think that is our major concern, because we find a reluctance right now to pull the decertification trigger, which may in fact be necessary.

Dr. LYNCH. I think that is critical, and I think that having this legislation go through and getting a responsible contractor or set of contractors will take some of that burden from you.

So, with all due respect, I do not want us to have to keep coming back to the principal. This is something that we should be figuring out in our own community, in our own transplant system, and with the right oversight and regulatory contractors, we can.

Senator CARDIN. We agree completely with that. I am just pointing out that I think the hurdle is, we have not yet convinced CMS to be very firm about these dates, and to have accountability if there are not the performance improvements that are expected under the rule that was issued.

And the second point, Senator Young, your point to Ms. Goldring, is that she found out, you found out that you were inactive on the list, and you were able to get it corrected. But I am equally certain that there have been other cases similar to yours, where the individual did not know to correct it, and that person may have ended up deceased.

The point that Dr. Lynch made in response to several of my questions is, delay equals life and death. Mistakes are life and death. So we are dealing with an urgent issue. Chairman Wyden said that over and over again. This is urgent.

Every day we are losing people, and it is just extremely upsetting and unacceptable to know that a clerical error that should be able to be easily caught by technology that is available today, would have prevented that from happening, or that tracking of transportation—which technology is pretty sophisticated today—why that is not being utilized.

As a result, it is very possible that lives—well, we know lives could have been saved that have been lost as a result of those types of mistakes. Well, you have heard Chairman Wyden and Senator Grassley and Senator Young and myself, as well as the other members of our committee, make it very clear that we intend to treat this with urgency.

Your testimonies have been powerful, as I said before. We sit through a lot of hearings. You have really motivated us in your testimony. All five of you have been very effective.

We know it is not easy for you to be here. I know professionally it is not easy for you to be here. We know that it is uncomfortable to go through some of these stories. But as I said earlier, when we look at numbers, yes, we are motivated by numbers, but we really are motivated to action by seeing the people who are directly impacted by the policies that we have here.

So I just really want to underscore again our thanks for your participation in this hearing. It is one that reinforces what we want to get done, but now I think gives us an additional impetus to move as quickly as we possibly can.

Chairman Wyden mentioned we are also working with Chairman Sanders of the HELP Committee, because we recognize that we have to work with two committees here in regards to these issues, and Senator Sanders has expressed strong support for the efforts that we are committed to doing.

I know there are a couple of other members who wanted to be asking questions who are en route. I am not going to hold up—do we have any updates?

[Pause.]

Senator CARDIN. We are going to just be a little patient for a few minutes, if you do not mind. We have a couple of other members who really want to weigh in. This is an important subject, and I want to make sure our members have the chance to express their views. So, if everybody will be patient, we will just stay in a quiet moment to reflect, and we will be back very shortly.

[Pause.]

Senator CARDIN. As I was saying, there is lot of interest of members of our committee on this subject. Senator Lankford's been very active in these discussions, and if Senator Lankford is ready, I will call on Senator Lankford to inquire.

Senator LANKFORD. Thank you very much. I apologize. I was literally running back and forth on the floor. We are dealing with pharmacy benefit manager stuff. That is some of next week as well, so I appreciate all your engagement and help on this.

I need help and clarification on this, and it deals with the kidney side of the transplants. About 1 percent of our Federal budget goes towards this issue. I mean, it is an enormous amount of money. There seem to be challenges here in multiple areas, both of getting kidneys to people and the process of actually doing the transplant.

Other treatments for all the kidney diseases and a whole multitude of those things out there, especially for diabetics and others, there are a lot of challenges there. Help unpack this for me, and what am I missing on this, and what can be done?

Mr. WADSWORTH. I think Dr. Lynch can weigh in a little bit on the transplant center side, but a lot of the incentives just do not

line up. So, from the OPO side, it has a lot to do with—I mean, what are you going after, what cases, how are you pursuing these cases, and are you building your organizations in a way that you can ask these families for the gift of donation and then manage these patients in getting the kidneys, getting the patient to surgery to remove kidneys for transplantation?

I think the way things have changed in terms of financial incentives and things like that—and then I think transplant centers are incentivized differently, and I think they have their own challenges. So, the OPO is trying to push for increased kidney transplantation, but I think—and correct me—transplant centers are more rewarded, a little bit, for being more conservative.

We are lucky in Ohio that we have one of the best transplant programs in terms of wait list and things in the country. But maybe Dr. Lynch can weigh in on this a little bit.

Senator LANKFORD. Yes. I am trying to find the incentives here and where they are. So, Dr. Lynch, go ahead.

Dr. LYNCH. So, renal failure is a crisis in America as a result of the epidemic of diabetes and organ failure. The difference in the incentives is the OPO is incentivized, or ideally will be incentivized, to recover as many donors as possible.

The center is incentivized to do as many transplants as possible, but it is also measured on both its pretransplant and posttransplant mortality. We need to make sure that there is a continuous chain of custody in these incentives, so that they really do align, and so that we take the best care of the donor patients, we get every potentially usable organ recovered, and then get it to the recipient who can make the best use of that—and we make sure that centers are incentivized to take what, in some measures, would be considered a risk, both with a riskier patient and a riskier organ, to give them that chance at a longer, better life.

Senator LANKFORD. So, tell me what that would mean as far as the incentive shift there. What would that look like? I understand what you are saying; practically, what would that look like?

Dr. LYNCH. So ideally, with better contractors as a result of this legislation, we would have a contractor that would measure everything in transplant, looking at our pretransplant listing policies, and looking at our predonor evaluation policies of who the OPOs are seeing as donor patients.

What we would do is make sure that every organ that is recovered is expedited to the best possible recipient for it, and that centers are able to remain competitive so that they are not routinely being pushed down the list or preempted in order to retain access for their patients.

Senator LANKFORD. So at this point, you are assuming, maybe rightfully so, that there are some individuals who could—that there may be a kidney available for them, but because they are considered a higher risk, they are kind of set aside?

Dr. LYNCH. Yes, sir. So if, for example, we hypothetically were to measure centers only on their pretransplant mortality or their posttransplant mortality, it will make centers conservative, and they will not list people who are at a higher risk of not making it to transplant, so dying before, or of not surviving as long after. But

they deserve that chance if they are medically able to get both those options.

Senator LANKFORD. Right, right.

Ms. McCarthy, you are nodding your head over here.

Ms. MCCARTHY. This is an area that PAC has really stepped forward in as well, in terms of allowing patients an opportunity to have a voice, to be included in those decisions. There are some patients who are more willing to take a more at-risk organ in exchange for not waiting so long. So definitely, this is something patients would advocate for.

Senator LANKFORD. Okay. Thank you. Anyone else want to make a comment? Yes, Ms. Cryer?

Ms. CRYER. I would just say that there are two ways to—I think what you are really asking is to reduce the costs of the ESRD program. And so, I think there are really two ways that the work that we are doing here today can do that.

If you have fewer people who have run into renal failure, you really have to focus on—and I know CBO has a hard time scoring prevention. So, we have to find a way to be able to—I know we have been discussing TROA and other things to reduce obesity, to reduce diabetes.

Most patients are not controlled for their hypertension, particularly Black and Brown patients. At the Global Liver Institute, we have more advocates coming from Oklahoma telling us of the issues in Native communities, of being able to deal with these issues that drive the need for transplantation.

To the point of incentives, the incentives are to keep people on dialysis, not to transplant. And so, the ESRD program would be relieved if we had, on both ends, people being swiftly moved to transplant instead of languishing on dialysis, and preventing the drivers of renal failure in the first place.

Senator LANKFORD. Okay. That is extremely helpful to be able to walk through, because we do have to fix the incentives in the process that are pushing people towards dialysis long-term, rather than trying to give them the opportunity to have a higher quality of life.

Thank you.

Senator CARDIN. Senator Warren?

Senator WARREN. Thank you, Mr. Chairman.

The Organ Procurement and Transplantation Network, or OPTN, was established by the Federal Government to manage the U.S. organ donation program. Today, OPTN is run by the United Network for Organ Sharing, or UNOS, which is the only entity ever to have been awarded this Federal contract.

Last year, the Senate Finance Committee released the findings of an investigation into UNOS that revealed that this system is deeply broken. Organs are getting lost in transit, infected organs are being transplanted into patients, and the individuals responsible for running the system are riddled with conflicts of interest.

So, let us talk about one of these conflicts. Federal law requires OPTN to have a board of directors. Makes sense. Most organizations are governed by a board of directors that, when working properly, serves as a check on the organization's performance and management.

Ms. McCarthy, you are a transplant patient yourself, and you serve as vice chair of the OPTN's Patient Affairs Committee. So you see up close the governance of the OPTN. So tell me, Ms. McCarthy, is there any difference in membership between the UNOS board of directors and the OPTN board of directors?

Ms. MCCARTHY. Senator, there is not. They are absolutely the same people.

Senator WARREN. So, they are identical, right?

Ms. MCCARTHY. They are.

Senator WARREN. And right now, that means the same people are in charge of overseeing how well the contractor runs the organ donation system, and those are the same people who are actually running it. So, Ms. McCarthy, how does this governance structure affect the integrity of the organ transplant system?

Ms. MCCARTHY. I would argue there is no integrity in the system. There is no accountability; there is no transparency; and sadly, the cost of that is that people are dying every day.

Senator WARREN. So what you are telling me is, nobody holds themselves accountable——

Ms. MCCARTHY. Absolutely not——

Senator WARREN [continuing]. Because this is an identity of interest. Okay.

My view on this is that OPTN changes are long overdue, and I support the reforms to HRSA, the Federal agency that oversees the OPTN. It was announced earlier this year that we are going to move in this direction.

I also joined Chair Wyden in introducing legislation to give HRSA additional statutory authority to strengthen government oversight. Among the many reforms, the legislation would support HRSA's proposal to break up the OPTN monopoly contract into multiple smaller contracts, which would allow some competition and allow the best vendors in the business to manage different parts of the transplant network operation.

That means hiring IT experts to do the IT. It means hiring logistics experts to do logistics, and so on. Now, UNOS does not want to lose control, so they are pushing to have the government limit eligibility only to nonprofit vendors that have worked in the past on organ donation, meaning for instance, that the IT company that is hired to run OPTN's computer systems would have had to have worked on an organ transplant network in the past, and be a nonprofit.

So, Ms. McCarthy, the requirement UNOS wants would seem to make it so that only one organization could apply for the new contract: UNOS. Would you have any concerns if HRSA awarded part of the OPTN contract to an entity that does not fit that narrow description?

Ms. MCCARTHY. Senator, absolutely not. Quite the contrary. We need to have diversity so that we can have the best in class serving patients.

Senator WARREN. I am glad to hear this. You know, I think what we are seeing here is nothing more than UNOS trying to protect its monopoly. The reforms that we have proposed are a commonsense step that everyone should be able to agree on.

Right now, Congress has an opportunity to root out corruption in this system. But if we do not act before the current contract expires, we do not have another shot for years. Patients have waited long enough. Congress should pass the Securing the U.S. Organ Procurement and Transplantation Network Act, and do it without delay.

Thank you. Thank you all for being here and for your work. Thank you, Mr. Chairman.

Senator CARDIN. Thank you, Senator Warren. We completely agree, and we have sensed the urgency here to act immediately. As Dr. Lynch pointed out, delay means life and death here, so thank you for very much for your comments.

Once again, I want to thank all five of our witnesses. It has been an extremely important hearing, and reinforces, I think, our desire to move quickly to open up competition, to provide transparency, to have accountability—all of the above that we have talked about before.

We need to have a much sounder basis for finding out whether there is an equitable system here, not only a system that is efficient at getting the maximum number of transplants to save lives, but also to make sure it is done in an equitable and fair way. All that requires us to act on transparency, accountability, and competition, which we intend to do.

So, thank you all for your testimonies, and with that, the subcommittee hearing will be adjourned.

[Whereupon, at 11:45 a.m., the hearing was concluded.]

# APPENDIX

## ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

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### PREPARED STATEMENT OF HON. BENJAMIN L. CARDIN, A U.S. SENATOR FROM MARYLAND

In the United States, the need for organs is far greater than those available. There are about 104,000 adults and children on the national transplant wait list, and every 10 minutes another person is added to it. In 2020, the Senate Committee on Finance did an investigation into the system and documented significant failures. Today, we discuss the path forward to a better system.

My constituents in Maryland have access to two excellent transplant centers in our State. Maryland also has a Tier 1 Organ Procurement Organization (OPO) that is taking innovative actions in some of the most underserved areas, like Baltimore City, to encourage organ donation. This OPO has been among the top 10 performers nationwide. Access to transplants in Maryland is far from perfect. Despite the high-performing transplant ecosystem, due to major underlying issues with the current transplant network, 148 people died while on the transplant waiting list in Maryland last year. That's unacceptable. Other States aren't so lucky. Marylanders and people across the Nation deserve better.

Nationally, 17 people die each day waiting for an organ transplant. OPOs are ranked between Tier 1, Tier 2, or Tier 3 depending on performance level—Tier 3 being the lowest that have one or both measures below the median. Further, according to the Centers for Medicare and Medicaid Services' 2023 performance review, 24 OPOs, or 42 percent, have been classified in Tier 3.

Senators Wyden, Grassley, Young, and I have been leading the Senate Finance Committee's investigation into the organ transplant system network for over 3 years, and each new line of inquiry has exposed more and more failures, which are often born by the sickest patients in the Nation.

Specifically, our committee has uncovered transportation and testing failures that have put patient lives at risk; outdated information technology underlying the network; a lack of oversight by the current Organ Procurement and Transplantation Network (OPTN) contractor, the United Network for Organ Sharing (UNOS); and misuse of Medicare funds.

These disparities impact people throughout the country, including those who are low-income, the uninsured, members of racial and ethnic minorities, people with disabilities, and rural populations.

Even more concerning, the U.S. Digital Service has found that UNOS is incapable of modernizing the OPTN IT infrastructure. The stakes of neglecting the needs of the underserved communities could not be higher.

During the last administration, CMS put out an OPO final rule which would establish a performance tiering system that triggers decertification, competition, and potential DSA reassignment. HRSA has taken critical steps to modernize the OPTN, but statutory changes are necessary to ensure that HRSA is able to work with the better-equipped organizations to ensure the OPTN is operating in an efficient and safe manner. When lives are at stake, Congress cannot accept logistics or poor administration as excuses.

Last week, we held a roundtable with senior officials from the Centers for Medicare and Medicaid Services (CMS) and the Health Resources Services Administra-

tion (HRSA). It was a productive conversation where we discussed efforts to modernize the organ transplant system and increase transparency and accountability.

Currently, we have a system that works well for some, as some of our witnesses will discuss today, but that is insufficient. Where an individual lives or their ability to afford to travel to get care should not determine access to lifesaving organs.

Today, we have the opportunity to hear from patients and professionals who are working on key reforms. Our committee will continue to address the biggest challenges facing our Nation, including the transplant system. We demand better, and we will not stop until we make it so.

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PREPARED STATEMENT OF DONNA R. CRYER, J.D., FOUNDER AND CEO, GLOBAL LIVER INSTITUTE

Thank you, Mr. Chairman, Mr. Ranking Member, and committee members, for your bipartisan support and commitment to save the lives of the more than 100,000 Americans waiting today for a solid-organ transplant by passing legislation to break up the deadly Federal organ donation monopoly and insisting that HHS steps fully up to its congressionally authorized role to protect donors and patients relying on the transplant system.

My name is Donna Cryer, and I am the president and CEO of Global Liver Institute, the only patient-driven, nonpartisan liver health nonprofit operating established in the United States and operating through partnerships with more than 55 countries and 200 medical societies, patient advocacy organizations, and other health promoting organizations through our councils, campaigns, and events.

I have worked in the organ donation field for almost 3 decades, since my own lifesaving liver transplant from a rare autoimmune disease and have seen these issues from all angles: as a Harvard and Georgetown educated lawyer; a nonprofit consultant, executive, and founder; a GAO appointee to the HIT policy committee; an SGE representative to the U.S. Food and Drug Administration; and the first call that thousands of patients and families who find themselves in the overwhelming circumstances of donating or waiting for the precious gift of life have made.

As far back as 1993, when I navigated the circuitous route to be diagnosed in liver failure, and evaluated for a transplant, the gaps, inequities, and burdens on families posed by what is called our transplant "system" were apparent. The decision to dedicate my gift of life to helping other transplant patients by finding ways to improve the system was clear. I started my career by serving in various roles for the United Network for Organ Sharing, UNOS, the Federal organ transplant monopoly contractor, which this very committee is investigating.

I have waited decades to give this testimony. Only by the grace of God am I alive to give it. The failures of the U.S. organ procurement system are devastating, leaving in their wake needless death and breathtaking inequity. The fault lies squarely with UNOS, as well as many of the Nation's Organ Procurement Organizations, or OPOs, which UNOS is supposed to oversee, under government contract.

At every turn, the organ industry is seen to prioritize executives over patients. But perversely, because organ donation is such a beautiful gift on behalf of generous donor families, and the science enabling it is such a marvel, the public has been blind to the hard truth that the industry behind it is corrupt.

I hope today that we are able to give you and everyday American citizens a chance to see behind the curtain.

My first role with UNOS was as a Patient Affairs Specialist which gave me views into policy, education, and communications. I sat in on staff leadership meetings, negotiation strategy sessions for dealings with HRSA, and it was even my job to draft the board minutes. Years later I was elected as a member of UNOS's Membership and Professional Standards Committee, or MPSC, which is charged with reviewing patient safety lapses and generating remediation plans. I hoped that would provide a different vantage point for me to make a difference.

The Senate Finance Committee's investigation findings revealed UNOS executives joking that the MPSC is "like putting your kids' artwork up at home; you value it because of how it was created rather than whether it's well done," and are consistent with my firsthand experiences.

The joke, I guess, is that UNOS knowingly leaves patients unsafe and unprotected. I fail to see the humor in it.

What I experienced firsthand was that MPSC decisions were made by a small cabal of industry insiders protecting each other, routinely ignoring or excusing abhorrent and dangerous behaviors.

The patient in me was traumatized. The lawyer in me wondered at what point the HHS staff in the room who were supposed to oversee the overseers would step in and act. UNOS has been well aware, for decades, of severe and often fatal risks to patients, and has worked far harder to cover them up than to fix them.

There is no reason to believe that UNOS has changed since then. Many of the same executives are not only still there, but have been promoted, for example the current CEO, Maureen McBride, who has been there since 1995.

UNOS executives know as well as I do that patients are dying needlessly in every stage of the system, yet I am not aware of a single meaningful action they have taken to address this. They post pretty words and press releases on their website pledging to do things that they have been empowered and requested to do for decades.

This time can be different. I have come before you to ask specifically for the Senate passage S. 1668, Securing the U.S. Organ Procurement and Transplantation Network Act, and to continue to keep the spotlight on the Centers for Medicare and Medicaid Services' (CMS) responsibilities in transplantation. CMS needs to, without further delay, use data that they do have to enforce regulations to hold Organ Procurement Organizations (OPOs), and the government contractors in charge of reaching out to donor families and securing donor organs, accountable for their performance, and to do so without caving to industry lobbying pressure to weaken these standards in any way.

With rare exceptions—which only demonstrate how good leadership and high performance are possible and in fact transformative to a region—a majority of OPOs are not only failing across multiple measures of performance, but have specifically been shown to systemically deprioritize outreach to Black and Brown families and communities, leading to fewer transplants to Black and Brown patients.

CMS taking the long-awaited actions requested by communities, patient, and donor family advocates across the country would make organ procurement safer, more equitable, and elevate the quality of organs available. Transplantation is often painted as complex, but a few simple steps would make a significant difference. Here are some examples. Openly publish OPO process data. Require that all staff interacting with patients have some baseline clinical training or licensure. Require adverse patient events to be reported publicly.

Innovation and reform will never come from the same people who are perpetuating the current dire status quo. Industry will push back, as it always does, with protectionist arguments that any change is disruptive, but I will assure you that nothing is more disruptive than dying. At my sickest point, doctors stood outside the ICU and told my mother that I only had 7 days left to live. Right now, under the current regime, 210 people are estimated to die in the next 7 days. They will not be saved by empty promises that reforms will come years down the line. They need you, Senators, to act today.

Thank you.

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## QUESTIONS SUBMITTED FOR THE RECORD TO DONNA R. CRYER, J.D.

### QUESTION SUBMITTED BY HON. SHELDON WHITEHOUSE

*Question.* OPOs are only one of two major programs left in Medicare that operate on what's called "cost-reimbursement basis," meaning they are reimbursed by taxpayers for whatever dollars they spend, rather than for the value they deliver. This incentivizes them to spend more money rather than to deliver high quality care for patients. The Federal Government has moved away from cost- reimbursement almost everywhere else in health care.

How do you suggest we move away from "cost-reimbursement basis" in organ transplantation?

Answer. Before considering changes to the reimbursement system for organ transplants, steps must be taken to modernize the OPTN, as is required by the Securing the U.S. Organ Procurement and Transplantation Network Act, legislation passed by Congress and signed by the President. A modern reimbursement system centered on value to the patient can only work with the data to support appropriate quality measures that drive accountability for high quality care. As I stated in my opening testimony, I urge the OPTN to take steps toward accountability by openly publishing OPO process data, requiring that all staff interacting with patients have some baseline clinical training or licensure, and requiring adverse patient events to be reported publicly.

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## QUESTIONS SUBMITTED BY HON. RON WYDEN

### GUARANTEEING EQUITY IN THE ORGAN TRANSPLANT SYSTEM

*Question.* Disparities in the organ donation and transplant system continue to persist. Black Americans are disproportionately represented on waiting lists and experience longer wait times for organs than other racial and ethnic groups. A few statistics that I find alarming are that Black Americans are four times as likely to develop kidney failure as White Americans, but are much less likely to receive a kidney transplant; and that Black Americans experience the highest rates of heart failure, yet receive heart transplants at lower rates than White Americans. These types of disparities are unacceptable.

Can you summarize the root causes of these disparities and describe how Congress can ensure that the U.S. transplant system better serves patients from minority populations and addresses these disparities?

Answer. For people of color, the unrealized potential of organ transplantation is devastating. We know people of color are significantly *less* likely to be put on the wait list, and also less likely than White patients to receive a lifesaving organ transplant once on the wait list.[1] While White people on the wait list have about a 50-percent chance of getting a transplant each year, the number is closer to 25 percent for Black people.[2] Studies also reveal the strong bias against Black people when it comes to assessing the "fit" of getting a transplant. In reality, people of color are more likely to be deemed medically unfit based on a nonclinical assessment highly subject to racial bias, or they may not be informed of the option at all.[3] For example, historically Black patients were less likely to be referred by hospital staff to OPOs,[4] including as the result of guidance by OPOs to not call them in specific circumstances "to avoid reporting on cases when the OPO believes donation is unlikely."[5]

Black families are also less likely to be approached for donation in a manner that is compassionate and culturally competent. Among the most common reasons they decline to donate are that the OPO did not "give [them] enough time to discuss important issues . . . or respond to [the family's] strong emotion with sensitivity and empathy."[6] Yet, we know families who have more contact with OPO staff are three times as likely to donate.[7]

When HHS announced the OPTN Modernization Initiative, the agency committed to strengthen accountability, equity and performance in the organ donation and transplantation system. The transplant community strongly supports their focus on technology, data transparency, governance, operations and quality improvement and innovation. I hope this committee will continue to provide the oversight needed to ensure increased transparency of the data needed to address its shortcomings and hold OPO's accountable for improving their performance, particularly for Black patients and their families.

### ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN) TECHNOLOGY

*Question.* The Senate Committee on Finance's investigation into the current OPTN contractor, the United Network for Organ Sharing (UNOS), uncovered crit-

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[1] *https://bloomworks.digital/organdonationreform/Inequity/#fn:23.*
[2] "Organ Donation and African Americans," Minority Health, HHS, 2020.
[3] *https://bloomworks.digital/organdonationreform/Inequity/.*
[4] *https://pubmed.ncbi.nlm.nih.gov/12545008/.*
[5] *https://bloomworks.digital/organdonationreform/Inequity.*
[6] *https://link.springer.com/article/10.1007/s40615-020-00806-7.*
[7] *https://jamanetwork.com/journals/jama/fullarticle/193976.*

ical system outages and failures by UNOS, to adequately manage lifesaving organ procurements and transplantations. In 2022, I, along with Senator Grassley, called for updates to the OPTN's information technology system in letters to the Federal Chief Information Officer and UNOS. This year, Senator Grassley and I sent another letter to UNOS, raising concerns about system outages of DonorNet, the organ transplant wait list database, which went off line on February 15th. The OPTN technology is a critically important component of the OPTN system, which is why it is imperative that the best in class are able to bid for a contract.

Given your experience as an Appointee to GAO's Health Information Technology (HIT) Policy Committee, can you speak to the importance of the OPTN technology?

Answer. As a member of the GAO's Health Information Technology (HIT) Policy Committee, I recognized that transparency, interoperability, and ease of engagement with data by clinicians and patients should be the hallmarks of U.S. health technology. Those are not present in this case. We know that the government has struggled to promote innovation or engage best-in-class expert contractors to serve patients due to OPTN policies that geared toward making the industry look good, while hiding patient safety concerns. For example, the U.S. Digital Service found that UNOS's technology is insecure and often crashes, creating periods of downtime during which lifesaving organs literally cannot be matched with recipients.[8] Other investigators found that UNOS maintains an archaic logistics infrastructure over which organs are tracked with phone calls and paper manifests, as opposed to using GPS or other electronic tracking. The result is lifesaving organs, often shipped on commercial flights, being lost or delayed and therefore unusable.[9]

Unfortunately, the protectionist culture of the industry was laid bare when Federal regulations in 2020 called on Organ Procurement Organizations to use objective—rather than self-reported—data to evaluate their performance and to make performance metrics legally enforceable. If you were approached or lobbied by anyone opposing an unbiased data repository, then you have already seen these conflicts of interest at work. The U.S. Digital Service reported that HRSA has tried many things over the years to encourage more transparency and accountability from UNOS through the OPTN contract, which were met with hostility from UNOS and even threats to walk away and continue operating the OPTN without a contract, which is illegal.[10]

*Question.* Additionally, why is it essential to have a contractor that can deliver the best-in-class system for patients?

Answer. The importance of technology to improve outcomes in transplantation cannot be understated. A less than efficient, modern technology infrastructure and data analytics staff can mean life or death to people on the waiting list. Patients erroneously made inactive on the list, therefore losing crucial waiting time or the actual opportunity to receive an organ is just the most glaring. Other areas of American life have seen technological innovation that demonstrates how much better it can be. A rapid delivery Amazon package of medical equipment or home delivery of prescription drugs support better health outcomes. There is no excuse for the secure and stable technology and reliable logistics management we see in other sectors to be absent from the organ donation system. Yet, the U.S. Digital Service ultimately found that UNOS lacked the capability to modernize its technology. If that is the case, isn't it time for OPTN to contract with a new entity to bring this innovation to the transplant system?

HHS projected these policies supporting transparency and accountability would save over 7,300 lives a year.[11] These reforms were supported by every major patient group [12] and celebrated by national health equity leaders.[13] Expert data scientists

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[8] *https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_11444ae6eeba4a65a3894a01d9095bed.pdf.*

[9] *https://kffhealthnews.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/amp/?utm_source=STAT%20Newsletters&utm_campaign=06e49f9ea7-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-06e49f9ea7-149550985&twitter_impression=true.*

[10] *https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_11444ae6eeba4a65a3894a01d9095bed.pdf.*

[11] *https://www.healthaffairs.org/content/forefront/new-organ-donation-rule-win-black-patients-and-health-equity.*

[12] *https://blog.petrieflom.law.harvard.edu/2021/02/05/recent-organ-procurement-organization-regulations-will-save-lives/.*

[13] *https://www.healthaffairs.org/content/forefront/new-organ-donation-rule-win-black-patients-and-health-equity.*

and epidemiologists, free of conflicts, now have the ability to conduct research that informs policies aimed at increasing the number of lifesaving organ transplants for patients every year.

The outcomes speak for themselves. More than 100,000 Americans are waiting for lifesaving organ transplants and new data shows that 17 people die daily waiting for an organ. According to a study by HRSA, in 2015, organs for transplantation were recovered from about 8,000 deceased donors per year, potentially only one-fifth of the true potential. These findings suggest that significant donation potential exists that is not currently being realized. Ninety-five percent of Americans support organ donation,[14] yet donation rates have not kept pace with simple population growth over the last 10 years, and clearly demands more structural incentives for innovation.[15]

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QUESTIONS SUBMITTED BY HON. TODD YOUNG

*Question.* Is there any formal policy in place regarding when and how to notify patients of any status change on the organ donation waiting list?

Answer. Unfortunately, as you heard from Ms. LaQuayia Goldring in her testimony, there is no requirement to notify a patient where they stand on the wait list, and so-called clerical errors are common. While there are patient notification policies in existence for transplant hospitals to notify patients when the patient is registered on a waiting list, when the patient's evaluation for transplant is complete, if the patient is *not* registered on the waiting list, and when the patient is removed from the waiting list for reasons *other than* transplant or death, these policies are not consistently followed and there is often no corrective or restorative action taken for failure to adhere.[16]

*Question.* What would be the most effective way to notify patients of their waiting list status?

Answer. I would recommend that patients have an opportunity to choose the method by which they prefer to be notified of their status on the wait list, whether by patient portal, phone call, email, or by regular mail (with address regularly updated) and that penalties be assessed if the information is not shared in a timely manner.

*Question.* What, if any, additional information would be useful for patients to have access to regarding their position on the waiting list?

Answer. Patients should be able to easily access their position on the wait list and whether they are active on the wait list, and if inactive, an explanation as to why with steps to address and become active again. It would also be useful to understand what factors would affect their position or status on the wait list.

*Question.* How many patients are listed as inactive?

Answer. As of December 27, 2013, 26,407 registrations were waiting with an inactive status for 1 year or longer without interruption, of which 87 percent were kidney registrations.[17] Reason codes do exist, and patients are often not notified.

*Question.* Is there any regular review/oversight by UNOS or others to ensure a patient listed as inactive is aware of their current status?

Answer. While HRSA has proposed a policy to notify patients of their inactive status, currently the rule only states, "If the candidate is temporarily unsuitable for transplant, then the candidate's transplant program may classify the candidate as inactive and the candidate will not receive any organ offers."[18]

*Question.* Is there any regular review/oversight by UNOS or others to ensure patients listed as inactive are appropriately designated as inactive, especially over an extended period of time?

Answer. I am not aware of such a requirement and would strongly support one.

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[14] *https://www.donornetworkwest.org/about-donation/organ-donation-facts-statistics/#:~:text=The%20majority%20of%20American_95,close%20and%20an%20important%20one.*
[15] *https://organdonationreform.netlify.app/assets/PDF/donation-increase.pdf.*
[16] *https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*
[17] *https://optn.transplant.hrsa.gov/media/1443/pubcommentpropsub_344.pdf.*
[18] *https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.*

*Question.* Are patients provided appropriate information and resources to determine any next steps needed to return to active status?

Answer. Unfortunately, this level of communication with patients is often lacking. We look forward to working with HRSA to update the requirements for communication with patients to assure that patients know and understand their status and concrete steps needed to return to active status if deemed inactive.

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PREPARED STATEMENT OF LAQUAYIA GOLDRING, KIDNEY TRANSPLANT RECIPIENT AND KIDNEY TRANSPLANT CANDIDATE

Hello and good morning, Chairman Cardin, Ranking Member Young, and members. Thank you for this opportunity to testify before you today.

My name is LaQuayia Goldring, and I am currently dependent on the U.S. organ donation system to save my life while I await the lifesaving blessing of receiving a 2nd kidney transplant—and the system is badly failing me.

As a toddler, at the age of 3 I was diagnosed with a rare kidney cancer called Wilms tumor (a golf-ball-size tumor) that took my left kidney. Due to that, at the age of 17, when I was diagnosed with stage five kidney failure, I was placed on the UNOS waiting list and received my first kidney transplant.

At the age of 25 I went back into complete kidney failure. I've now been waiting 9 long agonizing years for a transplant, dependent upon a dialysis machine 5 days a week to live. I was told I should receive a kidney transplant within 3–5 years, and still I wait as I continue to undergo monthly surgeries on my dialysis access to get adequate treatment. The UNOS wait list isn't like 1–100; I am never notified of where I stand on the list because an algorithm is meant to determine my fate. Every day that I'm waiting, I'm closer to becoming one of the 30 Americans who die each day waiting for an organ transplant.

I know this all too well, and that's why I've had to turn to social media to try to find a living donor. I've lost multiple friends and family to organ failure. I've seen more funerals than success stories. I don't want to be next.

The reason it's so hard for me to get a transplant is because the government contractors running the organ donation system are failing and corrupt.

I grew up in rural Kentucky, where the Organ Procurement Organization, or OPO—like more than half of OPOs across the country—is failing. OPOs fail to recover as many as 28,000 lifesaving organs every year. And even when they do recover organs, they waste them. More than one in four kidneys are thrown in the trash after a generous family has donated them.

It's even worse for minority-labeled patients. Our kidney function was wrongly calculated by UNOS race-based calculations, delaying our access to transplant. OPOs are less likely to respond to potential donation cases if the donor patient is of Black/Brown descent, and they treat those of us with less urgency, care, and compassion. I know this firsthand, as my grandmother was a donor, and we had to reach out for our OPO just to show up.

These failures lie at the feet of the monopoly contractor in charge of managing the U.S. organ donation system—UNOS.

Patients like me are completely forgotten by the system. Just a few weeks ago, a donor's family wanted to make a directed kidney donation to me, meaning that they chose for me to receive their loved one's kidney. This should have been my second chance at life, but my name was unable to be found at first as active on the UNOS transplant wait list, but I was told that this was a "clerical error," and that I should have been listed as "active."

This wasn't a one-off event. UNOS's technology is insecure and unreliable. It crashes regularly for hours at a time, meaning patients like me can't get organs, and kidneys are regularly lost at airports and thrown in the trash. Every time this happens, patients like me die. You can't even imagine how that feels.

In UNOS's system, Black patients are three times more likely to need kidney transplants than White patients, but less likely to get them. The inequity isn't an accident. It's by design.

An email from an OPO CEO, who at the time was a UNOS board member, justified a policy proposal that would systematically hurt minorities based on where we

live by saying that we are "dumb [expletives]" for living in the South and rural America in the first place.

What they think I'm too dumb to realize is that they've rigged the game for themselves. OPOs waste taxpayer money on 7-figure salaries, private planes, golf tournaments, and retreats to wine country. The whole system is set up to make a few people rich. They get beach houses; patients get coffins, especially patients who look like me.

But there is never any consequence for them because the government has never held them accountable. The government has failed me. The only solution is to replace failing OPOs and to get rid of UNOS.

This is urgent. We need to break up the UNOS monopoly now. Not in 2 to 4 years, but now. Not tomorrow, but today. I am grateful for this committee for introducing legislation to do exactly that, and I hope you will do everything you can to ensure that it passes. Lives are at stake.

In 2021, I testified before the House Oversight Committee alongside another patient, Tonya Ingram. She urged the government to hold OPOs accountable, warning that she would die if they did not. Her calls were ignored, and Tonya passed away last December. She deserved better, as do patients across the country.

Please help give us a different fate.

Thank you.

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## QUESTIONS SUBMITTED FOR THE RECORD TO LAQUAYIA GOLDRING

### QUESTION SUBMITTED BY HON. SHELDON WHITEHOUSE

*Question.* OPOs are only one of two major programs left in Medicare that operate on what's called "cost-reimbursement basis," meaning they are reimbursed by taxpayers for whatever dollars they spend, rather than for the value they deliver. This incentivizes them to spend more money rather than to deliver high quality care for patients. The Federal Government has moved away from cost-reimbursement almost everywhere else in health care.

How do you suggest we move away from "cost-reimbursement basis" in organ transplantation?

Answer. The current cost-reimbursement structure is clearly not sufficient to incentivize OPOs to allocate financial resources towards effective and equitable care delivery and has particularly led to a breathtaking divestment from hospitals which serve Black and Brown patients. A transplant candidate cannot receive an organ that was damaged before or after being harvested for organ donation, while an OPO can still receive payment for delivering an organ that may not be viable for transplantation. I suggest we come away from "cost-reimbursement basis" to improve our U.S. organ transplant system so more individuals can receive vital transplants.

In parallel, cost-reimbursement has done little if anything to control wasteful spending, with government audits and investigative journalists finding rampant fraud, waste, and abuse in the $3-billion-per-year OPO industry. I believe there are urgent and important opportunities to transition OPO reimbursement models away from cost-reimbursement and toward value-based care models. For further information, see this report from Organize and the Bridgespan Group *(https://www.bridgespan.org/getmedia/4905f7a5-41d7-4240-bd31-0017ec500029/Bridgespan-OPO-Report-FINAL-Appendix-A.pdf).*

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## QUESTIONS SUBMITTED BY HON. RON WYDEN

### URGENT NEED FOR REFORM

*Question.* Currently, one out of four procured kidneys are discarded, yet every day, 17 people die waiting for a lifesaving transplant. The Finance Committee's investigation of the United Network for Organ Sharing (UNOS), found several failures in the current organ transplantation system. Whether its technology outages or damaged, lost, discarded organs, each of these failures are vital to someone's life.

On May 17, 2023, I introduced legislation that would improve the National Organ Transplantation Act of 1984 (NOTA) and provide the U.S. Department of Health

and Human Services (HHS) with clear authority to expand competition for contracts related to the operation of the Organ Procurement and Transplantation Network (OPTN)—breaking up the monopoly that UNOS has held since 1984. This legislation is a first step in addressing the critical failures in the current transplantation system.

Patients in need of a transplant are already fighting for their lives. The system shouldn't make their fight harder. For example, one Oregonian shared their story of how they donated their kidney into the system so that her family member could receive one, yet months later, their family member is still waiting for a kidney.

Would you agree that every donated organ is vital and there are no minor errors?

Answer. Thank you for asking this vital question that sets a precedent of why organ donation is so vital to every candidate waiting. As a previous transplant recipient, and someone currently awaiting a lifesaving kidney transplant, and the granddaughter to a nonliving donor, I believe firsthand that all donated organs are vital to increasing organ donation and there is no room for any minor errors. A thorough health evaluation of the organs being used for procurement should have set guidelines and policies that all Organ Procurement Organizations and health personnel should be required legally to follow so there is no room for human error. HRSA and CMS should set better guidelines and policies that hold OPOS, transplant hospitals and insurance companies accountable so that vital organ transplants can occur at larger successful rates. One nonliving donor can save up to 75 lives with the donation of their eyes, organs, and tissues. A living donor can save multiple lives as they choose through blood and plasma donation, one kidney, a partial liver, and/or one lung lobe. Minor errors that are occurring at UNOS and through OPOs are human errors that can be addressed and fixed through quality control, hiring in new individuals dedicated to the mission of organ donation, and introducing new technologies and policies that address and fix the human errors created by UNOS technology so those who choose to be organ donors can donate vital organs, corneas, and tissues.

When it comes down to it, we need every OPO and transplant hospital to work together to provide vital organs that can save the lives of those individuals like me awaiting a lifesaving transplant. There is no room in our society for any organ donated to be lost in transit, discarded, or expired because of human or technological errors. As mentioned by an advocate and friend of mine, Jennifer Erickson, 28,000 organs go unrecovered from generous donors. If the system works correctly, we could use all the vital donated organs to eliminate the long waiting lists. With over 103,000 individuals awaiting lifesaving organs and 500,000 plus on dialysis, there is no room for minor errors so therefore, every organ is vital to reduce wait times on the transplant list and reduce the cost of alternative medications and medical devices to temporary keep one alive while waiting for that vital organ transplant.

*Question.* Can you tell me why reforms in this system are so urgently needed for patients?

Answer. This question is the key basis of why every advocate across the country stood up to vote to overhaul the current organ donation system, ridding it of the taxpayer-funded monopoly, UNOS. We urgently need organ donation reforms to aid in eliminating health disparities, financial, racial, and geographical disparities to transplantation. By enforcing new reforms, this would hold Organ Procurement Organizations accountable for their lack of accountability, transparency, and failure of basic performance measures. New organ donation reforms would save Medicare and taxpayers millions of dollars because we could shorten wait list times of those awaiting kidneys by promoting living organ donation and giving incentives to all living donors by passing Federal living donor protections; get more patients off dialysis; lower hospitalizations from organ failure complications; and increase survival rates of transplants.

Writing new reforms that include patient-focused initiatives would allow for voices from the community that incorporate patient voices, nonprofit organizations, clinicians, etc. who are focused on organ donation reforms, and in turn, more patients will want to work towards getting a transplant. Patients will be more compliant and more involved with their care and trusting of providers and OPOs. These reforms could eliminate the power health insurance and Medicaid has over transplants by allowing patients like me who need transplants, to use their primary and secondary health insurance to travel over State lines to be listed for a transplant. Lastly, reforms are so urgently needed for patients because we need a better, more dependable system for matching algorithm and organ placement, and for transportation

and tracking organs that works closely with experts from STEM and the FAA to ensure a collaborative, diverse, and patient-focused U.S. organ donation system that will save more lives than ever before, going forth.

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PREPARED STATEMENT OF RAYMOND J. LYNCH, M.D., M.S., FACS, PROFESSOR OF SURGERY AND PUBLIC HEALTH DIRECTOR, TRANSPLANTATION QUALITY AND OUTCOMES, THE PENNSYLVANIA STATE COLLEGE OF MEDICINE

Chairman Wyden, Ranking Member Crapo, and members of the committee, my name is Raymond Lynch. I am a liver and kidney transplant surgeon and professor of surgery and public health at Penn State College of Medicine in Hershey, PA. Thank you for the opportunity to speak today.

In my time as a surgeon, I have had the privilege of recovering organs from more than 200 generous, compassionate organ donor patients. I have performed hundreds of liver and kidney transplants. I have published more than 50 peer-reviewed papers in academic medical journals, and I am the principal investigator of an NIH-funded grant to study and improve organ procurement clinical care in Veterans Administration medical centers.[1]

I am here because Congress has the ability to take action to save the lives of my transplant wait list patients. I am here to advocate not only for their chance at a lifesaving transplant, but also to ask for your help in improving a system that thousands of patients depend on. I ask the committee to take concrete steps to make organ procurement and transplant safer, more reliable, and more effective for all patients, by:

- Supporting legislation that permits authentic competition for the OPTN contract, allowing specialized, highly skilled organizations the opportunity to move our transplant system into the 21st century.
- Ensuring that CMS and HRSA collect and report on how OPO workers provide clinical care, in the same way that CMS provides data on clinical care and health-care organizations in all other parts of our health-care system.
- Ensuring that CMS enforces the current OPO performance threshold without delay or dilution.

I want to take a moment to differentiate between *organ donation,* the altruistic decision that the donor patients and their families make to help others, and *organ procurement,* the clinical care provided by staff at Organ Procurement Organizations, that turns those gifts into usable organs for transplant.

Organ procurement is a clinical specialty—the last medical care that many patients will ever receive. It is fully reimbursed by the Federal Government, and it is administered by providers—the OPOs—who are the *only* provider option in their respective territories.

Fundamentally, when we talk about organ procurement, we are talking about health care and health-care providers, such as hospitals or nephrologists. Just like any other providers, OPO workers evaluate patients, gather information from patient health records, make clinical judgements, and intervene medically to get the best possible outcome.

Right now, patient care delivered by OPOs is some of the *least visible* in American health care.[2]

I can't tell you how many patients were evaluated by OPO workers in 2022. I can't tell you how many patients were examined, or how many families were given appropriate information and care regarding the option for donation, or even how many times an OPO worker showed up to a hospital for this critical duty.[2]

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[1] Doby, B.L., Brockmeier, D., Lee, K.J., Jasien, C., Gallini, J., Cui, X., Zhang, R.H., Karp, S.J., Marklin, G., and Lynch, R.J. (2021). Opportunity to increase deceased donation for United States veterans. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons,* 21(11), 3758–3764. *https://doi.org/10.1111/ajt.16773.*

[2] Doby, B.L., Boyarsky, B.J., Gentry, S., and Segev, D.L. (2019). Improving OPO performance through national data availability. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons,* 19(10), 2675–2677. *https://doi.org/10.1111/ajt.15508.*

I don't know of any other contractors or providers in American health care, especially ones that are reimbursed by CMS, that have so little information reported about what patient care is actually occurring.

This lack of information about what OPO providers actually do for patients is a root cause of the variability of rates of organ procurement around the country.[3] My own research has shown that what we euphemistically call "OPO performance" is a measurable restriction on the supply of organs that results in the unnecessary deaths of patients with organ failure.[3, 4] For example, if the lowest performing or Tier 3 OPOs had simply reached the median level of performance between 2013 and 2019, there would have been 4,957 more organ donors, yielding an estimated 5,641 kidneys, 2,678 livers, 1,047 hearts, 1,895 lungs, and 446 pancreases for transplant.[4]

These missing organs are equivalent to 9.4 percent of the total number of kidney candidates who died or were delisted over the study period, as well as 14.0 percent of the liver candidates, 22.5 percent of heart candidates, 75.6 percent of lung candidates, and 23.0 percent of pancreas candidates.[4]

Because I am a researcher, I just read you a list of calculated values. But because I am a physician, I want you all to think of each of the patients behind those numbers, with names like LaQuayia Goldring, Donna Cryer, and Molly McCarthy.

Because many OPOs operate in a low-quality data environment and without appropriate oversight, 4,957 patients did not get adequate organ procurement care. Without procurement care, organs weren't made available for transplant. Patients like Ms. Goldring, Ms. Cryer, and Ms. McCarthy then carry the burden for the failures of our system.

OPO clinical work is not visible, not benchmarkable, and not able to be evaluated, analyzed, or compared.[2] This can and must be remediated if we want to improve the organ supply. Much of the hidden data about how OPOs provide care to patients is known to one entity in the system: UNOS.[4]

The front-line OPO providers who administer procurement care are some of the most dedicated and hardest-working individuals in medicine. UNOS could report on how well and how equitably care is delivered by OPO workers at every step. Yet, UNOS has actively refused to help OPOs get better at providing care. Instead of offering assistance, UNOS has advocated for a deadly status quo, where fearmongering and finger-pointing take the place of concrete, achievable action to address quality of patient care. Even worse, UNOS frequently claims recent increases in organ donors as measures of their own success. I have published peer-reviewed research that reveals a primary driver of a large portion of those increases: the American opioid epidemic.[5] Between 2009 and 2018, of the 2,700 additional organ donors procured, 94.6 percent died from a "drug-related" cause. Increasing, tragic deaths driven by this epidemic in our communities should not function as a commendation for UNOS.

The current OPTN contractor, UNOS, is *simply not capable* of managing a safe, effective, and innovative transplant system. I know many of us have served to the best of our ability on UNOS committees, and I want to emphasize that I entirely direct my critical comments to UNOS leadership and their network of cronies. In spite of our best efforts, UNOS's incompetent policymaking and ineffectual oversight prevents patients from becoming organ donors or receiving transplants. Instead of UNOS, which is a legacy contractor with a proven history of obstructive and self-serving behavior, we need a new network of highly skilled specialist organizations, each attending to areas of expertise in the management of the OPTN contract.

I ask you to listen to patients, researchers, and front-line health-care workers at OPOs, transplant centers, and hospitals. I ask you to remove the burden from patients and put a new OPTN contractor to work—my patients' lives depend on it.

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[3] Johnson, W., Kraft, K., Chotai, P., Lynch, R., Dittus, R.S., Goldberg, D., Ye, F., Doby, B., Schaubel, D.E., Shah, M.B., and Karp, S.J. (2023). Variability in Organ Procurement Organization Performance by Individual Hospital in the United States. *JAMA Surgery,* 158(4), 404–409. *https://doi.org/10.1001/jamasurg.2022.7853.*

[4] Lynch, R.J., Doby, B.L., Goldberg, D.S., Lee, K.J., Cimeno, A., and Karp, S.J. (2022). Procurement characteristics of high- and low-performing OPOs as seen in OPTN/SRTR data. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons,* 22(2), 455–463. *https://doi.org/10.1111/ajt.16832.*

[5] Goldberg, D., and Lynch, R. (2020). Response to: Deceased donors: Defining drug-related deaths. *Clinical Transplantation,* 34(5), e13828. *https://doi.org/10.1111/ctr.13828.*

## QUESTIONS SUBMITTED FOR THE RECORD TO RAYMOND J. LYNCH, M.D., M.S., FACS

### QUESTION SUBMITTED BY HON. SHELDON WHITEHOUSE

*Question.* OPOs are only one of two major programs left in Medicare that operate on what's called "cost-reimbursement basis," meaning they are reimbursed by taxpayers for whatever dollars they spend, rather than for the value they deliver. This incentivizes them to spend more money rather than to deliver high quality care for patients. The Federal Government has moved away from cost-reimbursement almost everywhere else in health care.

How do you suggest we move away from "cost-reimbursement basis" in organ transplantation?

Answer. My research work regarding Organ Procurement Organizations has not yet examined the intersection of financial incentives and procurement effectiveness, although I *strongly* agree with the Senator that the unique reimbursement structure of OPOs is likely a material consideration for improving quality and efficiency of OPO care.

I believe that with increased transparency into the frequency and quality of patient care interactions, and objective reporting regarding quality of that care, as provided to patients by OPOs, there will be opportunities to describe how changes in reimbursement mechanism could support the industry in improvement and innovation. As a component of public health, with outcomes measurable at a population level, organ procurement clinical care may be amenable to a capitated model of payment. Capitation is just one way that OPO reimbursement could be modernized, and there could well be other viable models that we cannot yet describe, due to the lack of information about the practices of these care providers. I hope that researchers, stakeholders, and regulators may be able to examine modernized models of payment for OPOs as soon as we can describe when, where, and how OPOs provide patient care. In the meantime, I agree with the Senator that the cost reimbursement basis used for OPOs is outdated, lacks transparency, and leaves the system at risk for corruption, fraud, waste, and abuse.

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### QUESTIONS SUBMITTED BY HON. RON WYDEN

#### GUARANTEEING EQUITY IN THE ORGAN TRANSPLANT SYSTEM

*Question.* Disparities in the organ donation and transplant system continue to persist. Black Americans are disproportionately represented on waiting lists and experience longer wait times for organs than other racial and ethnic groups. A few statistics that I find alarming are that Black Americans are four times as likely to develop kidney failure as White Americans, but are much less likely to receive a kidney transplant; and that Black Americans experience the highest rates of heart failure, yet receive heart transplants at lower rates than White Americans. These types of disparities are unacceptable.

Can you summarize the root causes of these disparities and describe how Congress can ensure that the U.S. transplant system better serves patients from minority populations and addresses these disparities?

Answer. In my career, I have been privileged to participate in the care of patients across a range of racial, ethnic and geographic settings. Transplant offers patients from all these backgrounds hope for longer and better quality of life. The disparities to which you allude are clearly unacceptable. Guaranteeing equitable access to care may be beyond the scope of what providers and regulatory entities within the procurement and transplantation system can address on our own, but it is incumbent upon us to characterize the drivers of observed differences. With this information, we can mitigate disparities that are within our control and report to policymakers and the public on issues that require broader efforts to correct.

Central to fully understanding disparities is to broaden our collection and analysis of patient care beyond our current categories. We have previously advocated that system entities report on all patients referred to either procurement or transplant providers. With this change, we will be able to characterize facilitators and barriers to progression either as an organ donor or a transplant candidate. These data will be critical to measuring differences in care and outcomes for patient populations, and devising institutional and system-wise measures to maximize equity access to care.

DATA AND TRANSPARENCY

*Question.* In 2019, a Columbia University study found that kidney candidates who died without a transplant received a median of 16 offers for a kidney (over a period of 651 days) while wait-listed. This type of wait list data is not accessible and available to patients and their families. In 2021 CMS published the Organ Procurement Organization (OPO) final rule, which was a major step towards improving transparency. However, there is still more to be done. For example, although current law requires that CMS collect OPO process data, the regulations do not require that CMS use the collected process data to inform their quality metrics. Additionally, CMS does not have a way to collect other types of data such as, objective OPO referral data and transplant center acceptance rates.

What type of data should HHS collect to incentivize better outcomes and transparency for patients?

Answer. As the Senator notes, under 42 CFR § 486.328, OPOs must collect and report to: the OPTN contractor, the SRTR contractor, and HHS, data about where, when, and how OPOs provide care and clinical evaluation for patients, and access, review, and extract patient health data.

Currently, the OPTN contractor collects at least some such data from OPOs under a form called the "Death Notification Registration" or DNR. Although the current OPTN contractor *has not* collected nor reported enough data from OPOs to fulfill the requirements of 42 CFR § 486.328, the good news is that every OPO already collects complete patient and process data that would meet the regulatory requirements.

It is imperative that HHS step in to ensure compliance with OPO data collection and reporting under 42 CFR § 486.328, and the best mechanism for such action is improving the DNR form to be compliant with current regulations. Such OPO patient and process data would power widespread quality improvement efforts that could be targeted to remediate any OPO that is falling behind, and improve access to organs for all patients on the transplant wait list.

Sometimes expressing this need in terms of regulations does not adequately describe just what a disadvantage we force upon patients by withholding quality data from them—data that is readily available for hospitals, hospices, long-term care facilities, et cetera.

It is deeply critical for potential donor and potential recipient patients to have access to complete data reporting for OPOs in order to answer basic questions like:

Should I register as an organ donor?

Does my local OPO provide timely, high quality care to patients?

Does my local OPO do a good job with procuring organs? If not, does that negatively affect my ability to receive a transplant?

Will my family receive culturally competent care and education from my local OPO, if I am a potential organ donor patient?

Does my local OPO fall short in serving communities of color, and does that negatively impact my ability to receive a transplant?

Patients deserve high-quality information about their OPO, and there is no logical reason why OPOs should not participate in *Medicare.gov* data reporting that empowers patients, whether potential donors or recipients, to learn more about what contractors will provide their care, or ensure that organs are procured to save their lives. In fact, our research group recently published[1] an early iteration of an OPO care comparison tool that seeks to describe the relative strengths and deficits of OPOs, available at *https://opo-dashboard.herokuapp.com/*.

Regarding data for transplant wait list patients, I strongly endorse the efforts of my colleagues who have described the need for transparency into organ offers and acceptances for all patients.[2] Our patients deserve more opportunities for shared

[1] Doby, B.L., Casey, K., Ross-Driscoll, K., Rahman Ovi, M., Hossain Bhuiyea, Md. S., Isty, I.A., and Lynch, R.J. (2023). What is visible is fixable: Visual dashboards for multi-domain assessment of OPO Performance. *American Journal of Transplantation. https://doi.org/10.1016/j.ajt.2023.08.020.*

[2] Husain, S.A., King, K.L., Pastan, S., Patzer, R.E., Cohen, D.J., Radhakrishnan, J., and Mohan, S. (2019). Association Between Declined Offers of Deceased Donor Kidney Allograft and

Continued

decision-making and information that will allow them to be empowered in their own care while waiting for their transplant.

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PREPARED STATEMENT OF MOLLY J. MCCARTHY, VICE CHAIR AND REGION 6 PATIENT AFFAIRS COMMITTEE REPRESENTATIVE, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK (OPTN), AND 3-TIME KIDNEY TRANSPLANT RECIPIENT

Chairperson Cardin, Ranking Member Young, and members of the committee, I'm grateful for the opportunity to testify today, and would like to thank you for your work to drive lifesaving, patient-centric reforms to the U.S. organ donation system through Senate bill 1668 to break up the national organ transplant monopoly.

My name is Molly McCarthy. I am a 3-time kidney recipient, having received my first 32 years ago. I'm one of the fortunate ones: I've made it despite the broken and corrupt organ donation system we have been saddled with, and I am all too aware that many patients aren't as fortunate. I received two living donations, one from my mother and one from my father—an option that I know many patients do not have.

Then 11 years ago, I received one from a generous deceased donor. I am acutely aware that I may need a transplant again in the future. And whether that happens is dependent on what Congress does now. I'm here today to plead with you to pass Senate bill 1668.

The reason why is as simple as it is heartbreaking: the Federal monopoly contractor managing the organ donation system—the United Network for Organ Sharing, or UNOS—is an unmitigated failure, and its leadership spends more time attacking critics than it does actually taking steps to fix the system.

I have seen this firsthand. As a passionate advocate for patients, I took on the volunteer role of vice chair of the Patient Affairs Committee, or PAC, for the Organ Procurement and Transplantation Network, the Federal contractor that UNOS holds. I thought this would be a chance to ensure that the patient voice was included in national policy. Sadly, I couldn't have been more wrong.

What I learned is that UNOS, at best, treats patients as props; at worst, it outright lies to us, and then uses us as a shield against much-needed oversight and reform. UNOS knows enough not to lie to Congress, so it lies to patients instead, and then launders its lies through us.

For the last year, much of my work on PAC has consisted of writing to congressional offices to fact-check UNOS misinformation, which I would like to take the opportunity to do here today.

For example, UNOS leadership has created a systematic effort to misrepresent the facts, regularly celebrating recent increases in organ donations as evidence of their success and a well-working system.

The reality, however, is that this growth is driven entirely by the opioid epidemic and skyrocketing gun deaths, as well as other increases in suicides and fatal car accidents. All UNOS is celebrating are national tragedies, not a well-run organ donation system.

Similarly, UNOS dramatically downplays the deadly toll of its failures by only publishing the number of deaths of patients who were already on the transplant waiting list. But most patients who need transplants are never even placed on the waiting list because of the severe organ shortage in UNOS's system.

And this is also where most of the inequity occurs, as UNOS does absolutely nothing to ensure that patients of color are added to the waiting list at the same rate as White patients.

For years, Black patients were even subject to a racist metric of kidney function; in fact, there is currently a class action lawsuit from 27,500 Black Americans alleging systematic racial discrimination against them in waiting list practices.

This is an issue that PAC had been raising for more than a year before UNOS took any action, and even then, the action wasn't enough to help many patients.

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Outcomes in Kidney Transplant Candidates. *JAMA Network Open,* 2(8), e1910312. *https://doi.org/10.1001/jamanetworkopen.2019.10312.*

Worse than being ignored, however, is that people who speak out have been bullied, threatened, and retaliated against. This is well documented, including in recent investigative journalism from the *Richmond Times-Dispatch,* UNOS's hometown paper.

I personally have been warned that the UNOS board is unhappy with my advocacy, and that there will be consequences if I continue to speak out. Imagine saying that to a patient. Further, I've been called by a board member telling me to stop focusing on system outages of the UNOS system; he told me that having the system down for a few hours wasn't a big deal, that the donors are dead anyway.

UNOS has also failed to oversee Organ Procurement Organizations (OPOs). As a patient, I don't understand why any Tier 3 OPO is still allowed to operate. This is a life and death business, and the Centers for Medicare and Medicaid Services (CMS) must immediately replace failing OPOs with successful OPOS that are getting the job done. Now. It's costing taxpayer dollars and thousands of lives.

There is no shortage of evidence that the system is broken. But what I hope I can communicate to you is that the problems are far worse than what is publicly known, and the rot is far deeper.

UNOS behaves like mob bosses, and for every whistleblower who speaks out, there are another hundred who remain silent. It is no exaggeration that *Forbes* once called UNOS a "cartel."

While we may never know the true toll of the gross negligence and abuse of the government's own organ contractors, we do at least know the solutions.

- CMS needs to move urgently to open data for Organ Procurement Organizations; replace failing OPOs without caving to industry pressure to weaken standards; and close the dangerous pancreas loophole that allows OPOs to pad their numbers and jeopardize patients' lives; and
- Congress needs to break up UNOS's monopoly by passing S. 1668, ensuring that the Department of Health and Human Services uses its authorities to replace UNOS as its contractor.

Before my last transplant, I waited 6 agonizing years. Watching the Senate Finance hearing last August, I realized that potentially years of that wait were unnecessary. Patients deserve an effective, safe, transparent, and equitable organ donation system. Speaking as a patient of this system, I have no zero confidence that we will ever have it if UNOS has any role in the transplant system.

Thank you.

**Appendices Below**

- Appendix A: "Fact Check of AOPO Misinformation," Posted on Medium,[1] February 2023.
- Appendix B: Fact Check of then-UNOS President Dr. Jerry McCauley sent to various congressional offices,[2] October 2022.
- Appendix C: OPTN Patient Affairs Committee Statement for the Record[3] for Senate Finance Committee August 2022 Hearing.

**Appendix A: "Fact Check of AOPO Misinformation," Posted on Medium,[4] February 2023**

On January 28th, *The New York Times*[5] ran a heartbreaking guest essay about Tonya Ingram,[6] a 31-year-old woman who died in need of a kidney transplant. Tonya had tirelessly advocated for reforms to the organ donation system, including the government's monopoly contractors charged with organ recovery, called Organ Procurement Organizations (OPOs).

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[1] *https://medium.com/@mollymccarthy_12951/correcting-aopo-misinformation-f7f8e58a7892.*
[2] *https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_e282c96a63c44f41812f5e6ecbe1e7dd.pdf.*
[3] *https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_f69399049254488b93a4ca57fbbd716d.pdf.*
[4] *https://medium.com/@mollymccarthy_12951/correcting-aopo-misinformation-f7f8e58a7892.*
[5] *https://www.nytimes.com/2023/01/28/opinion/organ-donation-reform-delays.html.*
[6] *https://www.latimes.com/entertainment-arts/books/story/2023-01-23/tony-ingram-an-inspiring-l-a-poet-and-lupus-warrior-died-waiting-for-a-kidney.*

Tonya even testified before the House Oversight Committee[7] in May 2021 that absent such reforms, she would die. No reforms came, and she was ultimately proven right: she died on December 30, 2022. Tonya was full of joy,[8] and her life was cut way too short.

In response, the Association of Organ Procurement Organizations (AOPO), which is currently the subject of a congressional investigation[9] for various abuses, including misinformation and anti-patient lobbying, issued an absolutely wild statement in which they spread falsehoods and deflected blame, and, implicitly, disparaged Tonya's work and dishonored her legacy.

Below is a fact-check of AOPO's statement, which I post with the hope that facts will prevail, and the reforms that Tonya fought so vigorously for may ultimately be finalized, saving the lives of tens of thousands of other future patients.

Molly McCarthy
3-time Kidney Transplant Recipient
Vice Chair of the Organ Procurement Transplantation Network Patient Affairs Committee

***AOPO wrote:*** *Sadly, 17 people die each day waiting for a lifesaving transplant. There is no question that Americans, especially those suffering from acute kidney disease, deserve greater access to organs for transplant.*

**Fact-check:** The number of people who die every day is much higher than 17. Inclusive of patients who die every day after having been removed from the waiting list for becoming "too sick to transplant," the current number is 32. (The OPTN database[10] is quite difficult to use, however, if you run a report for "waiting list removals by reasons by year" and then add the columns for "died" and "Too Sick to Transplant" for 2022 and then divide by 365, the number is 31 deaths per day. In 2021, when Tonya Ingram testified before House Oversight, it was 33—*see Washington Post.*[11])

Of course, inclusive of patients who never even reach the waiting list—disproportionately patients of color because of racial bias in waiting list practices—the number is much, much higher than that. Using the number 17 erases their deaths and suffering from the story and is simply a function of UNOS's "accounting practices" in wait list management to downplay the scale of the system's failures.

***AOPO wrote:*** *Recent data released by the Organ Procurement and Transplantation Network (OPTN) shows how these efforts have resulted in an increase in the number of deceased organ donors year over year for the last 12 consecutive years. Since 2010, the data represents an 87-percent increase overall in deceased organ donors. Notably, in 2022, OPOs recovered a record number of kidneys from deceased donors resulting in over 25,000 kidney transplants.*

**Fact-check:** These statistics are wildly devoid of context, as has been pointed out repeatedly in response to misleading UNOS lobbying. As former United States Chief Data Scientist DJ Patil[12] has published, "To deflect criticism, OPOs and UNOS have lobbied aggressively[13] to confuse the recent increases[14] in organ donors from opioid and other external causes (*i.e.,* non-medical deaths like trauma, substance use, and suicide) with improved performance overall. If donation numbers are increasing, their argument goes, then the system must be performing well, and so the push for reform must be misguided. This is a cynical attempt to politically profit from the opioid scourge and other second-order effects of the deadly pandemic, mischaracterizing the data to evade accountability."

In fact, peer-reviewed data published in *JAMA*[15] has found that, after controlling for increases in donation outside of OPO control (*e.g.,* public health trends), donation

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[7] *https://www.youtube.com/watch?v=TnKo8Q-Hemk&t=127s.*
[8] *https://www.instagram.com/p/Bd3GSnpDBwk/?igshid=Zjc2ZTc4Nzk%3D.*
[9] *https://oversightdemocrats.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and.*
[10] *https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/.*
[11] *https://www.washingtonpost.com/health/organ-collection-agencies-told-to-improve-performance-or-face-tighter-rules/2021/05/04/68847bce-ad06-11eb-acd3-24b44a57093a_story.html.*
[12] *https://www.medpagetoday.com/opinion/second-opinions/98363.*
[13] *https://www.pogo.org/investigation/2021/04/americas-transformative-new-organ-donation-rule-goes-into-effect-over-objections-from-monopolistic-contractors/.*
[14] *https://unos.org/news/deceased-organ-donation-and-transplant-annual-trend-continues-2020/.*
[15] *https://pubmed.ncbi.nlm.nih.gov/33026442/.*

rates in recent years have not even kept pace with simple population growth (see data visualization—here).[16] If a baseball player had 5 hits in 10 at-bats his rookie year, and then 10 hits in 100 at-bats during his second season, we would all find it risible if his agent argued that he deserved a huge new contract because he doubled his number of hits. Only in this case, what AOPO is shamefully claiming credit for are terrible American public health tragedies, including spikes in opioids overdoses, gun deaths, suicides, and fatal car accidents, including as second-order effects of the COVID pandemic.

The fact that AOPO does not seem to understand the drivers of donation, or even how to describe procurement practice in the U.S., calls into question its ability to identify and rectify system failures. In case anyone has not seen it, here is a video of AOPO CEO Steve Miller testifying before Congress[17] that he does not have a deep understanding of the OPO regulatory system. Based on his comments, I believe him.

***AOPO wrote:*** *These numbers show improvement and support that the U.S. is the world's most successful organ donation and transplantation system, yet there is more to do.*

**Fact-check:** As alluded to above, these numbers do not actually show system improvement. In fact, as a relative matter, the system has gotten worse over this period. Likewise, these numbers absolutely do not show that the U.S. has the "world's most successful organ donation and transplantation system." As DJ Patil[18] wrote in the editorial I referenced above:

> Similarly, a common OPO and UNOS refrain is that the U.S. now has the highest number of organ donors per capita[19] of any country, which they use to characterize the American organ donation system as the "best in the world."[20] But context is critical. The higher organ donation rates in the U.S. actually reflect higher levels of societal ills, rather than superiority of the organ procurement system.
>
> More plainly: We have more organ donors in America not because we have a strong—or even remotely adequate—organ procurement system, but because on a per capita basis among wealthy nations, we have many times more deaths in those subsets of deaths that allow for organ donation to occur. This includes 20 to 30 times[21] more opioid deaths, 25 times as many gun deaths, the highest suicides rates,[22] and more than twice as many fatal car accidents[23]—a number that spiked again[24] precipitously last year.

To give an even more plain-speak analogy, imagine that 100 Americans were in one room, and in another room, there were 100 Canadians. In the American room, let's say 15 of them die in organ donation-eligible ways, and our system successfully converts 2 of them into organ donors. In the Canadian room, 2 people die in such ways, and their system converts 1 of them into an organ donor. It is simply not statistically reasonable—or intellectually honest—to suggest that this means the U.S. system is twice as good as the Canadian system simply because it had 2 donors per capita instead of 1.

Obviously, the numbers used in the example above are for simplicity, but it is to make the point that using a per capita comparison across different countries is nonsensical. That the U.S. has more organ donation eligible deaths than other countries *(e.g.,* from opioids, gun deaths, suicides, and car accidents) is one tragedy; when we fail to recover potential organ donors, that's another, and the two compound.

***AOPO wrote:*** *A key area of improvement is in the number of organs recovered by OPOs but refused by transplant centers and instead go to waste. That number is rising dramatically. In fact, 7,540 kidneys, amounting to 26 percent of all kidneys re-*

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[16] *https://bloomworks.digital/organdonationreform/assets/PDF/donation-increase.pdf.*
[17] *https://www.youtube.com/watch?v=TnKo8Q-Hemk&t=6351s.*
[18] *https://www.medpagetoday.com/opinion/second-opinions/98363.*
[19] *https://oversight.house.gov/sites/democrats.oversight.house.gov/files/AOPO%20Joint%20Testimony.pdf.*
[20] *https://unos.org/transplant/opos-increasing-organ-donation/.*
[21] *https://www.washingtonpost.com/health/2021/11/17/overdose-deaths-pandemic-fentanyl/.*
[22] *https://www.commonwealthfund.org/press-release/2020/new-international-report-health-care-us-suicide-rate-highest-among-wealthy.*
[23] *https://www.cbsnews.com/news/us-car-crash-death-rate-worse-than-other-affluent-countries/.*
[24] *https://abcnews.go.com/Politics/wireStory/us-road-deaths-rise-record-pace-risky-driving-82600871.*

*covered and offered by OPOs for transplantation in the U.S., were turned down by transplant centers last year.*

**Fact-check:** Discards in the U.S. are too high and are rising. There is broad agreement on this. AOPO's framing of the problem as entirely a transplant center issue, however, is incorrect and overly reductive. There are many contributing factors, certainly including transplant center "weekend effect"[25] and transplant center risk aversion, though also including:

- Differential effort and ability from OPOs in clinical management of donors and wait list navigating, as evidenced by wildly different organ placement rates across OPOs for clinically similar organs;
- DonorNet inefficiencies and frictions, as identified by the United States Digital Service[26] and reported on by *The Washington Post,*[27] and testified before the Senate Finance Committee by Mid-America's Diane Brockmeier;[28]
- Failures of organ logistics and transportation, including deeply unprofessional OPO practices of selecting and managing transportation vendors, as well as gross failures of the UNOS Organ Center, as reported on by *Kaiser Health News*[29] and covered in the Senate Finance Committee hearing;[30] and
- OPOs often recover kidneys they have no intention of placing for transplant, but, because of an arcane reimbursement system, OPOs are able to overbill Medicare through cost-shifting enabled by explanting more kidneys[31] even if they are not transplanted. There is, honestly, likely an issue of systemic Medicare fraud here.

The best way to inform solutions on this is to have more transparency into the system. Ironically, this is one of the solutions explicitly called for in the *NYT* piece—as well as Tonya's advocacy: to follow the Senate Finance Committee's recommendations for CMS to publish OPO process data.[32] This is standard in every other mature transplant system in the world, including, of course, all systems with lower discard rates than ours.

***AOPO wrote:*** *In Los Angeles, where Tonya Ingram lived, organ donation was up 10 percent last year—a 2-decade upward trend. The local OPO recovered a record 2,143 organs in 2022 but also saw 520 organs rejected by transplant centers, up from 376 the year before. Moreover, 397 of the 520 rejected organs were kidneys, up from 273 the year before. One of these kidneys may have saved Tonya's life. This rise in rejection rates is disheartening to the OPOs that work each day to increase the number of organs they are recovering. But it is devastating to patients living—and often dying—on dialysis, waiting for an organ. OPOs have no control over whether organs are actually transplanted into patients. Our Nation's transplant centers make this critical decision, determining whether to accept an organ offered from an OPO.*

**Fact-check:** The "2-decade upward trend" framing is addressed above, as well as the organ discard issue. I will note here, though, that OneLegacy's OPO is Tier 3,[33] failing according to CMS, as it has been for every year that CMS has published tier ranking data. (In the most recently available data from 2020 released by CMS last year, OneLegacy's failure to reach Tier 1 standards by 328 transplants, or—in plain speak—328 preventable deaths.) I would also note that OneLegacy is under investigation by the House Oversight Committee[34] for "shocking mismanagement."

***AOPO wrote:*** *The exclusion from this discussion of our Nation's transplant centers and their regulators as important stakeholders involved in improving the sys-*

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[25] *https://www.medscape.com/viewarticle/866260.*

[26] *https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_11444ae6eeba4a65a3894a01d9095bed.pdf.*

[27] *https://www.washingtonpost.com/health/2022/07/31/unos-transplants-kindeys-hearts-technology/.*

[28] *https://www.finance.senate.gov/imo/media/doc/Diane%Brockmeier%20Written%20Testimony-Senate%20Finance%20Committee.pdf.*

[29] *https://khn.org/news/how-lifesaving-organs-for-transplant-go-missing-in-transit/amp/?utm_source=STAT%2BNewsletters&utm_campaign=06e49f9ea7-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-06e49f9ea7-149550985&__twitter_impression=true.*

[30] *https://www.finance.senate.gov/hearings/a-system-in-need-of-repair-addressing-organizational-failures-of-the-uss-organ-procurement-and-transplantation-network.*

[31] *https://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/Bridgespan-OPO-Report-FINAL-Appendix-A.pdf.*

[32] *https://www.finance.senate.gov/imo/media/doc/040722%20Wyden%20Grassley%20Young%20Transplant%20System%20RFI%20letter.pdf.*

[33] *https://opodata.org/opo/CAOP.*

[34] *https://oversightdemocrats.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and.*

*tem's ability to save more lives is a serious oversight. For the entire system to save more lives, we need to ensure that transplant centers have declared clear organ acceptance criteria, have the appropriate resources to process the influx of available organs, and utilize organs from more medically complex donors.*

**Fact-check:** While transplant centers (and UNOS) certainly have some responsibility related to discards, as further expounded on above, the NYT piece itself highlights that the Indiana OPO, in response to oversight pressures, increased organ donation rates by 44 percent in 1 year[35] by simply approaching 57 percent more donors. Restated: the increase did not necessitate behavior changes at transplant centers, new OPTN technology, or any other changes; the major increase resulted through the single intervention of applying oversight pressure to the OPO to follow the existing legal mandate of approaching every donation referral it receives.

***AOPO wrote:*** *The National Academy of Science, Engineering, and Medicine's (NASEM) report—"Realizing the Promise of Equity in the Organ Transplantation System"—which was developed in 2021 at the request of Congress and sponsored by the National Institutes of Health (NIH) is the only peer-reviewed, data-driven assessment of the entire organ donation and transplantation system, and it focuses specifically on kidneys. The report categorically states that the whole system—the Center for Medicare and Medicaid Services (CMS), the United Network for Organ Sharing (UNOS), transplant centers, OPOs, and donor hospitals—bears responsibility for increasing the number of transplants in the U.S. NASEM found that "on average, patients who die waiting for a kidney had offers for 16 kidneys that were ultimately transplanted into other patients, indicating that many transplant centers refuse viable kidney offers on behalf of those on the waiting list (Husain et al., 2019)."*

**Fact-check:** The NASEM report is currently being investigated by two separate congressional committees—House Oversight Committee[36] (see *Kaiser Health News*[37]) and Senate Finance Committee[38]—for apparent financial conflicts of interest among its members, with the Senate Finance Committee writing upon the publication of the NASEM report: "We are concerned that the NASEM report seems to align with the lobbying positions of UNOS and the Association of Organ Procurement Organizations (AOPO), and that these recommendations will not address the concerns raised during our investigation."

AOPO can help shed light on this by sharing any contracts it—or its member OPOs—have signed with any of the consultants who were members of the NASEM study, including Dennis Wagner of Yes And Leadership.[39] (See Senate Finance letter.[40]) If AOPO is looking for support of the NASEM study as an unbiased, unconflicted resource, there is no reason AOPO shouldn't be willing to share the financial relationships that would inform whether or not such conflicts exist.

Put another way, if there were no conflicts, AOPO would presumably be very eager to clarify that.

***AOPO wrote:*** *Rather than referencing NASEM, however,* The New York Times *editorial relies on the privately funded Bridgespan study from 2019, which claims that OPOs fail to recover an additional 28,000 organs a year is unrealistic. This estimate would only be possible if all potential organ donors said yes to donation, all their organs were medically suitable for transplant, and transplant centers accepted and successfully transplanted all their organs. The report notes that the figures represent the "full potential" of the system, assuming 100 percent donation rates and 100 percent organ utilization, an unfeasible measure in the medical field. OPOs nationwide are unwavering in their commitment to saving patients' lives and reducing the numbers on the waiting list.*

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[35] *https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.16442.*

[36] *https://oversightdemocrats.house.gov/news/press-releases/chair-krishnamoorthi-and-rep-porter-request-documents-regarding-potential.*

[37] *https://khn.org/news/article/national-academies-conflict-of-interest-congress-cites-khn-investigation-drug-waste/.*

[38] *https://www.finance.senate.gov/chairmans-news/wyden-grassley-cardin-young-raise-conflict-of-interest-concerns-related-to-national-academies-report-on-organ-donation-system.*

[39] *https://www.bing.com/ck/a?%21&p=156965a9111613cdJmltdHM9MTY3NTI5NjAwMCZpZ3VpZD0yOTI3ZTg4Zi1hNmEzLTZjZTctMGY0OC1mOTEzYTc4ZTZkMzMmaW5zaWQ9NTE3Mw&ptn=3&hsh=3&fclid=2927e88f-a6a3-6ce7-0f48-f913a78e6d33&psq=YEsandleadership&u=a1aHR0cHM6Ly95ZXNhbmRsZWFkZXJzaGlwLmNvbS8&ntb=1.*

[40] *https://www.finance.senate.gov/imo/media/doc/111722%20Wyden%20Grassley%20Cardin%20Young%20Letter%20to%20NASEM%20-%20conflicts%20of%20interest%20organ%20procurement.pdf.*

**Fact-check:** This one is, candidly, quite bizarre, as investigative reporting[41] has already highlighted that the AOPO/OPO talking points about Bridgespan are objectively, factually false. Similarly, a letter to the House Oversight Committee from a then-AOPO board member[42] clarified the same. For the abundance of clarity, I will repeat the fact-check below: AOPO is simply factually incorrect in its assertion that Bridgespan's study—which was based on peer-reviewed research[43] from leading researchers at the University of Pennsylvania, a former U.S. Surgeon General, and two OPO executives—assumes that "all [of every donor's] organs were medically suitable for transplant."

The study estimates a donor potential of 24,007 annually for the years 2009–2012, and an organ potential of just over 50,000 annually (see figure on page 5[44]). As a matter of simple math, this assumes an average of just over 2 organs transplanted per donor, representing an estimate far more conservative than the 3.45 medically suitable organs recovered per donor which AOPO states is industry average. The methodology for this study is clearly laid out in the peer-review publication. It is unclear why AOPO believes that the study assumes 8 organs per donor, or why they continue to assert it despite numerous fact-checks to the contrary.

Additionally, if AOPO does not like Bridgespan's research, it can also rely on a publicly funded study which HRSA funded and the OPTN performed, which found an even larger donor potential than Bridgespan did. Specifically, the deceased donor potential study,[45] published in 2015, found (see page 8): "Currently, organs for transplantation are recovered from about 8,000 deceased donors per year, potentially only one-fifth of the true potential. These findings suggest that significant donation potential exists that is not currently being realized." (Note: the donor potential today is now certainly even much higher, given the above-referenced spikes in donor potential driven by the opioid epidemic and other public health trends.)

Finally, I will also note the incredible irony (or gall?) of AOPO breathlessly asserting that Bridgespan's peer-reviewed 51,000 organ potential conclusion is "unfeasible," while in the very same statement self-celebrating their imagined future success of 50,000 transplants.

***AOPO wrote:*** *Too many patients have put their faith in our system for anyone to waste another minute avoiding responsibility or spreading falsehoods.*

**Fact-check:** Yes, agreed. Extensive investigative reporting[46] has found that AOPO, many individual OPOs, and UNOS have been responsible for the active spreading of misinformation and outright falsehoods.[47] As far as "avoiding responsibility," not a single sentence in AOPO's comment accepted any responsibility for anything. I wish they had.

**Appendix B: October 2022 Fact Check of UNOS Misinformation**

Dear Dr. McCauley,

As a 3-time kidney transplant recipient and patient advocate who has previously corrected misinformation from UNOS, I write this letter to:

- Clarify misinformation from your letter dated 28 October 2022, which a UNOS lobbyist is disseminating;
- Alert HRSA Administrator Johnson, the Senate Finance Committee, and the House Oversight Committee as well as Senator Booker and Congressman Jones, to ongoing UNOS efforts to disseminate such misinformation; and
- Most importantly, to express my disappointment at your condescending implication that Ben Jealous, a known civil rights icon and distinguished scholar who has published on organ donation reform issues (see here and here), was unable to understand the pro-patient, pro-equity congressional letter which he endorsed, in line with his previous advocacy.

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[41] *https://www.postbulletin.com/newsmd/organ-failure-the-gatekeeper-of-minnesotas-organ-transplant-system-is-underperforming-it-may-be-costing-lives.*
[42] *https://www.documentcloud.org/documents/20529240-wadsworthletter.*
[43] *https://pubmed.ncbi.nlm.nih.gov/28726327/.*
[44] *https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf.*
[45] *https://optn.transplant.hrsa.gov/media/1161/ddps_03-2015.pdf.*
[46] *https://www.postbulletin.com/newsmd/organ-failure-the-gatekeeper-of-minnesotas-organ-transplant-system-is-underperforming-it-may-be-costing-lives.*
[47] *https://www.pogo.org/investigation/2021/04/americas-transformative-new-organ-donation-rule-goes-into-effect-over-objections-from-monopolistic-contractors.*

On the last point, I note the irony that it was your letter to Mr. Jealous which demonstrated a shocking grasp of basic facts and context, which I will address below. People are dying while UNOS is spending its time protecting its reputation and contract, and I fear that should the day come that I need another kidney, I, too, will die if the status quo is allowed to continue.

Urgently submitted,

Molly McCarthy
3x Kidney Transplant Recipient
Vice Chair, OPTN Patient Affairs Committee
Redmond, WA

**You stated:** "The number of deceased donor transplants has increased every year for the last nine consecutive years to a record high of 41,356 transplants in 2021. The number of deceased donors has increased every year for the past eleven consecutive years, for a record high of 13,863 in 2021. Deceased organ donor recoveries have increased 58 percent since 2007."

**Fact-check:** These statistics are wildly devoid of context, as has been pointed out repeatedly in response to misleading UNOS lobbying. As former United States Chief Data Scientist DJ Patil has published, "To deflect criticism, OPOs and UNOS have lobbied aggressively to confuse the recent increases in organ donors from opioid and other external causes (*i.e.,* non-medical deaths like trauma, substance use, and suicide) with improved performance overall. If donation numbers are increasing, their argument goes, then the system must be performing well, and so the push for reform must be misguided. This is a cynical attempt to politically profit from the opioid scourge and other second-order effects of the deadly pandemic, mischaracterizing the data to evade accountability."

In fact, peer-reviewed data published in *JAMA* has found that, after controlling for increases in donation outside of OPO control (*e.g.,* public health trends), donation rates in recent years have not even kept pace with simple population growth.

The fact that UNOS does not seem to understand the drivers of donation, or even how to describe procurement practice in the U.S., calls into question its ability to identify and rectify system failures, and further underscores the need for additional data transparency and competition for the OPTN contract, the two very suggestions proposed by Senator Booker and Congressman Jones.

**You stated:** "A single study from 2003 as cited in the 'Dear Colleague' letter cannot responsibly be applied to the state of the organ donation and transplant system of 2022, much less serve as the basis for a system overhaul. A great deal has changed in nearly 20 years, and the study from 2003 does not reflect those reforms, new polices [sic], improvements and new data."

**Fact-check:** By no means is a single study from 2003 the "basis" for a system overhaul; it is rather one data point in a litany of evidence, and in the estimation of countless experts who have noted deadly system deficiencies. For example, the Senate Finance Committee, now more than 2 years into a bipartisan investigation into UNOS, recently published a report concluding that "From the top down, the U.S. transplant network is not working, putting Americans' lives at risk."

Similarly, the United States Digital Service (USDS) published a scathing report about the state of UNOS's technology entitled "Lives Are at Stake," and determined that "it has become apparent that the organ transplantation system in this country is not set up to enable the best outcomes for patients waiting for lifesaving transplants. In order to properly and equitably support the critical needs of these patients, the ecosystem needs to be vastly restructured."

The reforms called for in the congressional sign-on letter are broadly supported by propatient groups including the National Kidney Foundation, American Society of Nephrology, Global Liver Institute and Organize; equity leaders including the ACLU, Just Equity for Health, Health Justice, Empower Her Health, and the Institute for Antiracism in Medicine; and editorial boards including *The New York Times;* as well as the House Appropriations Committee and leaders from the House Oversight Committee and Congressional Black Caucus.

In fact, perhaps most interestingly, the reason that there have not been more peer-reviewed studies on inequitable care provision for patients of color since 2003 is that the United States is unique among mature international transplant systems in its failure to make transparent the data necessary to evaluate such OPO performance. Additionally, based on other proxy points, there is every reason to believe this

inequitable care persists. For example, based on the most recent data available from CMS, there is a 10x variability in OPO recovery rates among Black donors. If UNOS is objecting to opening OPO data, as called for in the congressional letter you object to, that seems designed to prevent this very analysis, thereby continuing to mask such inequities. Any position against opening OPO data is antithetical to patient needs.

**You stated:** "The results of new organ allocation policies have shown large gains in access to transplant for wait-listed patients of color. One report shows significant increases in the number of kidney transplants for key populations, including a 23-percent gain for Black patients, 31 percent for Hispanic patients, and 21 percent for Asian patients."

**Fact-check:** Per above, this is reflects a complete misunderstanding of the role public health trends—including increases in opioid deaths, gun deaths, fatal car accidents, and suicides as second-order effects of the COVID pandemic—which have increased the absolute number of organ donation eligible deaths.

Additionally, some of the increase also appears to have resulted from increased public scrutiny of the organ donation system, as well as CMS's recent regulatory interventions to hold OPOs accountable, both of which UNOS has vehemently opposed, including through untoward tactics such as the dissemination of misinformation.

**You stated:** "The assertion that an additional 28,000 transplants are possible reflects a poor understanding of how donation works and reveals a faulty assumption that every person who has died in a hospital is a 'potential donor,' even if they were not medically cleared to be an organ donor. Less than 1 percent of all deaths in the U.S. occur in ways clinically compatible with organ donation; people who die of cancer, sepsis, certain infectious diseases, or organ failure cannot be cleared for donation by the OPO based on medical criteria established by transplant physicians for the safety of their patients."

**Fact-check:** This is objectively false. The 28,000 number in no way assumes that every person who dies in a hospital is a "potential donor." The research itself, which was peer-review published by leading researchers, a former United States Surgeon General, and two OPO executives, explains that "these estimates were compared to patient-level data from chart review from two large OPOs" and found that "among 2,907,658 inpatient deaths from 2009–2012, 96,028 (3.3 percent) were a "possible deceased-organ donor." The methodology, which your letter entirely misrepresents, is clearly laid out in Figure 1 of the peer-review analysis.

The 28,000 number is significantly more conservative than UNOS's own analysis, funded by HHS, which found in 2015 (see page 8) that: "Currently, organs for transplantation are recovered from about 8,000 deceased donors per year, potentially only one-fifth of the true potential. These findings suggest that significant donation potential exists that is not currently being realized."

The mischaracterization of this research seems to parrot lobbying points from an OPO special interest misinformation campaign, including which the Project on Government Oversight characterized as "replete with personal attacks, and political maneuvering"—as well as a particularly odious Astroturf campaign run by a lobbyist for the New Jersey OPO—and which is currently animating a House Oversight Committee investigation into OPO antipatient lobbying.

Lastly, the research identifying 28,000 additional potential transplants—which you seem to, albeit based on a complete misunderstanding of the underlying, reject as impossible—calculated those numbers based on a total organ of just over 50,000 annually (see Figure 2). I note the irony that UNOS has never once publicly rebuked AOPO's 50,000 organs campaign.

As a matter of basic math and logic, I do not understand how you can simultaneously believe that 50,000 organs can be wholly impossible as a denominator in peer-reviewed research, and yet laudable when promoted in industry lobbying materials as a numerator. I also highlight previous fact-checks of these same industry talking points which have been sent to other congressional offices.

**You stated:** "Our national, forty-two member board of directors is comprised of [sic] a broad, diverse cross-section of the community, and includes [sic] one quarter patient and donor affairs representatives, one quarter donation and transplant professionals, and half physicians and surgeons. Together with HRSA, the OPTN board serves as the voice of the community."

**Fact-check:** I note emails from UNOS's previous CEO Brian Shepard, which were unsealed by a Federal judge, revealing his belief that UNOS "do[es]n't have a real board." I also note that, far from being the "voice of the community," that UNOS has lobbied against accountability reforms championed by "every major patient group" engaged in transplant advocacy—including leadership and members of the OPTN's own Patient Affairs Committee—and that Senate Finance Committee testimony from UNOS board members has detailed a culture of retaliation and retribution.

**You stated:** "In February 2022, the OPTN welcomed a report from the National Academies of Science, Engineering, and Medicine (NASEM), a congressionally mandated 2-year study including a diversity of stakeholders, donation and transplant experts, and patient and donor perspectives."

**Fact-check:** The NASEM organ donation study is under investigation from the House Oversight Committee for conflicts of interest among its committee members, which included two past UNOS presidents. This appears to be just another example in a long history of UNOS attempts at regulatory capture, dating back to at least 1999, when *Forbes* characterized UNOS as a "cartel" and "the Federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly."

**You stated:** "In contrast to this approach, the development of the U.S. Digital Service's unreleased report referenced in this letter was conducted without our engagement, and was developed without review of the OPTN, UNOS or any of its technology infrastructure."

**Fact-check:** The reason that the USDS report was conducted "without [UNOS's] engagement" is because, as *The Washington Post* reported, "UNOS has not allowed anyone in government to analyze its code base, instead providing only the English-language description of it, known as pseudocode, officials said. That surprised Digital Service analysts; it was the only time that its engineers' request to inspect code used by government agencies and contractors has been refused on nearly 100 occasions, according to the former White House adviser who was involved but not authorized to speak."

This seems to be part of a larger pattern of UNOS obstructionism, including, as the Senate Finance Committee report detailed, "Resistance to Requests for Information and a Valid Subpoena."

**You stated:** "The challenges that face the system are complex and multifaceted, and no one entity can address them all."

**Fact-check:** This is actually correct, and presumably is precisely why, in part, the congressional letter from Senator Booker and Congressman Jones urges HHS to demonopolize the OPTN contract, in line with so many leaders in Congress as well as external stakeholders.

Dr. McCauley, in closing and as discussed at our virtual meeting on October 13, 2022, I continue to be extremely concerned at what appears to me to be an utter lack of accountability on the part of UNOS to face its failings. It's hard for me not to read your letter and see it as anything more than a purposeful effort to mislead investigators, patients and the general public. As a recipient and on behalf of patients across this country, I implore you and the UNOS leadership to stop investing your time in these evasive letters, tactics and misleading PR, and instead to invest the time in addressing the issues for which UNOS is being investigated

**Appendix C: OPTN Patient Affairs Committee Statement for the Record for Senate Finance Committee August 2022 Hearing**

August 2, 2022

Dear Members of the Senate Finance Committee,

As the leaders of the OPTN Patients Affairs Committee (PAC), we are reaching out to share our experiences on the committee that we believe indicate a systemic failure of UNOS to serve patients as the OPTN. This is all the more urgent in light of investigative reporting from the Washington Post.

Antiquated technology and an apathetic culture cause patients to languish with incomplete and often incorrect information, and leave people to die every day on the list. OPTN PAC members have raised these points often with UNOS leadership, and have seen our calls for reform ignored. We have been aghast at the absolute failure of UNOS to operate the practice and business of transplant, and to acknowledge—

much less effectively serve—patients who are waiting and dying on the organ wait list.

On July 28th, in preparation for the upcoming August 3rd Senate Finance Committee hearing into UNOS, PAC leaders received an email from UNOS CEO, Brain Shepard, referring to your investigation, in which he makes four assertions that UNOS has shared with the committee.

We wish to correct the record for your urgent consideration.

> Shepard: "Our IT system remains safe, secure, and routinely meets and surpasses Federal standards."

*The Washington Post* reported: "The system for getting donated kidneys, livers and hearts to desperately ill patients relies on out-of-date technology that has crashed for hours at a time and has never been audited by Federal officials for security weaknesses or other serious flaws."

We hope the committee asks UNOS how many patients have died due to the inability to match organs during downtime, as well as other technological inefficiencies such as data error due to manual entry, as well as how many patient life-years have been lost due to delays in organ transportation. That said, given the lack of transparency in the UNOS tech system, it is difficult to imagine anyone at UNOS could answer this question with any confidence.

> Shepard: "We have worked together as a community to improve the transport of organs with innovative, evidence-based products."

The UNOS transportation record on organs is woefully—and fatally—inadequate, as outlined by investigative reporting from *Kaiser Health News*—as well as cases brought before the Senate Finance Committee. Put simply, UNOS operates as an antiquated, closed system that keeps out external innovators that could help patients with better tools and services.

> Shepard: "Our committees and staff are proud to work collaboratively with all members to serve as partners in improvement."

PAC members have often sought—and not received—clarity on how patient input is used. When PAC takes clear positions (such as the need to fast-track proposed changes to using eGFR results to list people of color), UNOS has refused to act. Compare this to a recent UNOS fast track process that addressed a hardware defect in a mechanical heart that went through in less than a month. Black patients deserved this kind of speedy remedy when eGFR was proven to have racial bias. We also note *Washington Post* reporting that UNOS's policymaking processes have been so divisive that they have "spark[ed] open conflict" among OPTN members.

> Shepard: "The system we are all so honored to be a part of just surpassed 41,000 transplants in 2021, while continuing to expand equitable access to transplant."

UNOS obscures its underperforming record behind recent increases in organ donation rates that have resulted from tragic spikes in opioid overdoses, gun deaths, and car accidents, including as second-order effects of the COVID pandemic, not from UNOS's own performance. See the former U.S. Chief Data Scientist making this point in *MedPage,* and research in the *Journal of the American Medical Association* finding that, after controlling for public health trends and scientific advancements which have increased the size of the donor pool, organ donation rates have not even kept pace with population growth.

The alarming revelations in *The Washington Post* (antiquated technology; covering for failures of Organ Procurement Organizations; and lack of cooperation with the government, even devolving to UNOS having "threatened to walk away") lead us to believe that UNOS has proven itself incapable of functioning as the OPTN.

We ask that you ensure that the Federal Government makes the fast-approaching contracting OPTN cycle competitive for the first time since the original OPTN contract was awarded in 1986, opening critical functions up to best-in-class innovators across the country; and we implore you to ensure that UNOS does not hold patients hostage in the process.

We urge you to continue with your oversight and institute urgent reforms that will literally result in lives saved.

Signed,

Garrett Erdle
Chair, OPTN PAC Living Kidney Donor
Alexandria, VA

Molly J. McCarthy
Vice Chair, OPTN PAC
3-time Kidney Transplant Recipient
Redmond, WA

Chris Yanakos
Former Member of OPTN PAC
Living Liver Donor, Caregiver and Donor Family Member
Pittsburgh, PA

Steve Weitzen
Region 2 Representative, OPTN PAC Heart Recipient
Randolph, NJ

Calvin Henry
Region 3 Representative, OPTN PAC Lung Recipient
Dacula, GA

Lorrinda Gray-Davis
Region 4 Representative, OPTN PAC Liver Recipient
Yukon, OK

Julie Spear
Region 8 Representative, OPTN PAC Donor Family Member
Boulder, CO

Eric Tanis
Region 10 Representative, OPTN PAC Liver Recipient
Gary, IN

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## QUESTIONS SUBMITTED FOR THE RECORD TO MOLLY J. MCCARTHY

### QUESTION SUBMITTED BY HON. JOHN THUNE

#### IMPACT OF DECERTIFICATION ON RURAL AREAS WITH AN OPO MONOPOLY

*Question.* I understand your concerns outlined in your opening statement regarding the performance of OPOs that have received a Tier 3 grade.

Could you expand on what you think the impact would be of decertifying Tier 3 OPOs in areas where they are the only ones serving transplant centers? How could the lack of an OPO nearby affect transplant centers' ability to do their important work, particularly in rural areas? And how could we mitigate this risk?

Answer. Any Tier 3 OPO is already failing patients and its surrounding area, so decertifying them and offering that coverage area to a high-performing, Tier 1 OPO would be an improvement in service to both donor families and patients waiting on the list, AND would save lives. The counterfactual is also true: any delays in decertifying failing OPOs, or any weakening of standards, results in lives being lost.

Additionally, if a Tier 3 OPO is replaced by another, higher-performing OPO, that OPO would assume the relationships with all transplant centers in that area, meaning that there would never be a situation of any transplant center ever running with a "lack of an OPO." CMS has stated this explicitly in the 2020 final rule.

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### QUESTION SUBMITTED BY HON. SHELDON WHITEHOUSE

*Question.* OPOs are only one of two major programs left in Medicare that operate on what's called "cost-reimbursement basis," meaning they are reimbursed by taxpayers for whatever dollars they spend, rather than for the value they deliver. This incentivizes them to spend more money rather than to deliver high quality care for patients. The Federal Government has moved away from cost-reimbursement almost everywhere else in health care.

How do you suggest we move away from "cost-reimbursement basis" in organ transplantation?

Answer. OPOs are one of only two major Medicare programs which still run on a cost-reimbursement basis, an archaic mechanism which is inherently susceptible to abuse, and does not lead to good health outcomes for patients. This is precisely why HHS has moved away from cost-reimbursement in almost all other areas of health care, and why it should do so for OPOs as well. Your leadership on value-based care provides an excellent roadmap for how HHS can consider paradigmatic reforms in OPO reimbursement.

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QUESTIONS SUBMITTED BY HON. TODD YOUNG

*Question.* Is there any formal policy in place regarding when and how to notify patients of any status change on the organ donation waiting list?

Answer. No, there is no policy in place to notify patients of a change in status, nor is there any system-wide operational policy to ensure patients on inactive are moved back to active. This results in patients unknowingly not being considered for organ offers, with no assurance that they'll be moved back to active state.

*Question.* What would be the most effective way to notify patients of their waiting list status?

Answer. Most effective would be a simple phone app or web portal where patients could view their real-time status. However, to create such innovations, HHS must replace UNOS as its contractor, given its complete technological ineptitude, as experienced by patients and identified by the United States Digital Service.

*Question.* What, if any, additional information would be useful for patients to have access to regarding their position on the waiting list?

Answer. Most useful would be their status in terms of active versus inactive, where they sit on the waiting list, whether they've received any offers and why those offers were rejected, and projected wait time for a successful match. It would be even more helpful to be told of other centers that may be able to get them transplanted more quickly. Most important, however, is shortening the waiting time for each patient, which would require increasing the number of transplanted organs every year. To do so, HHS needs to strongly enforce the OPO rule, without any weakening or delay, as well as move swiftly to replace UNOS with more competent contractors.

*Question.* How many patients are listed as inactive?

Answer. The OPTN Patient Affairs Committee (PAC), of which I serve as the vice chair, has been told that 40 percent of the patients on the wait list are inactive.

*Question.* Is there a clear reason recorded for why a patient has been listed as inactive?

Answer. PAC has not been provided with any documentation, but we know patients may be listed as inactive in cases of planned travel (*e.g.,* where their destination would make it impossible for them to return to their transplant center in time to receive an organ), active infection, or other health complexities that may make it impossible for them to receive. Sadly, we also know that some patients are listed as inactive due to clerical error, as Ms. Goldring testified in her own particular case. This is why patients are rightly demanding to have a method to look at their own status, so they can take ownership of correcting errors.

*Question.* Is that reason communicated to the patient?

Answer. Not systematically, no. A patient may be told if they're currently being treated as a hospital inpatient, but there is no policy or system-wide practice to notify patients of any change in their status.

*Question.* Is there any regular review/oversight by UNOS or others to ensure a patient listed as inactive is aware of their current status?

Answer. No, there is not. Another important piece to consider on this topic is that when patients are moved to inactive, not only are they not able to receive organ offers, but they also stop accruing time on the wait list, which affects their rank on the list. The longer a person waits while they are considered "active," they get "credit" for that waiting time, which increases their chance of receiving an offer. When patients are put into inactive status, that accumulation of "credit" pauses, which means they likely wait longer and get sicker, ultimately reducing their

chances of a successful transplant. This is an added tragedy of patients being incorrectly listed as "inactive," as was the case for Ms. Goldring.

*Question.* Is there any regular review/oversight by UNOS or others to ensure patients listed as inactive are appropriately designated as inactive, especially over an extended period of time?

Answer. No, this is left entirely to the transplant hospitals with no required or documented practice to be followed to ensure accuracy, fairness and equity.

*Question.* Are patients provided appropriate information and resources to determine any next steps needed to return to active status?

Answer. Not at all. UNOS has completely failed them.

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PREPARED STATEMENT OF MATTHEW D. WADSWORTH,
PRESIDENT AND CEO, LIFE CONNECTION OF OHIO

Chairman Cardin, Ranking Member Daines, and members of the committee. My name is Matthew Wadsworth, and I serve as the president and CEO of Life Connection of Ohio, the Organ Procurement Organization responsible for facilitating organ donation in northwest and west-central Ohio.

My job is to help as many patients as possible receive lifesaving transplants. Most days, I try to do that through continually improving practice at our OPO. But to affect meaningful change at scale, we need Federal policy reforms.

The current system is broken. OPOs have geographic monopolies, which has made too many sluggish and complacent, at the expense of patients' lives. There are absolutely no guard rails in place to ensure that OPOs are adequately serving patients, and many of them aren't. And yet the Centers for Medicare and Medicaid Services (CMS) has never once decertified an OPO for performance failures.

In recent years, it appeared as if things may finally be starting to change. CMS finalized new regulations in 2020 to hold OPOs accountable for the first time in 40 years. Three years later CMS has still not taken the steps to provide OPOs with any guidance on how the rule will be enforced, or any indication that it will support meaningful competition to ensure that patients are only served by the best OPOs. Furthermore, CMS has remained silent on waivers filed by hospitals who want to work with higher performing OPOs immediately instead of waiting until 2026.

Additionally, CMS has not yet taken any apparent steps to close a dangerous loophole in the rule which gives OPOs credit for recovery of pancreata that are never transplanted, pancreata labeled for research, and which many OPOs have begun to flagrantly exploit, evidenced by over a 400 percent increase in the number placed for research since this new rule.

This means that OPOs that are failing at their central task—recovering organs for transplant—can avoid accountability simply by recovering one organ and labeling it research. The fact that executives in our industry lack the moral compass not to exploit this loophole is incredibly perverse; I am deeply appreciative of this committee for investigating this abuse.

This should be proof positive of a perhaps self-evident notion: OPOs respond to their incentive structure. Unfortunately, those incentives are currently entirely misaligned with what patients need.

This is not only regulatory, but financial; the OPO industry, including OPO boards, are often rife with financial conflicts of interest, which means OPOs all-too-often spend taxpayer resources on special interest projects rather than on investing in organ recovery.

Another issue that deserves urgent attention is the lack of safety guard rails. There isn't even a standardized process for declaring brain death across the country. The reality is that the quality of care that donor patients and donor families receive depends on where in the country someone dies.

The fact that the organ procurement system has been so broken for 40 years speaks directly to the complete abandonment of patients by the organization at the top of the system—UNOS.

Even now, more than 3 years into this committee's investigation into UNOS's failures, UNOS has transitioned from an organization that is inept and possibly incom-

petent to one that takes an active role in preventing patients from being transplanted.

Take, for example, recent reporting in *The Washington Post* that UNOS is proposing changes to its terms of service which disallow external organizations from conducting data-driven research into the most effective ways to place organs for transplantation, even as organ discard rates skyrocket.

UNOS only appears to be doing this to interfere with the business of a potential competitor for its contract, showing that once again the system has been held hostage by a terrible actor—one which values its own contract far above the lives of the patients we are meant to serve. This is a perfect microcosm of the problem: at every turn UNOS stifles innovation and hides deadly failures, all to keep its monopoly contract.

There are three things the Department of Health and Human Services needs to do immediately to ensure patients receive safe and high-quality organ procurement care:

(1) Prepare to enforce the OPO rule, without weakening or delaying it, including closing the pancreas for research loophole, publishing guidance on how the rule will be enforced, and requiring the publication of OPO process data.
(2) Break up the OPTN contract and allow for competition so that patients are served by the best in areas such as technology, logistics, data analytics, business development, and process improvement.
(3) Eliminate board and financial conflicts that exist in our industry that prevent OPOs and any OPTN contractors from investing their dollars in areas that grow organ donation and transplantation.

I commend this committee for introducing legislation to finally break up this monopoly, and I stand ready to work with you in any way possible to ensure that this bill passes. It is the only way this industry will be able to save more patients' lives.

**Appendices Below**

- Appendix A: "Temporal Changes in Procurement of Pancreata for Research," *American Journal of Transplantation,* May 2023.
- Appendix B: Fact-Check of AOPO Misinformation Sent to House Oversight Committee, Spring 2021, as Published by the Project on Government Oversight.

**Appendix A: "Temporal Changes in Procurement of Pancreata for Research," *American Journal of Transplantation,* May 2023**

Title Page

Manuscript title: Temporal Changes in Procurement of Pancreata for Research

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Abbreviations:

Organ procurement organizations (OPOs)
Centers for Medicare and Medicaid Services (CMS)

**Organ Procurement and Transplantation Network (OPTN)**
**United Network for Organ Sharing (UNOS)**

To the Editor:

Organ procurement organizations (OPOs) are the Federal contractors who manage all aspects of deceased organ donation, including procurement of organs from deceased donors for research purposes. In 11/20/2020 the Centers for Medicare and Medicaid Services (CMS) updated the "Final Rule" for OPO Conditions for Coverage, which included redefining an organ donor for regulatory purposes as an individual with: (a) ≥1 organ transplanted; or (b) pancreas procured for research or islet cell transplantation (only performed under research protocol).[1–3] We sought to evaluate for temporal changes in procurement of pancreata for research purposes, and whether there were changes that coincided with the CMS rule change.

We conducted a retrospective cohort study using data from the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS). We evaluated data over a 10-year period from 1/1/2013–12/31/2022. Pancreata donated for research were identified based on OPTN/UNOS codes, and pancreas-only donors were those for whom a pancreas was procured for research, and no other organs were donated. OPTN/UNOS data does not include data on the disposition of the organ, the specifics of the research study, and whether the research was related to all aspects of the pancreas, or solely islet sell isolation.

Based on the new CMS definition of a deceased donor, there was a steady increase in the number of donor with ≥1 organ transplanted, increasing from 11,578 in 2020 to 12,753 in 2022 (Figure 1a), with a more than tenfold from 2020 (n=25) to 2022 (n=353) in the number of individuals classified as a donor solely because their pancreas was procured for research (Figure 1a). This phenomenon of increased organ procurement for research purposes was limited to pancreata, despite stable numbers of other organs procured for research (data not shown).

The increase in the number of pancreata procured for research varied across OPOs (Figure 1b). Of the 57 OPOs, 8 (14.0 percent) procured >100 pancreata for research in 2022, accounting for 1,548 (58.2 percent of the national total) pancreata research procurements. These 8 OPOs were geographically dispersed. The procurement of pancreata research-only donors was also geographically dispersed and concentrated in a small number of OPOs, with nine OPOs procuring ≥20 pancreas research-only donors in 2022, accounting for 242 (68.6 percent of the national total) pancreas research-only donors (Figure 1c). One OPO (OneLegacy, CAOP) had 74 pancreas research-only donors in 2022, accounting for 21 percent of the national total.

Over the last 2 years, there has been a striking increase in the number of pancreata procured for research. As transplant professionals, we are supportive of advancements in the field that may ultimately increase the number and/or longevity of organ transplants. However the temporal relationship to the CMS rule changes merits further study (*e.g.,* specifics of research studies, disposition of research pancreata) This would include potential re-evaluation of the CMS OPO final rule to determine whether an unintended consequence of the Federal rule change is increased procurement of research pancreata to improve an OPOs metric without increasing the number of lifesaving transplants.

**Acknowledgments**

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**Figures and Figure Legends**

1. Figure 1 (three panels):

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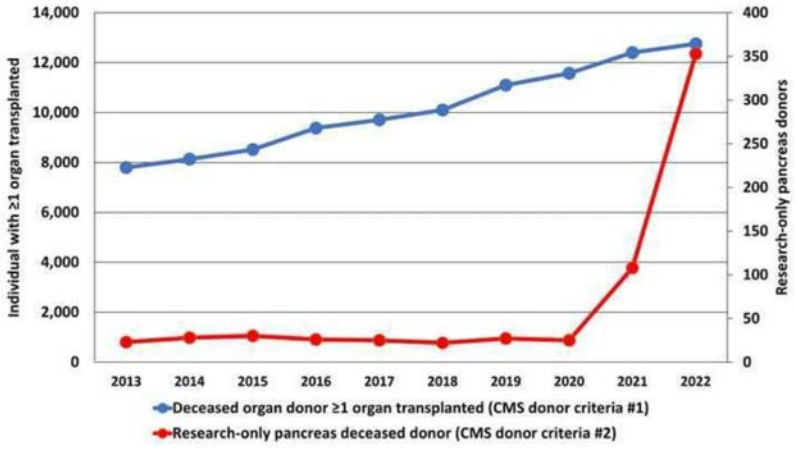
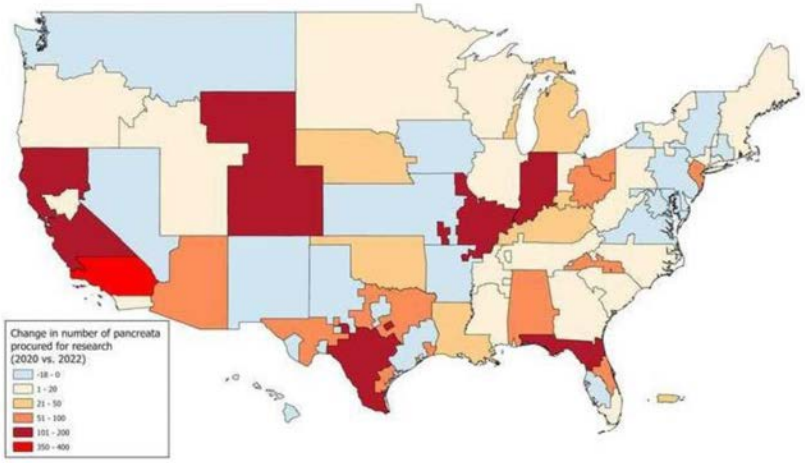
[1] Centers for Medicare and Medicaid Services. Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS–3380–F. Accessed January 19, 2023, *https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos.*

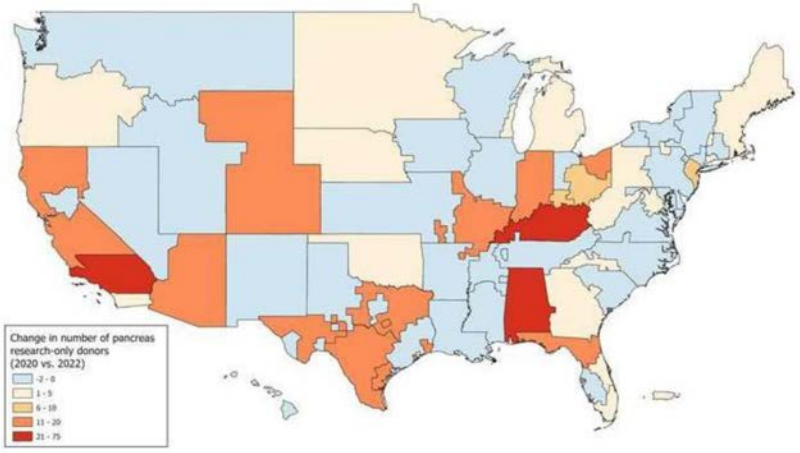
[2] Heinze G, Wallisch C, Dunkler D. Variable selection—A review and recommendations for the practicing statistician. *Biom J.* May 2018;60(3):431–449. doi:10.1002/bimj.201700067

[3] U.S. Department of Health and Human Services. Advancing American Kidney Health. Accessed January 19, 2023, *https://aspe.hhs.gov/sites/default/files/private/pdf/262046/AdvancingAmericanKidneyHealth.pdf.*

a. Figure 1a: Annual number of deceased donors based on CMS criteria of ≥1 organ transplant or a pancreas procured for research or islet cells from 2013–2022.
b. Figure 1b: OPO-level changes change in total pancreata procured for research in 2022 vs 2020.
c. Figure 1c: OPO-level changes in the number of individuals classified as an organ donor solely due to having their pancreas procured for research in 2022 vs 2020.






**Appendix B: Fact-Check of AOPO Misinformation Sent to House Oversight Committee**

Dear Chairman Krishnamoorthi and Representative Porter,

I write today to thank you for your much-needed oversight of the U.S. organ procurement system in effort to ensure it is working effectively and transparently on behalf of patients. Given COVID–19 leaves patients with organ failure particularly at risk, and the disease itself is also damaging patients' organs, and given your point that OPO is an urgent health care equity issue, your investigation is particularly important to some of our country's most vulnerable patients.

I am an Organ Procurement Organization (OPO) CEO and currently a member of the Association of Organ Procurement Organizations (AOPO), which also makes me an AOPO board member. As such, I understand that AOPO recently responded to the committee's oversight letter, and I wanted to clarify that I had not seen AOPO's response before it was sent; I do not feel it represents my views, nor do I feel it is grounded in science.

Given this, I felt a duty to clarify misstatements and misrepresentations contained within AOPO's letter. The irony is not lost on me that, in response to the committee's inquiry about bad-faith lobbying, AOPO's 8-page letter necessitated a 10-page fact-check.

I hope to serve as a resource in your ongoing inquiry. Patients deserve transparency and accountability.

Signed,
Matt Wadsworth

***AOPO wrote:*** *In 2020, OPOs increased organ donation by 6 percent, which makes 10 consecutive years of growth over which time organ donation has increased by 58 percent. As a result of these improvements since 2010, there are now, on average, 110 lifesaving, deceased donor organ transplants per million population, and 128 living and deceased transplants per million.*

*Fact check/relevant context:* As has been well-documented, and has certainly been pointed out to AOPO repeatedly (see fact-check letter [1] from the former Chief Technology Officer of the U.S. Department of Health and Human Services (HHS)), the increase in donation in absolute terms over the last 10 years does not owe to OPO improvements, but rather an expanding donor pool. In fact, peer-reviewed research [2] finds: "it is indisputable that nationally the increased number of donors is almost wholly attributable to the drug epidemic, and reflects the byproduct of a national tragedy, rather than an improved system to be celebrated."

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[1] *https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_b7d0e7fec4754ae0a8ec9d0bb65b4417.pdf.*

[2] *https://onlinelibrary.wiley.com/doi/full/10.1111/ctr.13755.*

Peer-reviewed research in the *Journal of the American Medical Association* [3] from authors including DJ Patil, the former Chief Data Scientist of the United States under President Obama, finds that advancements in transplant science have also contributed to an expanding donor pool. In fact, after controlling for increases owing to the opioid epidemic, as well as transplant center advancements which have increased the absolute size of the donor pool, over the last 9 years it turns out the OPO industry has not even kept pace [4] with simple population growth.

This should not be surprising given the lack of structural incentives for OPO improvement and innovation. As *The Washington Post* editorial board [5] noted: "in a system in which [OPOs] have an effective monopoly on organ recovery within their zones, there are few incentives for them to improve unless decertification is a serious possibility."

While the OPO industry, on net, actually seems to have backslid over the last 10 years relative to donor potential, there have certainly been individual OPOs that exhibited improvement. As research finds, this has largely resulted from replacing underperforming OPO leadership,[6] as well as, tellingly, a response to the very oversight pressure that AOPO is fighting.

According to research [7] supported by Schmidt Futures and Arnold Ventures, "Since the [2019] executive order announcing the proposed new metrics and increased oversight, data show that OPO performance has already begun to improve, perhaps early evidence of the 'Hawthorne effect' (*i.e.,* increased scrutiny and observation by itself drives behavior change that leads to improved outcomes). That such gains were possible, and yet unmade prior to the executive order, underscores the importance for HHS to institutionalize such regulatory pressure for OPOs to improve performance."

I applaud the committee's active interest in oversight and reforms on behalf of patients, and would be happy to serve as a resource to support any current or future lines of inquiry.

Lastly, AOPO also includes living donor transplants per million population "as a result of [OPO] improvements." This is curious, as OPOs are in no way involved with living donation. In fact, there is anecdotal evidence to suggest that increases in living donation occur, at least in part, as a reaction to OPO failures.[8]

***AOPO wrote:*** *Your December 23 letter references a figure of 28,000 available organs from deceased donors that could be procured for transplantation, but ultimately are not transplanted. However, the non-peer reviewed consultant's report on which this number is based shows that it presumes many conditions which are unrealistic.*

*Fact check/relevant context:* As has been pointed out to AOPO before in previous fact-checks to misleading AOPO claims,[9] the 28,000 available organs number does, in fact, come from peer-reviewed research [10] coauthored by researchers from the University of Pennsylvania, a former Surgeon General of the United States, and two OPO executives, validated against administrative data voluntarily provided by two OPOs. Notably, in AOPO's public comment [11] to HHS regarding the then-proposed OPO rule, AOPO cited this very peer-reviewed research as the most accurate published estimate of donor potential (see page 497 [12]):

*"An important starting point is to define the donor pool. Published estimates range from 10,500 to 24,000 to 37,000 to a staggering 272,000; however, literature and published studies based on review of hospital records suggest a figure closer to 20,000 to 24,000."*

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[3] *https://jamanetwork.com/journals/jamasurgery/article-abstract/2771051.*
[4] *https://jamanetwork.com/journals/jamasurgery/article-abstract/2771051.*
[5] *https://www.washingtonpost.com/opinions/many-die-waiting-for-organs-the-trump-administration-could-help/2020/07/31/77e3a102-dfd6-11e9-b199-f638bf2c340f_story.html.*
[6] *https://jamanetwork.com/journals/jamasurgery/article-abstract/2765994?appId=scweb.*
[7] *https://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-dec2020-update.pdf.*
[8] *https://nypost.com/2020/01/08/americas-deadly-failure-on-organ-donations/.*
[9] *https://static1.squarespace.com/static/53bafd3ce4b0ae714af7153f/t/5dc9a78c0665e33d542575c4/1573496733189/GLI_Azar+Verma+_OPO+103019-2.pdf.*
[10] *https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.14391.*
[11] *https://www.dropbox.com/s/ppnjkdhxav64gkm/Comments%20-%20CMS%20Proposed%20OPO%20Outcome%20Measurements.pdf?dl=0.*
[12] *https://www.dropbox.com/s/ppnjkdhxav64gkm/Comments%20-%20CMS%20Proposed%20OPO%20Outcome%20Measurements.pdf?dl=0.*

As noted in AOPO's citation, the latter figure, which AOPO notes is based on review of hospital records, refers to the research from which the 28,000 figure was derived.

Additionally, as has also been previously pointed out to AOPO, the write-up[13] of this study also specifically States that the donor potential research is meant to inform the scale of what is possible: "It is important to note that the above figures represent the 'full potential' of the system, assuming 100-percent donation rates and 100-percent organ utilization. Achieving even 20-percent of this potential improvement would result in approximately 6,000 lives saved per year and $2.6 billion in taxpayer savings over 5 years."

These projections are in line with HHS's projections for expected increase in donations resulting from the increased accountability brought by the new metrics. If the 58 percent increase in donations over the last 10 years were truly the result of OPO improvements (rather than an ever-growing donor pool), it is unclear why AOPO seemingly believes a relatively modest prospective increase would be unattainable.

***AOPO wrote:*** *To achieve this [28,000] number of organs, all of the following conditions would be necessary:*

- *100 percent of donor hospitals would have to notify their local OPO in a timely manner of 100 percent of all potential organ donors.*
- *100 percent of the potential donors would need to be registered as an organ donor or alternatively 100 percent of families of potential donors must approve the donation. Currently, CMS requires a conversion rate of 75 percent.*
- *100 percent of all eight organs must meet medical suitability for transplant.*
- *100 percent of organs must be accepted by the transplant centers to which they are offered. Currently, on average 3.45 organs recovered from a donor are considered medically suitable and accepted for transplantation.*

*While we recognize there is room for improvement in the number of available organs, basing a regulation on the assumption of 100 percent success rates in each of these categories is simply unrealistic for OPOs, donor hospitals, and transplant centers to achieve.*

*Fact check/relevant context:* As noted above, neither the study AOPO references, nor HHS's final rule—which was based on HHS's independent analysis—presume that OPOs can or should recover 100 percent of potential. As such, it is not necessary to respond to every point above.

It is important to note, however, that AOPO is simply factually incorrect in its assertion that the donor potential study in question assumes that "100 percent of all eight organs must meet medical suitability for transplant." The study estimates a donor potential of 24,007 annually for the years 2009–2012 (see Figure 1[14]) (note: this number has since increased for reasons explained above), and an organ potential of just over 50,000 annually (see Figure 2[15]).

As a matter of simple math, this assumes an average of just over 2 organs transplanted per donor, representing an estimate far more conservative than the 3.45 medically suitable organs recovered per donor which AOPO states is industry average. The methodology for this study is clearly laid out in the peer-review publication. It is unclear why AOPO believes that the study assumes 8 organs per donor.

In response to AOPO's assertion that "100 percent of donor hospitals would have to notify their local OPO in a timely manner of 100 percent of all potential organ donors", I note a quote from Tom Mone, CEO of the OPO based in Los Angeles, in *The New York Times:*[16] "If I can't engage the hospitals and inspire them and motivate them to actively participate in donation, and we are not performing at the expected levels, the buck has to stop with our leadership." I agree with Mr. Mone on this point.

Regarding the AOPO position that many organs that OPOs recover are not ultimately utilized by transplant centers, please see a report[17] from alumni of the

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[13] *https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf.*
[14] *https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.14391.*
[15] *https://www.med.upenn.edu/goldberglab/data.html.*
[16] *https://www.nytimes.com/2018/07/11/nyregion/organ-donation-is-desperate-in-new-york.html.*
[17] *https://bloomworks.digital/organdonationreform/OPO-Best-Practices/#drop-off-point-5-when-an-opo-does-not-place-an-organ-while-it-is-still-viable.*

United States Digital Service regarding the myriad reasons organs, even once recovered, are not transplanted. While some percentage of these discards do owe to transplant center behavior, much also owes to differential ability and effort from OPOs in placing organs, a dynamic which CMS noted in the Final Rule,[18] and which AOPO continually minimizes or outright ignores.

Additionally, much of the problem also results from the deeply outdated UNOS technology system[19] on which organ offers are made, and I note the House Appropriations Committee's 2020 Report[20] calling for increased competition for the Organ Procurement and Transplantation Network (OPTN): "The committee supports HHS's Request for Information for the technology system over which these organ offers are facilitated and encourages HHS to promote competition for this contract."

Finally, AOPO's assertion that the regulation is "bas[ed] on . . . the assumption of 100-percent success rates in each of these categories is simply unrealistic for OPOs, donor hospitals, and transplant centers to achieve" is nonsensical. As AOPO presumably—although perhaps not necessarily—understands, the new regulation simply evaluates OPOs compared against each other. This is in effort to address the unexplainable performance variability of 470 percent[21] across OPOs.

In no way is the regulation based on the assumption that any OPO will achieve 100-percent success rates. In actuality, it is this very recognition that informs the rationale for comparing OPOs relative to each other rather than on an absolute basis.

***AOPO wrote:*** *The prevalence of organs being lost or delayed on commercial flights or other transportation is extremely rare.*

*Fact check/relevant context:* Investigative reporting from *Kaiser Health News* reviewed 8,800 organ and tissue shipments handled by the UNOS Organ Center and found, "between 2014 and 2019 nearly 170 organs could not be transplanted and almost 370 endured 'near misses,' with delays of 2 hours or more, after transportation problems."

*These data indicate that multiple organs are lost or damaged in transit every month, and have been for years.* In total, about 7 percent of all organs shipped by the UNOS Organ Center experience transportation problems, which means, as noted by the American Society of Nephrology: "UNOS is approximately 15 times[22] as likely to lose, damage or mishandle an organ as the airline industry is your luggage."

Organs handled by the UNOS Organ Center represent only a small subset of all organs shipped, with the balance of cases handled by the OPO, either directly or via a courier engaged by the OPO. Research[23] indicates that this process is highly variable and often inefficient.

***AOPO wrote:*** *In addition, through the adoption and deployment of perfusion technologies, OPOs are using innovative techniques to help drive substantial increases in donation and transplantation of organs. We now have normothermic perfusion devices for hearts, lungs and livers. These technologies, which preserve organs for longer periods of time, are especially important during Donation After Circulatory Death ("DCD")—which refers to recovery of organs for the purpose of transplantation from patients whose death was confirmed using cardio-respiratory criteria. In 2020, DCD donations increased by 18.6 percent over 2019 and this trend will continue with advancements in perfusion technologies.*

*Fact check/relevant context:* This seems to validate that the increases in donations AOPO cites are, at least in part, driven by scientific advancements[24] driven by transplant centers, rather than by OPO performance improvements. In most cases, the perfusion machines AOPO references are owned and operated by transplant centers, rather than OPOs.

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[18] *https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf.*

[19] *https://bloomworks.digital/organdonationreform/Technology/.*

[20] *https://appropriations.house.gov/sites/democrats.appropriations.house.gov/files/LHHS%20Report%20-%20GPO%20-%207.8.20.pdf.*

[21] *https://bloomworks.digital/organdonationreform/Summary/.*

[22] *https://www.kidneynews.org/policy-advocacy/leading-edge/kidney-donation-transportation-issues.*

[23] *https://bloomworks.digital/organdonationreform/OPO-Best-Practices/#drop-off-point-7-when-an-opo-fails-to-transport-an-organ-to-its-destination-in-a-timely-manner-or-if-on-arrival-the-organ-is-unsuitable-for-the-intended-recipient.*

[24] *https://www.modernhealthcare.com/safety-quality/hepatitis-c-treatments-could-expand-organ-donor-pool-study-suggests.*

***AOPO wrote:*** *OPOs are highly regulated organizations held to accountable standards.*

*Fact check/relevant context:* As has been highlighted in previous fact-checks[25] of misleading AOPO claims, while OPOs are titularly regulated by various bodies, none of that oversight is functionally effective. As *The New York Times* editorial board[26] wrote, "an astounding lack of accountability and oversight in the Nation's creaking, monopolistic organ transplant system is allowing hundreds of thousands of potential organ donations to fall through the cracks."

For example, and as your oversight letter to AOPO correctly noted, while OPOs report performance data to CMS, AOPO itself[27] has argued that such data should not be legally enforced because it is "unaudited and self-reported [and] there is no provision for even random audits," and the former Chief Data Scientist of the United States has gone as far as to characterize OPO data reporting as "functionally useless."[28]

It is unclear what AOPO means by "held to accountable standards," but no OPO has ever lost a contract for underperformance, despite what even AOPO implicitly concedes has been massive historical underperformance.

Consider AOPO's position that OPOs have improved performance by 58 percent in 10 years, which AOPO implies is not related to an expanding donor pool. If this were true—and, again, peer-reviewed data clearly finds it is not—then AOPO's position would simultaneously suggest that the OPO industry was underperforming by at least 58 percent 10 years ago; and that, despite no OPO losing its contract for that underperformance, OPOs are held to "accountable standards."

For further analysis of the systemic failures of OPO oversight, see a new report[29] from alumni of the United States Digital Service, which finds "Failures within the U.S. organ donation and transplantation system—which disproportionately harm patients of color—are left unaddressed by oversight bodies."

***AOPO wrote:*** *Indeed, this model is replicated worldwide; none of the countries with high-performing deceased donation utilize or permit entities to compete in a free-market system for the recovery of deceased organ donation. The reality is that having OPOs, or other potentially for-profit entities, competing for organs would be antithetical to the very purpose of donation as a precious resource requiring public trust and not a commercial enterprise.*

*Fact check/relevant context:* It is unclear why AOPO makes this assertion—which mirrors similar, uninformed statements from some OPOs and/or their surrogates—as no one is proposing a free market for organs. By statute, OPOs must be nonprofit entities, and in no way does HHS's regulation introduce a free market (though, to the extent that AOPO is concerned that for-profit, commercial activities would undermine public trust in organ donation, I would encourage them to support the committee's oversight requests seeking to understand the extent to which OPOs are already engaged in such activities).

The actual issue at hand is simply how to increase transparency and accountability for OPOs using objective data, specifically *because* OPOs operate as nonprofit, geographic monopolies in the public trust. As a past president of AOPO wrote:[30] "All OPOs operate as geographic monopolies, which means we have neither regulatory nor competitive pressure to provide high service to patients. And while there may be legitimate reasons for at least some monopolism (*e.g.,* potential donor families should not have two OPOs competing for their attention), the trade-off must be increased transparency and oversight."

Regarding AOPO's invoking of the need for public trust, I highlight CMS's comment in the final rule[31] that "The current OPO outcome measures are not sufficiently objective and transparent to ensure public trust." Thank you for your support of HHS's final rule.

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[25] *https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_b7d0e7fec4754ae0a8ec9d0bb65b4417.pdf.*
[26] *https://www.nytimes.com/2019/08/20/opinion/erika-zak-organ-donor.html.*
[27] *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf.*
[28] *https://twitter.com/dpatil/status/1148867331180785664.*
[29] *https://bloomworks.digital/organdonationreform/oversight/.*
[30] *https://morningconsult.com/opinions/organ-donation-can-save-more-lives-through-reform/.*
[31] *https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf.*

***AOPO wrote:*** *Additionally, every OPO is also required to submit an annual cost report for audit to ensure compliance with CMS allowable expenses.*

*Fact check/relevant context:* As the committee's oversight itself indicated, previous audits from the Office of the Inspector General (OIG) have detailed fraud, waste, and abuse at certain OPOs, though, inexplicably, and as your colleagues on the Senate Finance Committee[32] have noted, the OIG has not conducted further audits since these findings.

Additionally, as a recent report from the Bridgespan Group[33] highlights, there is much reason to question whether CMS's current definition of "allowable expenses" for OPOs does, in fact, serve patients: "OPOs are reimbursed based on self-reported costs—passing these costs along to the Centers for Medicare and Medicaid Services (CMS) and transplant centers—regardless of performance. The current OPO payment model does not give OPOs an incentive to reallocate resources in order to increase the number of organs available for transplant, and it reimburses OPOs for costs that may not, in fact, help produce the desired outcomes."

***AOPO wrote:*** *Equally important, the Health Resources and Services Administration ("HRSA") oversees the OPTN contract.*

*Fact check/relevant context:* I refer you to research from alumni of the United States Digital regarding deficiencies in HRSA's management[34] of the OPTN contract, including a roadmap for how HHS can more effectively manage[35] this contract going forward.

As a factual matter, as of January 15, 2021, HHS has moved the Division of Transplantation from HRSA to the Office of the Assistant Secretary for Health (OASH), in line with calls from patient advocates[36] to bring more active oversight of the OPTN going forward.

***AOPO wrote:*** *The OPTN performs ongoing reviews of OPO performance and compliance with OPTN policy. The OPTN also surveys all OPOs every 3 years to ensure they are in compliance with operating and productivity requirements. Finally, the Food and Drug Administration regulates all tissue recovery within an OPO.*

*Fact check/relevant context:* As covered comprehensively in the aforementioned report by alumni of the United States Digital Service, UNOS, which currently operates as the OPTN, is deeply conflicted. As *The Los Angeles Times*[37] has noted in investigative reporting, UNOS is a "reluctant enforcer" with "collegiality built into [its] very structure." Senators Grassley and Young have characterized UNOS's oversight over its members as "the fox guarding the hen house."

The FDA's regulation of tissue recovery is confined only to clinical regulation; there is no oversight over OPO business practices related to tissue donation.

***AOPO wrote:*** *If any OPO fails to meet the regulatory standards put forth by these Federal organizations, they must commit to a performance improvement plan to continue organ recovery operations in their DSA.*

*Fact check/relevant context:* As detailed in a new report[38] from the Bridgespan Group: "Further strengthening the case for [OPO] decertifications: there is no evidence to suggest that HHS's alternatives have ever been successful." Specifically, in 2012, HHS placed an underperforming OPO on a "performance improvement plan" in lieu of decertification, in hopes that such a governmental plan would lead the OPO to turn around. As noted in *The Washington Post,* since 2012, CMS has required the OPO to submit at least three "corrective action plans." Despite such plans, for at least the past 8 years, the OPO "has consistently registered one of the poorest performances in the Nation," and "ranked as the country's second-worst OPO [in 2017]."

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[32] *https://www.finance.senate.gov/imo/media/doc/CEG.Young%20to%20HHSOIG%20(OPO%20Oversight)%20Dec.18.2019.pdf.*

[33] *https://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-dec2020-update.pdf.*

[34] *https://bloomworks.digital/organdonationreform/Buying-OPTN-Tech/.*

[35] *https://bloomworks.digital/organdonationreform/Buying-OPTN-Tech/#procurement-strategy.*

[36] *https://www.dayoneproject.org/post/addressingorgandonorcrisis.*

[37] *https://www.latimes.com/news/la-me-transplant22oct22-story.html.*

[38] *https://www.bridgespan.org/bridgespan/Images/articles/transforming-organ-donation-in-america/transforming-organ-donation-in-america-dec2020-update.pdf.*

Representatives Porter and Bass have highlighted the ineffectiveness of OPO performance improvement plans in a previous oversight letter.[39] And as the past president of AOPO[40] has written, if "an OPO is not able to rise to the challenge of a high standard, the focus of our attention and energy must be on better serving patients on the national wait list [by replacing them with a higher-performing OPO, as HHS's final rule will enable], not on protecting specific OPOs."

***AOPO wrote:*** *OPOs have not, as you assert in your letters, misrepresented their efficiency at identifying donors and recovering transplantable organs. In support of this allegation, you cite an opinion piece and a non-peer reviewed report that is based on faulty data and funded by committed critics of OPOs. OPOs report data on identifying donors and recovering transplantable organs consistent with government requirements.*

*Fact check/relevant context:* The data cited by *The New York Times*[41]—in which a whistleblower said "I used to work at an OPO and we reported false numbers to make it appear we were doing better than we were"—is based on peer-reviewed research[42] which AOPO cited in its HHS public comment as the single most accurate estimate of donor potential. Criticism of OPOs from disinterested third parties, informed by objective, peer-reviewed data, is a logical response, and only further validates the need for HHS's OPO reforms.

More importantly, OPOs have written[43] to the White House Office of Management and Budget (OMB) that, currently, "the data that OPOs submit to CMS in connection with the outcome measures is self-reported and unaudited . . . errors have been found in the data on which CMS has relied as the basis for judging OPO performance. . . [and that] clearly, this type of 'evidence' fails to meet any reasonable definition of empirical."

To the extent that OPO reporting has, in fact, been "consistent with government requirements" and yet OPO-reported data still is not legally enforceable,[44] this only underscores the importance of HHS's final rule, which AOPO has vigorously opposed and continues to oppose. Thank you for your support of HHS's propatient, pro-accountability reforms.

***AOPO wrote:*** *Far from lobbying against such reforms, as your letter alleges . . . AOPO has advocated on behalf of its member OPOs as part of a committed effort to work collaboratively with policymakers.*

*Fact check/relevant context:* Whether AOPO has "worked collaboratively with policymakers" is a matter of judgment, and, in this case, I will defer to yours, though will note that the emails and other communications you have requested from AOPO would certainly inform such a judgment, and also note from investigative reporting from the Project on Government Oversight:[45] "UNOS did not deny that industry players are lobbying to undermine the President's reform initiative."

***AOPO wrote:*** *It is worth noting that AOPO's 501(c)(3) entity will continue to exist, and that the 501(c)(6) organization will act as a complimentary [sic] organization.*

*Fact check/relevant context:* It is my understanding as an AOPO board member that, counter to AOPO's representation to the committee, the 501(c)(6) will serve as the primary program.

I call your attention to the following email sent from Steve Miller to all OPO CEOs and executive directors, dated June 2, 2020 at 8:19 p.m. EST, and subsequently covered in investigative reporting from the Project on Government Oversight:[46]

> As noted above, we are recommending spending down the funds in the 501(c)(3) to the level determined by the executive committee while transitioning operations to the new 501(c)(6). To accomplish this, all new dues and revenue streams will be directed into the 501(c)(6), while all spending

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[39] *https://porter.house.gov/uploadedfiles/cms_hhs_opo_oversight_final_7.9.20.pdf.*
[40] *https://morningconsult.com/opinions/organ-donation-can-save-more-lives-through-reform/.*
[41] *https://www.nytimes.com/2019/06/11/opinion/organ-transplant-deaths.html.*
[42] *https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.14391.*
[43] *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/oira_0938/0938_10292013b-1.pdf.*
[44] *https://www.washingtonpost.com/national/despite-low-performance-organ-collection-group-gets-new-federal-contract/2019/02/04/9b9ba2aa-2895-11e9-b2fc-721718903bfc_story.html.*
[45] *https://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/.*
[46] *https://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/.*

not related to advocacy will be paid out of the 501(c)(3). Any spending related to advocacy will be paid out of the 501(c)(6). This will allow reserves to be built up in the 501(c)(6) while spending down the funds in the 501(c)(3) to the level determined by the executive committee. The full transition in operations will take approximately 12 to 24 months to finalize.

***AOPO wrote:*** *AOPO's recent advocacy efforts are aimed at ensuring those reforms are thoughtful and driven by science. The OPO community supports independently verifiable metrics based on sound data. AOPO believed the proposed metrics included in the 2020 OPO Rule failed to meet this standard on several fronts.*

*Fact check/relevant context:* As highlighted above, AOPO's claims that its policy positions are "driven by science" is spurious. HHS's final rule has been supported by the former Chief Data Scientist of the United States[47] as well as the Day One Project at the Federation of American Scientists,[48] among other expert researchers.[49]

***AOPO wrote:*** *AOPO's recent efforts to add a 501(c)(6) entity to the overall organization is part of an effort to engage more effectively in First Amendment-protected advocacy.*

*Fact check/relevant context:* No one is questioning AOPO's protections under the First Amendment. The problem is that AOPO is using these protections to promote spurious claims in order to push anti-accountability, antipatient policies.

***AOPO wrote:*** *The Chief of Mortality Statistics Branch at the CDC's National Center for Health Certificates recently stated, "1 in 3 death certificates were already wrong before COVID–19." While he later revised this estimate down to 25 percent, still an unacceptable high error rate when determining donor potential for OPOs.*

*Fact check/relevant context:* As has been pointed out in previous fact-checks of misleading AOPO claims,[50] "Almost all errors in death certificate data pertain to the chain of events leading to death, not the final cause, so do not impact the ultimate determination as to whether the donor was viable for transplant. In fact, 92 percent of all causes of donor death are asphyxiation, blunt injury, drug intoxication, gunshot wounds, drowning, stroke, or cardiovascular causes, which is obvious to diagnose. AOPO's invoking of "death certificate errors" is a red herring."

More simply, organ donation-eligible deaths represent a subset of all deaths which are uniquely insulated from the issues AOPO cites. For further information, I also refer to the committee to peer-reviewed research in the *Journal of the American Medical Association.*[51]

***AOPO wrote:*** *The concern that death certificates are a poor data source for accurately calculating the denominator for donation rate was echoed in the public comments to the 2020 OPO rule's performance measure regulation made by a wide range of expert stakeholders in the field including medical examiners.*

*Fact check/relevant context:* I refer the committee to extensive reporting in *The Los Angeles Times* detailing how OPOs have been able to co-opt medical examiners for lobbying purposes through gifts, sponsorships, and other forms of payment.

***AOPO wrote:*** *AOPO also had strong reservations regarding the 2020 OPO rule's proposed threshold to pass CMS certification of OPOs at the top 25 percent.*

*Fact check/relevant context:* Much of OPO and AOPO messaging[52] has centered on a misleading message that the new rule would necessarily result in 75 percent of OPOs being decertified, even despite various fact-check responses.[53] Presumably, the emails and other communications that the committee is seeking would inform whether such statements reflect AOPO's complete misunderstanding of the mechanics of the rule versus a more willful misrepresentation.

***AOPO wrote:*** *Despite all the challenges brought about by the pandemic, OPOs recovered almost 1,000 more organs that were transplanted in 2020 than during 2019,*

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[47] *https://jamanetwork.com/journals/jamasurgery/article-abstract/2765994?appId=scweb.*
[48] *https://www.dayoneproject.org/cms-policy-change.*
[49] *https://58425eca-649a-42d4-b265-d1e1743b6c48.filesusr.com/ugd/581bc3_e7064016057049 1b9855d21980e87092.pdf.*
[50] *https://www.globalliver.org/news/2020/8/bipartisan-reform-of-organ-procurement-organizations-opos-will-save-lives.*
[51] *https://jamanetwork.com/journals/jamasurgery/article-abstract/2765994?appId=scweb.*
[52] *https://www.abqjournal.com/1518295/attacks-on-organ-procurement-are-unfair.html.*
[53] *https://thehill.com/opinion/healthcare/516882-patients-are-dying-unnecessarily-from-organ-donation-policy-failures.*

*a 6 percent increase, which led to a 3 percent increase in transplants from deceased donors.*

*Fact check/relevant context:* Recent reporting in *The New York Times*[54] finds that, as a second-order effect of the pandemic, drug overdose deaths represented a record high in 2020. While AOPO represents that the increase in donation in 2020 was "despite" the pandemic, the data suggest that the increase actually resulted *from* the pandemic.

On a personal level, I find AOPO's use of the pandemic to deflect criticism to be exploitative, and also call the committee's attention to a comment from an OPO executive at a UNOS conference that: "OPOs are fortunate for COVID,"[55] which afforded AOPO more time to "organize and lobby harder against proposed rules to implement reform."

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## QUESTIONS SUBMITTED FOR THE RECORD TO MATTHEW D. WADSWORTH

### QUESTIONS SUBMITTED BY HON. JOHN THUNE

*Question.* In your testimony, you noted the geographic monopolies of OPOs in some areas.

Could you expand on what you think the impact would be of decertifying Tier 3 OPOs in areas where they are the only ones serving transplant centers? How could the lack of an OPO nearby affect transplant centers' ability to do their important work, particularly in rural areas? And how could we mitigate this risk?

Answer. Decertifying Tier 3 OPOs and assigning their donation service areas (DSAs) to higher-performing OPOs will improve system performance and organ recovery, meaning more organs will be available for transplant centers to serve their patients. Related: if higher-performing OPOs are expanding their DSAs, they will definitionally be near transplant centers in their DSA. As part of the competitive process to decide which OPOs should serve DSAs from decertified OPOs, any bidding OPO should present a plan to CMS on how it will provide adequate support for all their transplant programs the same way they would need to show how they support the entire geography they are bidding on.

#### ORGAN DISTRIBUTION

*Question.* As I'm sure you may know, in 2018, UNOS adopted principles of geographic organ distribution that some have suggested discourage donations in smaller or rural areas.

What is your response to this, and how could this be addressed? And how has the algorithm for assigning donations affected your organization?

Answer. The changes in organ distribution, in my opinion, were put into place to support transplant programs whose OPO wasn't providing adequate service to their DSA. It is my opinion that the root of the problem is OPO performance; we must make the pie bigger (in this case, better serve donor families, in turn recovering more organs for transplant) instead of just cutting the same pie differently (reallocating the existing organ supply and assuming it is fixed). My OPO, Life Connection of Ohio, has always been a massive organ exporter so it hasn't been as impactful for us. What has changed though is the number of kidneys that we are exporting versus allocating to our local transplant center. When I first arrived at Life Connection of Ohio, we grew so rapidly that the transplant program couldn't list patients fast enough to keep up. It is unquestionably true that if all OPOs performed at a Tier 1 level there would be literally thousands more organs available for transplant every year. Focusing on allocation fights misses the real point, which is that there should be a much larger pool of organs available, and literally every geography in the country would be better served by increased OPO accountability rather than focusing on organ allocation.

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[54] *https://www.nytimes.com/interactive/2020/07/15/upshot/drug-overdose-deaths.html.*

[55] *https://www.pogo.org/investigation/2020/10/heartless-organ-donation-contractors-lobby-against-a-popular-health-care-initiative-while-pocketing-pandemic-relief-loans/.*

QUESTIONS SUBMITTED BY HON. SHELDON WHITEHOUSE

*Question.* In your testimony, you mentioned that Organ Procurement Organization (OPOs) "are often rife with financial conflicts of interest, which means OPOs all too often spend taxpayer resources on special interest projects rather than on investing in organ recovery."

Can you explain the conflicting financial incentives of OPOs and solutions to address these incentives to improve patient outcomes?

Answer. To identify the conflicting financial incentives for OPOs, you don't need to look any further than their board structures and composition. It is my belief that the potential for innovation and appropriate resource allocation at some OPOs is essentially being "snuffed out" by their boards. For example, transplant surgeons, tissue processors, and other interests groups very often have positions on OPO boards, and the institutions and interests they represent may have financial or operational interests in conflict with those of the OPO. Further, hospital-based OPOs arguably have the highest level of financial conflicts. It is rumored that hospital-based OPOs essentially must pay a "deans' tax," and their resources are gobbled up by their parent institution instead of being invested into the mission of organ donation and transplantation.

*Question.* Would you agree that the mismatched incentives of OPOs is part of the reason so many of them are failing to recover enough organs to help patients?

Answer. OPOs are only one of two major programs left in Medicare that operate on what's called "cost-reimbursement basis," meaning they are reimbursed by taxpayers for whatever dollars they spend, rather than for the value they deliver. This incentivizes them to spend more money rather than to deliver high quality care for patients. The Federal Government has moved away from cost- reimbursement almost everywhere else in health care. I believe that the cost reimbursement structure has created a system that was meant to support OPOs and their mission, but HHS has not provided the needed oversight, and unfortunately many OPO leaders have taken advantage of that.

*Question.* How do you suggest we move away from "cost-reimbursement basis" in organ transplantation?

Answer. I think strict enforcement of the OPO rule will drive regulatory pressures on OPOs to better allocate financial resources, increase transparency around OPO costs, and will serve to stop wasteful or abusive spending.

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QUESTIONS SUBMITTED BY HON. RON WYDEN

OPO ACCOUNTABILITY (PANCREATA LOOPHOLE AND CMS RULE)

*Question.* As part of President Trump's Executive Order on Advancing American Kidney Health, CMS published the final rule, titled, "Medicare and Medicaid Programs: Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final Rule," (the "OPO Final Rule") which creates stronger new quality and transparency requirements for OPOs. According to CMS, the intent of the OPO Final Rule is to ensure that OPO performance and outcome measures are more transparent, reliable, and enforceable. The new OPO final rule became effective on March 30, 2021 *and* HHS has made meaningful first steps at reform, but more remains to be done.

However, this new rule also introduced a new loophole that allows OPOs to falsely inflate their performance by procuring pancreases for research. In the 2 years since the rule was finalized, the number of pancreases recovered by OPOs for "research" has skyrocketed, increasing by more than 400 percent. The Finance Committee has been investigating this potential loophole with the OPO Final Rule. So far, the committee's investigation has found that some OPOs have increased their pancreas research more than 700 percent since the rule went into effect.

Why is it imperative that CMS addresses the Pancreata loophole created by the 2021 OPO Final Rule?

Answer. The number of pancreata for research has increased dramatically since the passing of this rule. Should CMS choose not to address this, they may lose their ability to decertify some of the worst-performing OPOs. The pancreas for research loophole allows for OPOs to falsely inflate their donation and transplant rates which puts them in a position to not only avoid decertification but to actually acquire other

territories. Through this acquisition process, these same OPOs would serve a larger population that they could further exploit. Anecdotally, I have heard that OPOs have adopted the practice of creating, "research banks," where they recover all pancreata and place them in freezers for possible future research. This is not only a gross exploitation that warps the intentions of the OPO rule, it is also a gross disservice to generous donor families. The other issue here is if an OPO were to go to surgery for blatantly nontransplantable kidneys, and simultaneously choose to recover the pancreas for research, all that expense is allocated to the Medicare cost report. You could potentially have OPOs committing Medicare fraud in hopes of not being decertified, which in turn could allow them to commit Medicare fraud on an even larger scale.

*Question.* Additionally, what else should CMS be doing to make sure the 2021 OPO Final Rule is enforced as intended?

Answer. CMS needs to be ready to enforce the rule immediately—without weakening the tier standards, including through risk-adjustments, or otherwise delaying or weakening implementation—running transparent, data-driven competitive cycles for DSAs that will best serve donor families and transplant patients. I believe that CMS will see proactive mergers, and then some OPOs may ask for more time to improve, because they have merged. My fear is that a group of Tier 3 OPOs or even a couple lower Tier OPOs proactively merge into a Tier 1 OPO and then claim they shouldn't be decertified, because they need time to turn the organization around. Any additional time for OPO rule enforcement will translate to additional patient deaths on the waiting list. History has shown us that this industry will exploit every opportunity they have to avoid accountability, and we need to be absolute in our enforcement of the rule.

Additionally, CMS should be much more active in promoting and approving waivers to allow hospitals to choose to work with higher performing OPOs. Firstly, it is definitionally better for patients to have more hospitals work with Tier 1 OPOs rather than Tier 2 or Tier 3. Additionally, a more ubiquitously used waiver system would create a constant pressure on OPOs to better serve hospitals, standing in for the regulatory incentives which are currently on a very protracted 4-year cycle.

Lastly, to the extent that CMS ultimately does have to decertify an OPO, presumably many of its hospitals would have chosen to exercise the waiver process during that OPO's 4-year contract, meaning that the number of decertifications for CMS to oversee would necessarily be smaller in nature.

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QUESTIONS SUBMITTED BY HON. TODD YOUNG

*Question.* There's been little guidance from the Centers for Medicare and Medicaid Services (CMS) to indicate that they are fully prepared to enforce the 2020 Organ Procurement Organization (OPO) rule.

What does CMS need to do to appropriately enforce this rule?

Answer. They must stay vigilant. CMS needs to close the pancreas for research loophole so we have a clear picture of who is actually transplanting organs. CMS also needs to close the pancreas for research loophole to protect donor patients. For example, there appears to be violation of section 2927.01 of Ohio Revised Code, Abuse of a Corpse, within my own State. This law states that:

(A) No person, except as authorized by law, shall treat a human corpse in a way that the person knows would outrage reasonable family sensibilities.

(B) No person, except as authorized by law, shall treat a human corpse in a way that would outrage reasonable community sensibilities.

(C) Whoever violates division (A) of this section is guilty of abuse of a corpse, a misdemeanor of the second degree. Whoever violates division (B) of this section is guilty of gross abuse of a corpse, a felony of the fifth degree.

If what I hear from staff level employees at OPOs is true, not only are some OPOs committing a felony, taxpayers are paying the bill. This must stop.

*Question.* Has CMS released any guidance or additional information on how competition for Tier 2 and Tier 3 OPO donation service areas (DSA) will occur?

Answer. We have received zero guidance on how competition will occur, what we can compete for, or what we obtain if we are awarded additional territory. This is

a massive disservice to donor families and patients on the organ waiting list, as every part of the country deserves to be served by a Tier 1, high-performing OPO.

*Question.* What specific guidance is needed for OPOs to fully prepare and participate in this competition process?

Answer. We need the guidance on the following:

- What are the criteria for awarding a territory?
- What are we acquiring? Only the contract?
- Is there financial support to do this, such as a zero/low interest loan? While most OPOs likely don't need financial support, an organization like mine will need to have support with resources to start.
- What is the timeline for turning around a failing DSA?
- Can we keep the acquired DSA separate in our org. structure to avoid decertification of the entire entity if we are unsuccessful turning the new territory around?
- What are the repercussions for board members that behave badly by allowing the OPO to shift money away from the parent organization, or otherwise interfere with the acquiring OPO operating within their facility?
- What type of data will we have access to in order to determine if we want to acquire a territory, or develop our strategic plan to turn that organization around?

*Question.* Given the timeline for decertification, when would CMS's release of this information be most beneficial to OPOs for their planning?

Answer. We must know no later than May 2024, which is the timing by which OPOs considering acquiring additional territory will need to start thinking through strategic planning to build our organizations up in 2025 in a way that we can acquire in 2026. The May 2024 deadline gives us time to evaluate the information, make determinations of what we want to bid on, seek board approval, and begin the process of growing our organization to be what it needs to be by 2026. Some organizations, Life Connection of Ohio included, don't currently have the bylaws or other organizational structures needed to allow acquisition. As the CEO, I need time to work with my board, and get everyone to the point that they feel confident in our structure to serve donor families and transplant patients.

# COMMUNICATIONS

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AMERICAN SOCIETY OF NEPHROLOGY
1401 H Street NW, Suite 900
Washington, DC 20005

**Statement of Michelle A. Josephson, M.D., FASN**

On behalf of the 37 million Americans living with kidney diseases, particularly the nearly 90,000 Americans including more than 1,000 children on the kidney transplant wait list, thank you for your efforts to transform transplant care. American transplantation has grown immensely over the past 40 years and must continue to evolve to meet the needs of people with kidney diseases.

The American Society of Nephrology (ASN) believes the North star of the entire transplant system should be to maximize access to kidney transplants, which are the optimal therapy for kidney failure and which improve patients' quality of life. As detailed below and published in the *Clinical Journal of the American Society of Nephrology,* there are five key changes that advocates and policymakers can take to achieve this goal.

Thank you for your leadership and dedication to the millions of Americans living with kidney diseases, especially to those who would benefit from a kidney transplant. ASN's leaders, staff, and members stand ready to assist in the implementation of these vital changes.

Sincerely,

Michelle A. Josephson, M.D., FASN
President

**Transforming Transplant in the United States**

Michelle A. Josephson, M.D., FASN and Rachel N. Meyer

**Published ahead of print in the *Clinical Journal of the American Society of Nephrology:*** doi: *https://doi.org/10.2215/CJN.0000000000000271.*

A recent Biden administration announcement, the Health Resources and Services Administration (HRSA) Organ Procurement and Transplantation Network (OPTN) Modernization Initiative—and bipartisan, bicameral proposed legislation supporting it, the Securing the U.S. OPTN (SUS OPTN) Act—aims to implement crucial reforms to help more patients receive a transplant. It is imperative that nephrologists, transplant professionals, patient advocates, and others collaborate to ensure these efforts fulfill their potential and pursue other opportunities to achieve the ultimate goal: maximizing patient access to kidney transplantation. Too often, that access is treated as a scarce resource, available to only a subset of the many people who could benefit.

By focusing on five key changes, described below, advocates and policymakers have a clear path to achieving that ultimate goal. The initiative and the legislation are foundational steps implementing needed reforms today—and enabling significant future advancements.

For most people with kidney failure, transplant is the optimal therapy. It is also the most cost-effective therapy, less than half the cost of dialysis. While 2022 saw a record number of kidney transplants, an unacceptable 12 people die waiting for a kidney every day. People who die on the wait list receive a median 16 kidney of-

fers that are declined, often without their knowledge.[1] Twenty-six percent of kidneys procured from deceased donors go unused, even though data show patients would have benefitted from transplantation with many of those non-used organs.[2]

Stark and unacceptable disparities also persist in kidney transplantation. As we work towards increasing transplantation, we must ensure equitable access regardless of patients' race/ethnicity, sex/gender, geography, and socioeconomic status. For example, Black patients are less likely to receive a pre-emptive transplant referral or complete the transplant evaluation. They are less likely to have a living donor and more likely to receive lower quality kidneys.[3] Americans who reside in rural areas are less likely to be wait-listed or transplanted, while socioeconomically disadvantaged people face similarly worse odds.[4, 5] Women are less likely to be referred for transplant than men.[6]

The initiative and legislation will contribute to changing these grim realities, yet additional safety net efforts supporting underserved populations—including transportation, post-transplant medication access, and financial assistance—are also needed. Transplant reimbursement often does not support best practices in, for example, community education, patient recruitment, living donor support, and post-transplant care—particularly for socioeconomically disadvantaged populations. We must align incentives, financial and otherwise, in a manner that allows all health professionals to make decisions that maximize access for all patients regardless of insurance or income.[7]

Because the kidney transplant community has a rich history of leading and embracing bold advancements, especially during the past decade, the American Society of Nephrology (ASN) is optimistic about the future of transplant policy. Stemming from recognition that the current system is not optimally serving patients, the HRSA initiative and related legislation build on work across the Obama, Trump, and Biden Administrations and on a bipartisan, bicameral basis across many Congresses. Informed by this history and bolstered by the HRSA Modernization Initiative and the SUS OPTN Act, we can maximize access to transplant and advance equity by focusing on at least five objectives.

1. **Expedite the clear government reforms necessary to maximize access to transplant.** Patients deserve a coordinated, system-wide approach that allows all stakeholders to work towards maximizing patients' access to transplant. By requiring OPTN and any OPTN contractor(s) to have separate governing boards, the legislation institutes good governance and increases accountability. Conflicting government incentives must be aligned—such as ending OPTN's use of a 1-year outcome metric for transplant centers, even though the Centers for Medicare and Medicaid Services (CMS) eliminated the metric because it impeded patients' access to transplant.[8] Ensuring patient safety and graft survival is paramount but can be achieved while also making transplant more accessible than current metrics allow. As with all regulatory changes, the effects should continuously be monitored and assessed, and updated as new evidence suggests future opportunities for improvement. Policies that conflict with current science must also be reformed—such as ending the use of race,

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[1] Husain, S.A., et al. "Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates." *JAMA Netw Open.* 2019;2(8):e1910312. doi:10.1001/jamanetworkopen.2019.10312.

[2] Mohan, S., et al. "Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy." *Kidney International Reports.* February 2023. Vol. 8 Issue 5.

[3] Purnell, T.S., et al. "Association of Race and Ethnicity With Live Donor Kidney Transplantation in the United States From 1995 to 2014." *JAMA* 319:1 Jan 2018.

[4] Axelrod, D.A., et al. "Rates of Solid-Organ Wait-listing, Transplantation, and Survival Among Residents of Rural and Urban Areas." *JAMA.* 2008;299(2):202–207. doi:10.1001/jama.2007.50.

[5] Axelrod, D.A., et al. "The Interplay of Socioeconomic Status, Distance to Center, and Interdonor Service Area Travel on Kidney Transplant Access and Outcomes." *CJASN* 5(12):p 2276–2288, December 2010. DOI: 10.2215/CJN.04940610.

[6] Smothers, L., et al. "Gender Disparities in Kidney Transplantation Referral Vary by Age and Race: A Multiregional Cohort Study in the Southeast United States." *Kidney International Reports* 2022 Jun; 7(6): 1248–1257 doi: 10.1016/j.ekir.2022.03.027.

[7] Moe, S.M., Brennan, D.C., Doshi, M.D., Gaston, R.S., Gurley, S.B., Mujtaba, M.A., Schmidt, R.J., Segal, M.S., Tucker, J.K., Wiseman, A.C., Josephson, M.A. The Importance of Transplant Nephrology to a Successful Kidney Transplant Program. *Clin J Am Soc Nephrol.* 17: 1403–1406, 2022. CJN.02000222. doi: 10.2215/CJN.02000222.

[8] Chandraker, A., et al. "Time for reform in transplant program-specific reporting: AST/ASTS transplant metrics taskforce." *AJT* Vol. 19 Issue 7. *https://doi.org/10.1111/ajt.15394.*

a social construct, in the algorithm that ranks and allocates kidneys, a step we commend OPTN for now undertaking.[9]

2. **Establish transparency to improve access to transplant and reduce barriers in the kidney health ecosystem.** Lack of transparency at every step in the transplant process makes navigating it difficult, exacerbating inequities and barriers. It is opaque to many patients and their nephrologists which transplant centers might be willing to accept them, and many cannot even ascertain whether they are wait-listed after clearing the many hurdles to be evaluated. A nationwide, centralized clearinghouse is needed to help patients match with a program with the expertise to accept and actually transplant them. HRSA's commitment to increased transparency and data-sharing should address these challenges.

   Transplantation generally confers a better, longer life versus dialysis, but many who would benefit aren't wait-listed. Nephrologists must embrace greater responsibility in championing transplant as the optimal therapy for most of their patients, supporting them during the early referral and evaluation stages and beyond. CMS and HRSA need to collect and share data about patients who are referred but never make it to the wait list so researchers can better understand—and advocates and policymakers can address—their barriers.[10] This transparency is particularly crucial for groups with disproportionate challenges to wait-listing, such as Black, rural, and socioeconomically disadvantaged Americans. Waitlisted patients also deserve transparency about decisions made on their behalf: most are never notified when surgeons decline kidneys for them, eliminating their voice in these life-or-death decisions. Would 1 in 4 donated kidneys still go unused if potential recipients were aware?

3. **Enable the use of more organs.** More patients could receive transplants if barriers to using deceased donor organs were removed, and the myriad challenges people must overcome to become living donors were mitigated. For example, regulations like the 1-year outcome metric have pushed transplant centers to become risk-averse, aiming for optimal results for a smaller pool of candidates with only the highest-quality donor kidneys instead of maximizing patient access and accepting more offered kidneys. Data show it is a mistake not to use many of the kidneys that go unutilized.[11] It is time for CMS and HRSA to change policy to encourage transplant centers to say "yes" to more offered kidneys, becoming accountable to patients' preferences over short-sighted metrics. While using 100% of deceased donor kidneys is not a realistic goal, we know we can better serve patients by using more than just 74%.

   Congress should increase appropriations to support living donors *and* base eligibility for those funds on donor—not recipient—income. No living donor should have to pay to donate their kidney, and the federal program that exists to support this goal, the National Living Donor Assistance Center (NLDAC), needs more support. HRSA, which oversees the program, should ensure it covers all donation-related costs and allow more donors to qualify. Recently, NLDAC eligibility increased from 300% to 350% of poverty level, a trend HRSA should continue.

4. **Expand investment in transplant-related research and innovation.** While transplantation has saved thousands of lives, transplant professionals and their patients largely rely on 40-year-old therapies. Establishing a National Institutes of Health (NIH) National Center for Kidney Health and Transplantation would centralize transplant research in one focused place instead of spread across NIH, creating efficiencies and ensuring a balanced portfolio across the research continuum.

   ASN is calling for the Centers for Medicare and Medicaid Innovation to launch a transplant model, particularly aimed at meeting patients' long-term needs instead of focusing on shorter-term outcomes. Living donors also deserve more long-term focus and support. By expanding the Living Donor Collective, a national longitudinal living donor data collection effort, we can narrow the gap

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[9] Gill, J.S., Kelly, B., Tonelli, M. "Time to Abolish Metrics That Sustain Systemic Racism in Kidney Allocation." *JAMA.* 2023;329(11):879–880. doi:10.1001/jama.2023.1076.

[10] Patzer, R.E., et al. "A Population Health Approach to Transplant Access: Challenging the Status Quo." *AJKD* Feb. 2022. Vol 80 Issue 3. *https://doi.org/10.1053/j.ajkd.2022.01.422.*

[11] Husain, S.A., et al. "Characteristics and Performance of Unilateral Kidney Transplants from Deceased Donors." *Clin J Am Soc Nephrol.* 2018 Jan 6;13(1):118–127. doi: 10.2215/CJN.06550617.

between the number of actual and potentially interested living donors and better meet their needs.

5. **Embrace modern technology to increase access to transplant.** Implementing a modern infrastructure for our transplant system is a foundational step to improving transparency and efficiency and is a focus of HRSA's Modernization Initiative. The legislation will enable competition and new ways of thinking about improving the nation's transplant system—particularly its IT system. For example, a successful information technology (IT) system would make widespread use of application programming interfaces to transfer of information across electronic health records, healthcare systems, and the OPTN registry, instead of relying on fax, phone, and email.

   As with every element of these technology and other reforms, the voices of patients and transplant and kidney health professionals should lead the way shaping these initiatives and ensuring they optimally serve patients.

At least 10 components within the Department of Health and Human Services (HHS) have a role in kidney health. Today's redundant and often contradictory agency rules impede a synergistic focus on meeting patients' needs. A new Office of Kidney Health and Transplantation, situated in the HHS Secretary's Office, could ensure all components work in coordination towards maximizing access to transplantation. Emphasizing the importance of patients' voices in policymaking, the office would focus on collaborating with patients to ensure their perspectives are central to any changes relating to the 37 million Americans with kidney diseases.

As the world's largest organization of health professionals dedicated to improving care for people living with kidney diseases, ASN's leaders and members stand ready to collaborate with patients, other nephrologists and transplant professionals, and Congress and the Biden Administration—especially HHS, CMS, and HRSA—to transform transplant in the United States, maximizing patients' access to the optimal therapy and ensuring that access is equitable.

The authors would like to thank Scott Bieber, D.O.; Zachary Kribs; Roslyn B. Mannon, M.D., FASN; and David L. White for their critical thought partnership and work on this effort.

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**AOPO Urges Congressional Action to Address Key Concerns in U.S. Organ Transplant System Reform**

On Thursday, July 20, 2023, the Senate Finance Committee (SFC) Subcommittee on Health Care held a hearing,[1] "The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System," which addressed the organ donation and transplantation system. As the national non-profit representing 48 Organ Procurement Organizations (OPOs) across the U.S., the Association of Organ Procurement Organizations (AOPO) stands firmly behind comprehensive reform initiatives to enhance data accuracy, transparency, equity, and alignment of stakeholder goals to save more lives. For the official record, our objective is to offer valuable insights and clarity on the current state of the U.S. organ donation and transplantation system and recommend opportunities for growth.

**NASEM Report**

In February 2022, the National Academies of Science, Engineering, and Medicine (NASEM) released a report titled "Realizing the Promise of Equity in the Organ Transplantation System."[2] This report provides data-driven recommendations for donor hospitals, OPOs, transplant centers, federal policymakers, and the Organ Procurement and Transplantation Network (OPTN) to advance the "fairness, equity,

[1] *https://www.finance.senate.gov/hearings/the-cost-of-inaction-and-the-urgent-need-to-reform-the-us-transplant-system.*

[2] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Care Services; Board on Health Sciences Policy; Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution; Hackmann, M., English, R.A., Kizer, K.W., editors. Realizing the Promise of Equity in the Organ Transplantation System. Washington (DC): National Academies Press (US); 2022 Feb 25. Summary. Available from: *https://www.ncbi.nlm.nih.gov/books/NBK580019/*.

transparency, and cost-effectiveness in the system of procuring, allocating, and distributed deceased donor organs." The NASEM report, requested by Congress and sponsored by the National Institutes of Health (NIH), serves as a valuable blueprint for driving productive system reform. The SFC should leverage these insights to guide its actions in promoting productive reform efforts.

**Organ Non-Utilization**

As determined in the NASEM research, the non-utilization of organs recovered by OPOs and declined by transplant centers poses a critical challenge to the donation and transplantation system. In 2022, the non-utilization rate reached a record high of 19%,[3] resulting in thousands of viable organs not transplanted.[4] In comparison, the organ non-utilization rate was 11% in 2002. This issue has increased exponentially each year, resulting in missed opportunities to save lives.

During the hearing, it was claimed that "poor performance by OPOs and UNOS" are responsible for 1 in 4 kidneys not being transplanted. This is false. Neither OPOs nor UNOS determines whether a recovered kidney is used for transplantation. The responsibility of accepting an organ offer and carrying out the kidney transplant lies with the transplant center. Tragically, last year, 4,318 kidney patients on the national wait list lost their lives while simultaneously, OPOs authorized, recovered, and offered 7,548 kidneys to transplant centers that were not accepted for use, many due to the outcome measure restrictions placed on transplant centers.[5] OPOs are recovering more organs than transplant centers are accepting for transplantation.

Research reveals the U.S. non-utilization rate for procured organs is nearly double the rate of other developed countries, such as France, where 62%[6] of kidneys declined in the U.S. would have been successfully transplanted.[7] Additionally, "on average, patients who die waiting for a kidney had offers for 16[8] kidneys that were ultimately transplanted into other patients, indicating that many transplant centers refuse viable kidney offers on behalf of those on the waiting list."[9] These statistics highlight the severity of the problem and demonstrate a huge oversight in the United States organ donation and transplantation system.

Organ non-utilization leads to unnecessary deaths on the transplant waiting list. It also impacts OPOs, which are evaluated based on transplantation rates influenced by a multitude of factors outside of the OPO's control, including proper use of organ acceptance filters, unintended consequences of the allocation system, and organ acceptance practices. AOPO urges the SFC to align performance metrics and incentives for OPOs and transplant centers in order to promote the increased use of organs, especially from older and medically complex donors. This issue warrants urgent attention and examination to ensure every available organ is successfully transplanted.

**HRSA Modernization Initiative**

AOPO supports the goals of the Health Resources and Services Administration (HRSA) *Modernization Initiative* to strengthen accountability and transparency in the OPTN with the goal of increasing organ transplantation to serve patients. As Congress coordinates with HRSA to advance its goals, AOPO suggests several recommendations.

As noted in our June 5, 2023, letter[10] to the sponsors of the *Securing the U.S. Organ Procurement and Transplantation Network Act* (S. 1668/H.R. 2544), AOPO supports enhancing the OPTN to better serve patients, donors, and donor families. AOPO believes this legislation allows HRSA "to engage in a competitive process to award discreet OPTN functions to multiple contractors and would also allow HRSA

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[3] *https://aopo.org/50k-transplants/organ-utilization/*.
[4] Based on OPTN data as of February 28, 2023.
[5] Based on OPTN data as of July 20, 2023.
[6] *https://pubmed.ncbi.nlm.nih.gov/31449299/*.
[7] Aubert, O., Reese, P.P., Audry, B., Bouatou, Y., Raynaud, M., Viglietti, D., Legendre, C., Glotz, D., Empana, J.P., Jouven, X., Lefaucheur, C., Jacquelinet, C., Loupy, A. Disparities in Acceptance of Deceased Donor Kidneys Between the United States and France and Estimated Effects of Increased US Acceptance. *JAMA Intern Med.* 2019 Oct 1;179(10):1365–1374. doi: 10.1001/jamainternmed.2019.2322. PMID: 31449299; PMCID: PMC6714020.
[8] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2749266.*
[9] Husain, S.A., King, K.L., Pastan, S., et al. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Netw Open.* 2019;2(8):e1910312. doi:10.1001/jamanetworkopen.2019.10312.
[10] *https://aopo.org/wp-content/uploads/AOPO-Letter-to-Senate-Finance-Committee-on-OPTN-Bill-6-5-2023.pdf.*

to award contracts to for-profit entities for the first time." However, "nothing in the bill text prevents a for-profit entity from taking on the policymaking role, as the statute does not explicitly list policymaking as the sole duty of the OPTN board." While Senator Wyden stated during the hearing that the OPTN policymaking role would be awarded to a nonprofit, AOPO emphasizes that such a decision is not codified in the legislation and, as a result, cannot be assured.

Stakeholder engagement and input are critical to improving organ donation and transplantation and should not be driven by profit. Donation relies on public trust, and introducing for-profit entities could damage the public's perception, negatively impacting individuals' decisions to authorize donation for themselves or family members. AOPO strongly recommends Congress ensure the policymaking component of the OPTN is overseen by a non-profit entity with proven experience in complex operations, as it's critical to ensure improvements in the organ donation and transplantation process are driven by fairness, equity, and sound medical principles without regard for making a profit.

Furthermore, AOPO recommends the OPTN Board's policy committees reflect diversity in race, ethnicity, ability, profession, and gender. As stated in our July 19, 2023, letter to HRSA, "changes to the Board of Directors and policy bodies of OPTN should better reflect the entire organ donation and transplantation system to further a patient-centric approach." The NASEM report supports this recommendation, advocating for an intensive, consensus-based, multi-stakeholder policy development process that would increase collaboration. AOPO agrees that developing a more expedient and responsive policymaking process with greater representation on the OPTN Boards and Committees would significantly improve the OPTN contract.

Lastly, the implementation of changes should be conducted in a stepwise manner, through collaboration with key stakeholders to address process changes and establish clear timelines. The organ donation and transplantation system is presently undergoing numerous reforms, and it is essential that HRSA's advancements of the OPTN align with the Centers for Medicare & Medicaid Services (CMS) changes. AOPO urges the SFC to advocate for an integrated approach that mitigates the risk of destabilizing the system and compromising quality patient care.

**CMS OPO Performance Metrics**

AOPO has voiced concerns regarding the CMS metrics and their ability to accurately evaluate OPO performance. Despite having one of the world's leading donation and transplantation systems, with notable advancements in deceased organ donation rates, organs recovered and made available for transplant, as well as successful transplantations, it is concerning that a record number of OPOs (42%) are disproportionately ranked in the lowest performance category, according to the latest released data.[11]

This raises alarm, as these OPOs are at risk of automatic decertification with no opportunity for remediation under the new CMS regulations effective in 2026. The data reveals highly fluctuating OPO Tiers, with some OPOs experiencing significant shifts within a single year. For example, the OPO serving Hawaii transitioned from Tier 3 in 2019 to one of the highest-performing OPOs in Tier 1 in 2020, only to fall back to Tier 3 in 2021. The Maryland OPO, Infinite Legacy, which Senator Cardin referenced in his opening statement, has been ranked in each of the three tiers over the same 3-year period. Such inconsistent performance findings have left the community concerned about potential implications for the system's integrity and the quality of support provided to donor families and transplant patients in the future.

Furthermore, CMS has not provided any guidance regarding the transition of OPO donation service areas after Tier 3 OPO decertification occurs, leaving OPOs without the necessary details to prepare for future operations and to mitigate disruptions to the system. Additionally, the majority of Tier 1 OPOs come from smaller geographical areas, emphasizing the need for meticulous planning to ensure a successful transition with minimal interference in larger service areas. Despite consistent efforts to seek clarification on these issues and more from CMS, including raising our concerns in a letter[12] to the SFC, AOPO has received no response to the following pending questions:

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[11] *https://www.cms.gov/files/document/opo-annual-public-performance-report-2023.pdf.*

[12] *https://aopo.org/wp-content/uploads/AOPO-Letter-to-Senate-Finance-Committee-4-18-2023.pdf.*

**I. Selecting OPOs**

- Will CMS consider risk corridors for OPOs in which a small number of organs (*i.e.,* less than five or ten) would have made a material difference in their tier?
- What criteria will CMS consider when selecting an OPO to take over a Tier 2 or 3 DSA?
- Will CMS use the same or different criteria when deciding whether a Tier 2 OPO can retain its own DSA?
- How, if at all, will recent improvement be taken into account when determining whether a Tier 2 OPO is allowed to retain its DSA?
- How will the letter ranking system be used in the decision-making process? For example, will a Tier 2 A OPO have a higher likelihood of retaining their DSA over a Tier 2 C OPO?
- In considering whether to allow a Tier 2 OPO to retain its DSA, will CMS consider whether the potential for long-term gains would outweigh inevitable disruptions in continuity of care, long-standing relationships with local hospitals, as well as the current OPO's potential and plans for future improvement?
- Will there be an opportunity to appeal Tier 2 decisions?
- What factors will CMS consider when selecting a new OPO? Having a DSA of similar population demographics, urban versus rural environment, and payer mix?
- What will CMS do if there is a situation in which no OPO is interested in taking over a particular decertified OPO's DSA?
- How long will the bidding process last?

**II. Merging DSAs**

- In the past, CMS has required that OPOs merge completely or retain separate staffing and operational structures. However, CMS states in the rule that the regulations "do not *require* that DSAs merge when a new OPO takes over . . . OPOs *could* merge, or service areas *could* be merged . . . since DSAs are not required to merge, one OPO could run several DSAs." Will CMS generally approve DSA mergers if requested by an OPO? Or will the agency establish certain criteria or consider specific variables?
- If the latter, what types of variables will be considered when deciding to allow OPOs to merge DSAs? Will it be the size of the DSA? Whether the two regions are contiguous? The number of hospitals within a DSA?
- Will CMS evaluate OPO mergers proposed before the 2026 recertification cycle differently than those after?
- When a new OPO wins a bid to take over a DSA, what types of ownership structures would CMS approve?

  **Note:** There are various potential structures, including (but not limited to) separate governing bodies and staffing with separate DSAs under a parent organization, merging into a single OPO with single governance and staffing but multiple DSAs, or combining OPOs and DSAs. We would appreciate more guidance on what type of structures CMS would allow (or prefer) and how documentation requirements may vary depending on the proposed organizational structure of the merger. Due to a range of factors that make each DSA unique, we encourage CMS to allow a sufficient degree of flexibility so OPOs can make a decision that is best suited for the circumstances of the DSA and donors and patients served. We also note that it is important to leverage the benefits of possible mergers, including efficiencies of scale and scaling successful cultural and operational strategies of the high-performing OPO to promote greater efficiency while ensuring a seamless transition that maintains important relationships with transplant and donor hospital partners and avoids potential workflow disruptions that could jeopardize lives.

- Will there be a certain timeframe within the decertification cycle when mergers must occur?
- After a winning OPO candidate is selected, how long will the OPOs have to take over the operations and DSA of the decertified OPO? Will there be a defined transition period, or will it depend on the circumstances of each merger (which AOPO recommends)?

  **Note:** We appreciate that CMS notes in the rule that: "careful planning and implementation of OPO de-certifications and OPO DSA competitions could ease such transitions" and urge the Agency to both allow sufficient time and work with both OPOs to agree on a mutually agreeable, reasonable transition timeline that considers the unique circumstances of that particular DSA and OPO and prioritizes minimizing service disruptions. Selecting an appropriate transi-

tional period will depend on when the applicant assumes control of the DSA and the operational and demographic considerations of each OPO and DSA. For instance, merging two DSAs under a single OPO organizational structure will conceivably take longer than if an OPO seeks to run a new DSA as a separate and distinct division maintaining the existing infrastructure of the OPO. Successful consolidation of this magnitude requires significant planning and implementation of management, cultural, staffing, and workflow changes, as well as likely could require approval by the state's Attorney General or other state agencies considering the charitable nonprofit corporate status of OPOs. Altogether, this typically entails a multi-year process. A thorough and well-planned integration is critical to long-term success.

**III. Implications for Future Certification Cycles**

- Given certification currently occurs at the OPO level, will CMS evaluate recertification differently moving forward to accommodate scenarios where a single OPO is responsible for multiple separate DSAs? Will performance metrics used for recertification be calculated at the OPO or the DSA level?
- If a merger occurred during or after the reporting year, will the OPOs and/or the DSAs be evaluated separately or jointly for purposes of recertification?
- If a single OPO manages multiple DSAs and one falls into Tier 2 or 3 for one of the DSAs, will this negatively impact the OPO's ability to maintain its other existing DSAs, or to take on new DSAs in the future? Will CMS consider offering certain time-limited protections to encourage successful OPOs to compete for DSAs of OPOs that have not performed as well?
- If an OPO is recertified for one DSA and decertified for another, could the OPO compete for tier 2 or tier 3 OPOs?
- CMS states in the rule that "if an OPO takes over another OPO's DSA on a date later than January 1 of the first year of the agreement cycle so that 12 months of data are not available to evaluate the OPO's performance in its new DSA, we will hold the OPO accountable for its performance on the outcome measures in the new area once 12 months of data are available." Does this mean that OPO would be evaluated on a different 12 months of data than all other OPOs? Could these 12 months span multiple calendar years?
- CMS notes in the rule that "it would be our preference not to merge DSAs so that we can properly assess whether the new OPO is improving performance in each DSA." Is there a certain minimum number of DSAs that CMS wants to preserve in order to ensure an "adequately diversified" market?
- Has CMS considered how the number of DSAs may impact median and upper quartile calculations for purposes of delineating tiers?
- CMS states in the rule that for purposes of distinguishing between tiers, "the percentiles are calculated based on the number of OPOs in the year prior to the reporting year." How will the number of mergers in the year between assessment calculation and the decertification year affect tier assignment?

**IV. Data Collection and Transparency**

- Will the Scientific Registry of Transplant Recipients (SRTR) be validating CMS' calculations? AOPO believes this would be an important way to help ensure transparency in the process and get buy-in from OPOs.
- Will CMS share the donor potential of all OPOs broken down by DSA or county level? This would greatly streamline the process of having to make individual requests to the Centers for Disease Control (CDC) for raw data.

Urgent action from policymakers and federal regulators is imperative to address these concerns promptly and provide an implementation plan to safeguard the highly successful U.S. organ donation and transplantation system, ensuring patient lives are not compromised.

**Pancreas for Research**

The inclusion of pancreata allocated to research in an OPO's donation rate and performance evaluation has raised concerns. AOPO previously expressed apprehension to CMS during the initial rulemaking process, highlighting the potential for skewed comparisons and inaccurate conclusions resulting from this inclusion. Despite the ongoing uncertainty surrounding this issue, OPOs have diligently complied with the adopted rule. OPOs actively recover pancreas for transplantation purposes and explore research options when an organ cannot be placed with a recipient, ensuring the gift is honored, and supporting research and innovation in the field to increase organs for transplant.

Meeting the research demand for pancreata is essential for studying human islet cells, which play a vital role in expanding scientific knowledge and developing effec-

tive treatments for patients with diabetes. Progress in this field has the potential to reduce the number of patients requiring pancreas transplants. AOPO urges policymakers to closely monitor this matter to ensure a fair assessment of OPOs' lifesaving capabilities in organ donation and transplantation.

**Opioid Epidemic**

The research frequently referenced in discussions about the impact of the opioid epidemic on donation rates, as cited by witnesses and legislators at the SFC hearing, is flawed. The study design states, "we hierarchically created four categories: (a) donor's mechanism of death coded as "drug intoxication" by the OPO; or donor coded as another mechanism of death but his/her history noted (b) intravenous drug use, (c) non-intravenous drug use (*e.g.,* snorting), or (d) no drug use. The first three categories were grouped as "drug-related."[13] Consequently, the estimates within the study include individuals who died of causes unrelated to drug use but may, at some point in their lives, have used drugs, leading to an overestimation of drug-related deaths that resulted in organ donation.

Furthermore, while the opioid epidemic is often credited as the primary reason for the increase in organ donation and transplantation in the U.S., it is essential to recognize that drug-related deaths contribute to only a small fraction of total organ donors. Over the last five years, deceased organ donation has seen a remarkable 39%[14] increase.[15] While drug intoxication deaths account for 6% of this rise, a substantial 33% can be attributed to other advancements in the system, including OPO process improvements and procurement techniques such as the implementation and expansion of donation after circulatory determination of death (DCDD).

It is also important to highlight that the causes of death can vary from year to year. Nevertheless, it remains the responsibility of the OPO to respond to all potential organ referrals, regardless of the cause of death, and diligently work to recover organs for lifesaving transplantation. Deceased organ donation is always the result of a traumatic event in which an individual dies in a hospital while on a ventilator. Potential organ donors must also meet medical criteria and be authorized, either as registered donors or through family authorization, for the organ donation to move forward. OPOs are involved in every step of this process and pursue all opportunities for donation to occur.

AOPO is concerned about the dissemination of misinformation surrounding the true impact of the opioid epidemic on the success of the organ donation and transplantation system. While opioid-related donations play a role, the significant increase in organ donors can be attributed to various factors and improvements, emphasizing the critical efforts of OPOs in saving lives through transplantation. AOPO strongly urges the SFC to consult with experts in the field, including the Scientific Registry of Transplant Recipients (SRTR), to validate and confirm research findings, ensuring the highest standards of accuracy in the information presented in congressional hearings and used as evidence for legislative and regulatory decisions on system reform.

**Conclusion**

AOPO appreciates the opportunity to provide our comments for the hearing record. However, we are frustrated that despite repeatedly sharing our concerns with Congress and CMS, AOPO and its members have not been solicited for input, which is based on extensive knowledge of the nation's OPO system and of OPO professionals with decades of experience in the field. We urge the SFC to broaden its examination of the system by actively engaging all stakeholders in advancing reform efforts. This collaborative approach will serve donors, donor families, and potential recipients who rely on the collective dedication of all entities involved in the organ donation and transplantation process.

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[13] Goldberg, D., Lynch, R. Improvements in organ donation: Riding the coattails of a national tragedy. *Clin Transplant.* 2020 Jan;34 (1):e13755. doi: 10.1111/ctr.13755. Epub 2019 Dec 2. PMID: 31742783.

[14] *https://aopo.org/wp-content/uploads/2023-AOPO-US-Donation-Highlights-Infographic.pdf.*

[15] Based on OPTN data as of January 18, 2023.

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**Statement of Michael Bindner**

Chairman Wyden and Ranking Member Crapo, thank you for the opportunity to address this issue. I made comments on ***A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network*** in August of 2022, which I am resubmitting to keep on the record. While the need is urgent, the solution will take time. As we used to say on the Air Staff, if you want it bad, you get it bad.

Other than its impact on Medicare and affordable care, we are leery of any congressional involvement in this issue. Ideally, it is based on science and best regulated by medical professionals. Even without intervention, putting pressure on the system is ill-advised. With political pressure often comes pressure from donors. The beauty of the current process is that the ability to pay is not part of it. Of course, if there are abuses on this front in the current system, they should be looked into and dealt with by the Congress and this Committee.

Even with the best of motives, adjusting the process (even if flawed) does not resolve the issues facing organ transplantation. There are simply not enough organ donors and the system, which relies on voluntary donation for its legitimacy, would not be helped with economic incentives—especially as these would be more attractive to the poor. This borders on abuse. Not only do we exploit them in life, incentives would continue this exploitation in death.

Ultimately, the solution is better science. This is where government involvement can help and where issues of fiscal equity come in. Any treatment must be provided to all, regardless of the ability to pay. While the private sector may be helpful in developing treatments, government funded research would help the process and assure equity.

A promising solution is the use of retargeted stem cells, either grown on cartilage or injected into the sick organ. Both would render donation and its possibility of rejection to the realm of temporary solutions, as would artificial organs.

Research in this process can always be sped up with more government money for NIH. To make sure everyone can benefit from advancements, such as using 3D printing to create cartilage on which to grow stem cells both outside and inside the body, research and actual organ generation can be publicly funded. Public organ manufacture, because of its expense in every case, is likely better than relying on for profit medicine.

As we have stated before, most recently in March of this year, but also in 2019 and 2020, orphan drug research and manufacture should be owned and managed by the federal government. The same path can be taken for the development of cloned organs. If the government owned the process, profiteering would be minimized. To facilitate cooperation and speed the process, creation of a quasi-governmental enterprise would be useful. It would combine NIH, NSF, FDA. To repeat our previous comments on drug pricing:

"A main problem with high cost drugs, especially orphan drugs, is the high development costs and the cost of small batch manufacturing. This could drive the need to raise drug prices for mature drugs in order to subsidize the orphans, although some hikes are undertaken because no one can stop them. The solution for this is for NIH and the FDA to own the rights to orphan drugs and to contract out research and development costs as it does basic research, as well as testing and production.

"Hospitals and doctors would still make reasonable profit, but the government would eat the risk and sometimes reap the rewards. NIH/FDA might even break even in the long term, especially if large volume drugs which were developed with government grants must pay back a share of basic research costs and the attached profits, as well as regulatory cost."

Another way to assure equity in the growth and distribution of cloned organs, health care reform is essential. Again, to repeat our comments from March:

"Universal coverage, starting with a public option under the Affordable Care Act, with eventual evolution to some type of single-payer system is inevitable. Unless we

start building negotiation into the system now, we will give the drug companies a reason to oppose reform later.

"A public option will only pass if pre-existing condition reforms are abolished with public option enrollment being automatic upon rejection. The public option must be subsidized, replacing Medicaid for the disabled and those not requiring long-term nursing care. Long-term care should be removed from states and replaced with a new federal Medicare Part E.

"The profit motive, with the need to constantly increase profits to attract Wall Street investment or keep stock prices growing, will lead to an ever increasing number of people who will be considered uninsurable, thus relying on the public option.

"Most healthcare systems will provide services to both comprehensive insurance beneficiaries, the retired, the disabled and those with the public option. In other words, Medicare for All is our future, with the only exception being firms abandoning the system and providing their own doctors while making arrangements with local hospitals and specialists—essentially creating local HMOs.

"The major issue here is funding, although more efficiency will reduce prices. Costs are already minimized by the for-profit and by governmental medical care (which often uses for profit networks). To repeat, with a shout THE ISSUE IS PRICE, NOT COST!"

Thank you again for the opportunity to add our comments to the debate. Please contact us if we can be of any assistance or contribute direct testimony.

**Attachment One—Hearing on Pathways to Universal Health Coverage, June 12, 2019**

There are three methods to get to single-payer: a public option, Medicare for All and single-payer with an option for cooperative employers.

The first to set up a **public option** and end protections for pre-existing conditions and mandates. The public option would then cover all families who are rejected for either pre-existing conditions or the inability to pay. In essence, this is an expansion of Medicaid to everyone with a pre-existing condition. As such, it would be funded through increased taxation, which will be addressed below. A variation is the expansion of the Uniformed Public Health Service to treat such individuals and their families.

The public option is inherently unstable over the long term. The profit motive will ultimately make the exclusion pool grow until private insurance would no longer be justified, leading-again to Single Payer if the race to cut customers leads to no one left in private insurance who is actually sick. This eventually becomes Medicare for All, but with easier passage and sudden adoption as private health plans are either banned or become bankrupt. Single-payer would then be what occurs when

The second option is Medicare for All, which I described in an attachment to June 18th and 19th's comments and previously in hearings held May 8, 2019 (Finance) and May 8, 2018 (Ways and Means). Medicare for All is essentially Medicaid for All without the smell of welfare and with providers reimbursed at Medicare levels, with the difference funded by tax revenue.

**Medicare for All** is a really good slogan, at least to mobilize the base. One would think it would attract the support of even the Tea Partiers who held up signs saying, "don't let the government touch my Medicare!" Alas, it has not. This has been a conversation on the left and it has not gotten beyond shouting slogans either. We need to decide what we want and whether it really is Medicare for All. If we want to go to any doctor we wish, pay nothing and have no premiums, then that is not Medicare.

There are essentially two Medicares, a high option and a low one. One option has Part A at no cost (funded by the Hospital Insurance Payroll Tax and part of Obamacare's high unearned income tax as well as the general fund), Medicare Part B, with a 20% copay and a $135 per month premium and Medicare Part D, which has both premiums and copays and is run through private providers. Parts A and B also are contracted out to insurance companies for case management. Much of this is now managed care, as is Medicare Advantage (Part C).

Medicaid lingers in the background and the foreground. It covers the disabled in their first two years (and probably while they are seeking disability and unable to work). It covers non-workers and the working poor (who are too poor for Obamacare) and it covers seniors and the disabled who are confined to a long-term care facility and who have run out their assets. It also has the long-term portion which should

be federalized, but for the poor, it takes the form of an HMO, but with no premiums and zero copays.

Obamacare has premiums with income-based supports (one of those facts the Republicans hate) and copays. It may have a high option, like the Federal Employee Health Benefits Program (which also covers Congress) on which it is modeled, a standard option that puts you into an HMO. The HMO drug copays for Obamacare are higher than for Medicare Part C, but the office visit prices are exactly the same.

What does it mean, then, to want Medicare for All? If it means we want everyone who can afford it to get Medicare Advantage Coverage, we already have that. It is Obamacare. The reality is that Senator Sanders wants to reduce Medicare copays and premiums to Medicaid levels and then slowly reduce eligibility levels until everyone is covered. Of course, this will still likely give us HMO coverage for everyone except the very rich, unless he adds a high-option PPO or reimbursable plan.

Either Medicare for All or a real single payer would require a very large payroll tax (and would eliminate the HI tax) or an employer paid subtraction value-added tax (so it would not appear on receipts nor would it be zero rated at the border, since there would be no evading it), which we discuss below, because the Health Care Reform debate is ultimately a tax reform debate. Too much money is at stake for it to be otherwise, although we may do just as well to call Obamacare Medicare for All and leave it alone.

The third option is an **exclusion for employers,** especially employee-owned and cooperative firms, who provide medical care directly to their employees without third-party insurance, with the employer making HMO-like arrangements with local hospitals and medical practices for inpatient and specialist care.

Employer-based taxes, such as a subtraction VAT or payroll tax, will provide an incentive to avoid these taxes by providing such care. Employers who fund catastrophic care or operate nursing care facilities would get an even higher benefit, with the proviso that any care so provided be superior to the care available through Medicaid or Medicare for All. Making employers responsible for most costs and for all cost savings allows them to use some market power to get lower rates.

This proposal is probably the most promising way to arrest health care costs from their current upward spiral—as employers who would be financially responsible for this care through taxes would have a real incentive to limit spending in a way that individual taxpayers simply do not have the means or incentive to exercise. The employee ownership must ultimately expand to most of the economy as an alternative to capitalism, which is also unstable as income concentration becomes obvious to all.

**Attachment Two—Tax Reform, Center for Fiscal Equity, December 7, 2021**

**Subtraction Value-Added Tax (S–VAT).** These are employer paid Net Business Receipts Taxes. S–VAT is a vehicle for tax benefits, including

- Health insurance or direct care, including veterans' health care for non-battlefield injuries and long-term care.
- Employer-paid educational costs in lieu of taxes are provided as either employee-directed contributions to the public or private unionized school of their choice or direct tuition payments for employee children or for workers (including ESL and remedial skills). Wages will be paid to students to meet opportunity costs.
- Most importantly, a refundable child tax credit at median income levels (with inflation adjustments) distributed with pay.

Subsistence-level benefits force the poor into servile labor. Wages and benefits must be high enough to provide justice and human dignity. This allows the ending of state administered subsidy programs and discourages abortions, and as such enactment must be scored as a must pass in voting rankings by pro-life organizations (and feminist organizations as well). To assure child subsidies are distributed, S–VAT will not be border adjustable.

The S–VAT is also used for personal accounts in Social Security, provided that these accounts are insured through an insurance fund for all such accounts, that accounts go toward employee ownership rather than for a subsidy for the investment industry. Both employers and employees must consent to a shift to these accounts, which will occur if corporate democracy in existing ESOPs is given a thorough test. So far it has not. S–VAT funded retirement accounts will be equal-dollar credited for every worker. They also have the advantage of drawing on both payroll and profit, making it less regressive.

A multi-tier S–VAT could replace income surtaxes in the same range. Some will use corporations to avoid these taxes, but that corporation would then pay all invoice and subtraction VAT payments (which would distribute tax benefits. Distributions from such corporations will be considered salary, not dividends.

**Tax Reform Summary**

1. Employers distribute the child tax credit with wages as an offset to their quarterly tax filing (ending annual filings).
2. Employers collect and pay lower-tier income taxes, starting at $100,000 at 7.2%, with an increase to 14.4% for all salary payments over $150,000 going up 7.2% for every $50,000—up to $250,000.
3. Shift payment of HI, DI, SM (ACA) payroll taxes to employers, remove caps on employer payroll taxes and credit them to workers on an equal dollar basis.
4. Employer paid taxes could as easily be called a subtraction VAT, abolishing corporate income taxes. These should not be zero rated at the border.
5. Expand current state/federal intergovernmental subtraction VAT to a full GST with limited exclusions (food would be taxed) and add a federal portion, which would also be collected by the states. Make these taxes zero rated at the border. Rate should be 19.5% and replace employer OASI contributions. Credit workers on an equal dollar basis.

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LETTER SUBMITTED BY ADAM FRANK, M.D.

To whom it may concern:

I think all professionals in the transplant space will obviously concur that whatever can be done to reasonably improve transplant access and outcomes should be done. However, the characterization of UNOS and the OPTN as a "monopoly," a "cartel," or "the fox guarding the hen house" is completely inaccurate and is a starting premise which will likely cause great harm to patients desperately awaiting transplant. Although the current system has major problems, including an increase in wastage of transplantable organs, the infrastructure it has provided has saved nearly a million American lives. I have worked in the transplant space for 23 years and have served on the OPTN board of directors recently. In all of that time, I have never encountered a single UNOS employee who is not a dedicated professional who prioritizes what is best for the patients served by United States transplant system. The current increase in wasted transplantable organs is a complex problem that does not have one simple quick fix. The senators running the July 20th, 2023, quickly made it clear that they are not truly looking for solutions, but rather are looking to blame. They will not find the answers through this type of inquiry. They should be wise enough to realize this. Their slanderous characterization of UNOS and professionals employed in that organization does the country a disservice. The senators should realize that not ever urgent problem has an obvious "villain." This is one of those cases.

Sincerely,

Adam Frank, M.D.

LETTER SUBMITTED BY THE FAMILY OF MARY ANN HOLLIS

U.S. Senate
Committee on Finance
Subcommittee on Health Care
Honorable Chairman Benjamin L. Cardin
221 Dirksen Senate Office Building
Washington, DC 20510

RE: Failure of the US Transplant System regarding Mary Ann Hollis of Imperial, Missouri

Dear Chairman Cardin and Subcommittee Members,

On October 30, 2022, wife, mother, and mother-in-law Mary Ann Hollis received a liver and kidney transplant at Barnes Hospital (BJC) in St. Louis, Missouri. On Page 1021 of the over 10,500 pages of BJC notes, it is admitted that the donor liver given to Mary contained cancer cells. The family was told the same donor, from which Mary also received her new kidney, also had prostate, bile duct, and gall

bladder cancer. We strongly believe the donated kidney was also compromised prior to transplantation. The compromised kidney later required surgical procedures, including a nephrostomy bag. We still have not been told by BJC from which U.S. Organ Procurement Organization (OPO) these organs were harvested for transfer to Barnes. BJC discovered the cancer cells via pathology two days post-transplant. She was again placed on a liver transplant list and, on November 8, 2022, received a second liver transplant. This second liver transplant, which should not have been necessary, took a drastic toll on Mary's quality-of-life. For three weeks post-transplant, she suffered delirium and hallucinations due to her body receiving a second transplant within a 10-day time span. Therefore, Mary had three livers in her body within 10 days. By the time of the second liver transplant, we believe the cancer had rapidly began metastasizing in her immunosuppressed body via anti-rejection medications. Another question is why Mary wasn't also given a second new kidney given the fact that it was known that the donor's liver contained cancer cells.

Following numerous exploratory procedures on her weakened body, for which she was frequently placed NPO, and the contraction of biological and fungal infections, the donor kidney began to fail. BJC Nephrology attempted to place a stent in her donated kidney twice but incurred an undefined blockage/masses about which we were never told the nature. Soon after, they inserted a nephrostomy tube. We lost Mary on January 13, 2023—approximately 2.5 months post-transplant—NOT from the rejection of the donated organs but from the negligence of the harvesting OPO, the lack of OPO oversight by the United Network for Organ Sharing (UNOS), and by BJC for not discovering the cancer cells pre-transplant. Mary passed all pre-transplant testing during September and October 2022, during which time she was both cancer and infection free. One, or all entities involved are negligent by not providing cancer-free organ(s) for Mary.

Ironically, the causes of death listed on her death certificate do not list cancer as a cause of death; however, cancer cells were found via thoracentesis three days before her death. We strongly believe the donated kidney also contained cancer cells OR the introduced liver cancer spread rapidly to her other organs. That cause of death is listed as "Acute Renal Failure." We also believe the uncontrolled cancer had spread into her GI tract. Mary developed a gastrointestinal blockage in her lower right abdominal quadrant of which nature we were never informed. As a result, Mary couldn't process her tube feeding properly and was also subjected to an NG vacuum pump to remove excess gastric juices. That eventually began removing her tube nourishment. Mary then began receiving IV nourishment for 10 days prior to her admission to the ICU. Through the many procedures, transfusions, and unsterilized conditions surrounding her central line access, Mary contracted and also passed from "Necrotizing Soft Tissue Infection" from the biological and fungal infections in her bloodstream. None of this would have occurred had the original organs been disease-free.

Our family is seeking legal counsel to find justice for Mary's untimely and certainly unfortunate, unnecessary death; however, we're having difficulty finding any firm willing to accept Mary's case. This, in and of itself, is a travesty for justice for Mary. She was never able to meet her new step-grandchildren and step-great grandchildren, and had also suffered the recent loss of her youngest daughter. Mary had been purchasing gardening materials for use this year once she became strong enough post-transplant. Mary looked forward to eating healthily again. She had been purchasing new clothes, looking forward to the day she could come home and be with her family and pets. Sadly, these things will now never occur. Her husband and high school sweetheart for over 50 years prayed by her bedside daily that she would return home healthy and happy. He now sits alone wondering what could and should have been.

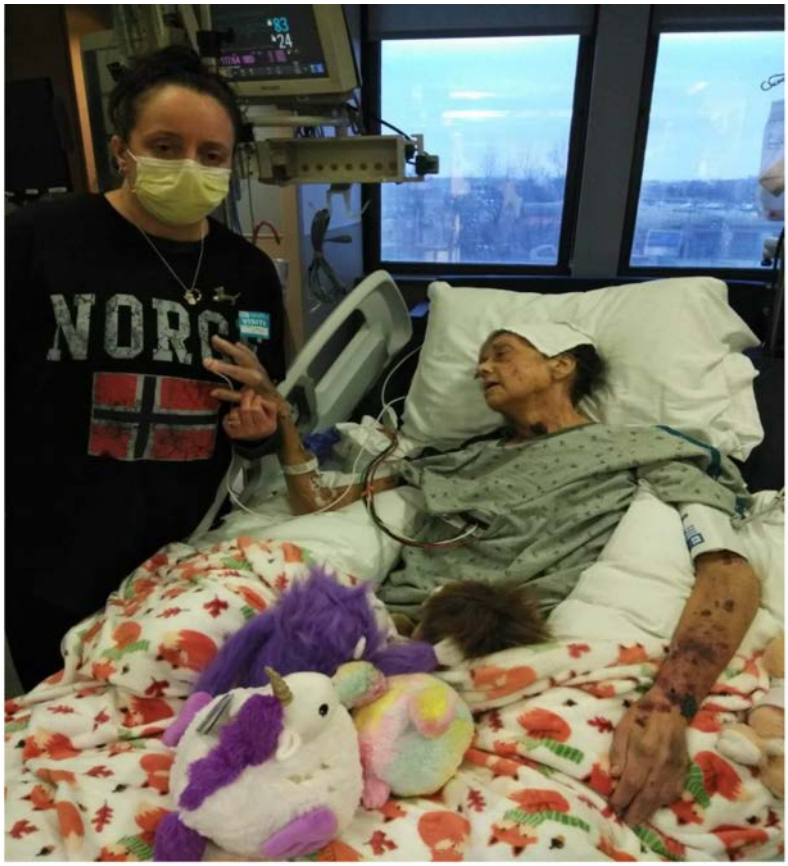
It's very sad that so much obvious negligence occurred surrounding Mary's case. Please ensure the U.S. Transplant System in place is completely overhauled. We simply want justice on Mary's behalf and to ensure that this extremely unfortunate situation doesn't occur ever again to any other family. Our question is who else received this donor's other organs? We pray the recipients and their families aren't suffering the same consequences as Mary's.

Each of us in Mary's family would cherish the opportunity to tell her story to each committee member, either via phone, Zoom, or in-person.

Thank you for your time and dedicated commitment to the rapid improvement of our Nation's organ transplant system.

Sincerely,

The Family of Mary Ann Hollis
Keith Hollis, Husband
Heather Hollis Knuckles, Daughter
Steven Knuckles, Son-in-Law



January 13, 2023—Three hours prior to Mary Hollis' death soon after life support was removed via her Living Will wishes. This is Mary's daughter, Heather, placing her mother's hand over her heart. This is the last time she would see her mother alive. Heather misses her greatly and continues receiving weekly grief counseling.

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LETTER SUBMITTED BY PATRICK MCGLONE

U.S. Senate
Committee on Finance
Subcommittee on Health Care

July 20, 2023

Dear Subcommittee Chair Cardin, Ranking Member Daines and all other members of the Finance Committee's Subcommittee on Health Care,

Thank you for your efforts to improve organ donation and transplantation.

My name is Patrick McGlone. I am a kidney and pancreas transplant recipient and I write to you on behalf of over 5,000 individuals across the nation who have come

together in a petition to oppose the potential introduction of for-profit companies to the U.S. organ donation and transplant system. Our petition grows with every minute and can be viewed at *https://sign.moveon.org/p/dont-profit-off-organs.*

As a representative of our petition, I sent a letter to you as well as other members of Congress, explaining our concerns regarding bills S. 1668 and H.R. 2544, which would modify the Public Health Service Act in ways that would allow for-profit companies to receive contracts to operate the Organ Procurement and Transplantation Network (OPTN). That letter is enclosed further below, and I urge you to please read it.

Regular changes and reforms are essential to maintaining the effectiveness of the OPTN. However, any such reform must be carefully examined for any intended or unintended consequences it would have on our nation's transplant patients, organ donors and their families. We fear that allowing for-profit companies to influence or guide OPTN responsibilities such as organ matching or policymaking would be a disaster for these people. For-profit companies are designed to make decisions based on what will maximize their revenue and market share, which is a mindset that has no place in a system designed to save patients in need no matter their wealth or backgrounds. Simply put: those two goals cannot coexist.

Thank you again for your time and attention to this urgent matter. As you work to reform the OPTN, we ask that you consider the voices of the thousands of petitioners who have spoken out in concern and prioritize human lives above all else.

Sincerely,

Patrick McGlone
Kidney and pancreas recipient (June 2021)
Petition to Stop For-Profit Takeover of Organ Donation

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July 19, 2023

Senator Bernie Sanders
332 Dirksen Senate Office Building
Washington, DC 20510

Representative Cathy McMorris Rodgers
2188 Rayburn House Office Building
Washington, DC 20515

Senator Ron Wyden
221 Dirksen Senate Office Building
Washington, DC 20510

**Subject:** Please Protect America's Patients by Keeping Profits Out of Organ Donation and Transplant

Dear members of Congress,

I write to you as one of the thousands of individuals who have come together to express our deep apprehension towards legislation that threatens our nation's organ donors and transplant patients.

As patients, donor families, volunteers and concerned citizens, we ask you to carefully consider the consequences that would occur should S. 1668[1]/H.R. 2544[2] be passed by Congress.

First and foremost, I must acknowledge the resounding support received for our petition on *MoveOn.org:* Stop For-Profit Takeover of Organ Donation. With over 5,000 signatures and growing, it is evident that the public recognizes the importance of protecting our country's transplant patients and honoring the priceless gifts that organ donors give to save lives. I have attached a list of our signers to-date to the digital version of this letter. You can also track the petition's growth in real time by visiting *https://sign.moveon.org/p/dont-profit-off-organs*.

The U.S. organ donation and transplant system is structured around a unique public-private partnership known as the Organ Procurement and Transplantation Network (OPTN). Created nearly 40 years ago through the passing of S. 2048, the Na-

[1] *https://www.congress.gov/bill/118th-congress/senate-bill/1668/text.*
[2] *https://www.congress.gov/bill/118th-congress/house-bill/2544/text.*

tional Organ Transplant Act,[3] the OPTN today is run much like a congress of its own. It combines the efforts and perspectives of our country's hospitals, laboratories, volunteers, agencies within the U.S. Department of Health and Human Services, and specialty non-profit contractors to keep the system moving.

To this day, U.S. law has mandated that the OPTN must be operated as a "non-profit entity that has an expertise in organ procurement and transplantation." This language is present in the Public Health Service Act, which S. 1668/H.R. 2544 would revise if passed. Specifically, those bills would delete the requirements that the OPTN has to be run as a non-profit, as well as the requirement that the OPTN must have expertise in organ procurement and transplantation.

In removing these legal requirements, S. 1668/H.R. 2544 would allow for-profit companies to bid on and receive contracts from the government to operate the OPTN. This would include the OPTN's most important work, such as setting the algorithms that match donated organs to patients and even the development and revision of policies controlling how organs are allocated nationwide.

Our petition does not represent any particular organizations, associations or other groups within or outside of the organ donation and transplant system, nor are we doing this in the interest of any such groups. We are patients and donor families, parents and friends, and everyday men and women who in one way or another have been touched by the noble gift of organ donation and the lifesaving surgeries it enables. We also do not oppose any true efforts to improve the organ donation and transplant system. However, we refuse to see those efforts subverted to the benefit of for-profit companies, which would jeopardize human lives.

Our primary concerns are that a for-profit takeover of the OPTN would inevitably prioritize financial gain over the well-being and survival of patients in need, undermine the trust of potential organ donors and recipients, and perpetuate existing disparities in transplant access based on wealth. The inherent strength of an OPTN run by non-profits is that they have no other goals than to save as many lives as possible. In contrast, for-profits are inherently conflicted between that mission and their existence as companies designed to maximize revenue for themselves and their shareholders.

There are plenty of for-profit hospitals and other organizations, such as software companies and couriers, who already play valuable roles in the OPTN. However, that is not the same as having for-profits control organ matching and organ policy-making for our entire country. It is troubling enough that S. 1668/H.R. 2544 do not include any "guardrails" against possible misuse of the OPTN by for-profits. We believe that even allowing them to take on leadership roles will bring us one step closer to a system that values the wealthy and privileged over the sickest and most underserved patients, who already struggle to receive medical treatment.

We implore you, as our elected representatives, to publicly provide assurance that lives will be prioritized over profits by revising S. 1668/H.R. 2544 to keep the OPTN a non-profit enterprise run by medical experts.

We trust that you will carefully consider our concerns and act in the best interest of the countless people who depend on the organ donation and transplant system. Please stand with us in preserving the generosity, compassion, and unwavering commitment to human life that organ donation represents.

Sincerely,

Patrick McGlone
Kidney and pancreas recipient (June 2021)
*https://sign.moveon.org/petitions/stop-congress-from-monetizing-organ-donation-reject-for-profit-healthcare.*

[3] *https://www.congress.gov/bill/98th-congress/senate-bill/2048.*

MID-AMERICA TRANSPLANT
1110 Highlands Plaza Dr. E, Suite 100
St. Louis, MO 63110
T 314–735–8200
*https://www.midamericatransplant.org/*

July 18, 2023

U.S. Senate
Committee on Finance
Washington, DC 20510

**Re: Thursday, July 20, 2023 Subcommittee Hearing "The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System"**

Dear Senate Finance Committee Members:

Mid-America Transplant appreciates the opportunity to provide a written comment in advance of the upcoming hearing, "The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System," on July 20, 2023. We support Congressional efforts to improve the organ donation system.

**Pancreata for Research**

Mid-America Transplant (MT) recognizes the need to improve the organ donation and transplantation system in the United States. MT fully supports the Centers for Medicare and Medicaid Services (CMS) in its efforts to improve the organ transplant process to maximize donation opportunities that will lead to more lives saved.

As stated in our April 3, 2023, letter to the Senate Finance Committee, we support changes to CMS' performance metrics that remove research pancreata from the calculation.

At Mid-America Transplant, placing organs for transplant to shorten the wait list and save more lives is always our priority. We move forward with an authorized donor *only* when we believe there is an opportunity for transplantation. There are instances in which transplant centers decline a previously accepted organ based on discoveries that take place during or after surgical recovery of that organ. For example:

- In 2021, MT took an authorized donor to the operating room on 13 occasions where, ultimately, no organs were transplanted.
- At the time of surgery, transplant centers had provided a provisional acceptance for at least one kidney for 12 out of these 13 donors.
- At the time of surgery, transplant centers had provided a provisional acceptance for the liver with 8 of these 13 donors.
- Ultimately, the transplant centers rescinded their acceptance of the kidneys and livers for transplant.
- In all 13 cases, MT placed the pancreas for research with one of the two academic medical centers located in St. Louis, Missouri.

Since 2017, Mid-America Transplant has partnered with researchers at Saint Louis University and Washington University in St. Louis to support pancreas research. These studies, two of which are NIH-funded, are IRB-approved and supported through a formal evaluation process.

Mid-America Transplant recognizes that medical advancements through research such as this may better help treat diseases like diabetes and ultimately reduce the number of people who one day need an organ transplant. The prevalence of diabetes is a national health issue, impacting minority communities at even greater rates and contributing to overall health inequities. Forty-three percent (43%) of the individuals waiting for a lifesaving transplant in MT's designated service area have diabetes. We believe these pancreata research programs have the potential to provide valuable clinical insights and will continue to partner in this manner.

Mid-America Transplant's research partnerships are not limited to pancreata; we currently have 35 active research agreements with researchers at the abovementioned institutions for organs and tissues that cannot be transplanted. All organs, including pancreata, are provided to the researchers at no charge.

Mid-America Transplant is committed to maximizing donation through innovative practices that are supported by research. Over the past ten years, MT's Chief Medical Officer has led or participated in multi-OPO and academic medical center research projects that have resulted in 25 peer-reviewed publications to date. This research has led to an increase in the number of organs recovered and transplanted across the nation, resulting in more lives saved.

Thank you for the opportunity to submit this comment. We are happy to provide additional data supporting our top priority of placing organs for transplant, and additional details surrounding our research initiatives at the Committee's request.

Mid-America Transplant is eager to continue the dialogue about ways to improve the system to ensure every community is served by a high performing Organ Procurement Organization.

Sincerely,
Kevin Lee
President and CEO

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NATIONAL DOWN SYNDROME SOCIETY
1155 15th Street, NW, Suite 540
Washington, DC 20005
800–221–4602
*https://ndss.org/*

U.S. Senate
Committee on Finance

The Honorable Ron Wyden
221 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo
239 Dirksen Senate Office Building
Washington, DC 20510

**RE: NDSS statement for the record, Senate Finance hearing on organ transplant reform**

Dear Chairman Wyden and Ranking Member Crapo:

The National Down Syndrome Society (NDSS) empowers individuals with Down syndrome and their families by driving policy change, providing resources, engaging with local communities, and shifting public perceptions. We write today in response to the Senate Finance Committee's hearing on "The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System." More specifically, we wish to highlight the prevalent discrimination against individuals with disabilities that persists in the organ transplant system today.

Organ transplants are a key part of our nation's health care system. They save lives every day. Unfortunately, people with disabilities have consistently been denied organ transplants in the United States based on unfounded assumptions on their quality of life and ability to comply with post-operative care. This is in direct violation of the Americans with Disabilities Act, Section 504 of the Rehabilitation Act of 1973, and Section 1557 of the Affordable Care Act, which prohibit discrimination on the basis of disability.

Despite these existing overarching protections, real-world discrimination persists. The National Council on Disability (NCD) reviewed applicable federal and state laws, the disability-related policies of various organ transplant centers, and policies of the Organ Procurement and Transplantation Network and issued a report in September 2019.[1] The report found that people with disabilities are frequently denied access to organ transplants based on written and unwritten policies excluding people with disabilities as organ transplant candidates, even in the nine states that, at the time, had state laws in place prohibiting such practice. Furthermore, some medical professionals even refused to evaluate a patient's medical suitability for organ transplant because of their disability.

In our community, the threat of discrimination in organ transplantation presents a real-world danger. About 50% of all people born with Down syndrome have congenital heart disease, which often requires heart surgery and, if unsuccessful, can lead to the need for transplantation. In October of 2021, NDSS learned of Zion Sarmiento, a baby born with Down syndrome in Florida. Zion had a congenital heart defect and underwent multiple surgeries, but ultimately, he needed a transplant to survive. Despite Florida having passed a state-law prohibition of disability discrimination in organ transplantation, effective July 1, 2020,[2] Zion was unable to access

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[1] National Council on Disability. (2019). Organ transplant discrimination against people with disabilities. Retrieved from *https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf.*

[2] Florida CS/HB 1179 (2020) *https://www.myfloridahouse.gov/Sections/Bills/billsdetail.aspx?BillId=69420.*

a transplant and tragically passed away in October. He was less than four months old.

While progress has been made since NCD issued their report, including the passage of laws in 39 states,[3] this patchwork system does not adequately ensure individuals with disabilities are protected because the organ transplant ecosystem, as a whole, is firmly interstate. **We therefore strongly urge members of the Committee to support the Charlotte Woodward Organ Transplant Discrimination Prevention Act (S. 2706),** which would prohibit discrimination against people with disabilities who need organ transplants, upholding, clarifying, and building upon rights established in the Americans with Disabilities Act of 1990, Section 504 of the Rehabilitation Act of 1973, and Section 1557 of the Affordable Care Act. This commonsense legislation is bipartisan in both chambers (with H.R. 1183) and has no fiscal impact.

NDSS strives to ensure all individuals with Down syndrome are assured their human rights and valued by a more inclusive society. We applaud the Committee for examining these important issues and look forward to working with Congress to advance bipartisan policies that improve the nation's organ transplant ecosystem, including protecting the civil rights of individuals with disabilities.

Sincerely,

Kandi Pickard
President and CEO

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NATIONAL KIDNEY FOUNDATION
30 East 33rd Street
New York, NY 10016

**Statement of Sharon Pearce, Senior Vice President, Government Relations**

The National Kidney Foundation (NKF) respectfully submits our statement for the record on behalf of the 37 million individuals in the United States, 1 in 7 adults, estimated to have chronic kidney disease (CKD).[1] The prevalence of kidney failure is expected to increase dramatically, possibly exceeding one million people who may need access to the transplant wait list by 2030.[2] There are not enough deceased or living donor organs to meet current or future needs creating a public health emergency that needs immediate attention. Although more than 25,000 people received a kidney transplant in 2022, far too many are still waiting. Many never access the transplant wait list or learn that a transplant is an option. More than 100,000 individuals are on the transplant wait list, and nearly 90,000 are waiting for a kidney.

The current transplant system infrastructure has numerous opportunities for improvement to better serve individuals who can benefit from a kidney transplant. NKF has worked to transform the transplant system so that it is more patient-centric, transparent, and equitable. We appreciate the Senate Finance Committee's continued efforts to amplify the critical need for a high-performing transplant system. The lack of appropriate oversight, accountability, and support from regulatory agencies has had life-threatening consequences for the people who rely on the American transplant system for another chance at a healthy life through transplantation. Patients are in dire need of a reformed transplant system that optimizes every single opportunity for organ donation and transplantation.

Approximately 14 people on the national transplant list die each day awaiting their lifesaving kidney.[3] Yet, more than 7,000 recovered deceased donor kidneys went untransplanted in 2022, according to data from the Organ Procurement and Transplantation Network (OPTN). Access to transplantation remains disparate for rural populations, communities of color, and people of lower socioeconomic status. Pa-

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[3] National Down Syndrome Society. (2022). Organ transplant discrimination state laws. Retrieved from *https://www.ndss.org/advocacy#p_health.*

[1] Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, 2021. Centers for Disease Control and Prevention; 2021.

[2] McCullough, K.P., Morgenstern, H., Saran, R., Herman, W.H., Robinson, B.M. Projecting ESRD Incidence and Prevalence in the United States through 2030. *J Am Soc Nephrol.* 2019 Jan;30(1):127–135. DOI: 10.1681/ASN.2018050531. Epub 2018 Dec 17. PMID: 30559143; PMCID: PMC6317596.

[3] OPTN/SRTR 2021 Annual data report: Preface. (2023). *American Journal of Transplantation,* 23(2). *https://doi.org/10.1016/j.ajt.2023.02.002.*

tients highly regard transparency and shared decision-making and desire the same from the stakeholders within the transplant ecosystem. The Senate Finance Committee's 2022 hearing on transplantation uncovered a disturbing array of shortcomings in our national transplant system and identified numerous opportunities for improvement that warrant its reformation and modernization to be best-in-class.

**Why Patient-Centricity and Transparency Matter**

> There does not seem to be any truth in disclosure. I have been on dialysis for three years, and it took two years to meet my transplant team due to the weight I was supposed to be. For two years, I had to struggle on my own with no guidance. They left me out to dry, more like drown, without any safety device.
>
> *E.F., NKF Kidney Patient Advocate*

Patients are deeply invested in their health and wish to be active participants in decision-making processes along the transplant journey, from initial transplant referral, through the transplant consultation and evaluation phases, through wait-listing, transplantation, and post-transplant recovery. However, inadequate patient education and opacity in transplant program processes make it difficult for patients to make informed decisions. Because transplant hospitals are not transparent about their patient selection criteria, patients do not have the information they need to determine which transplant program will be best able to serve someone with their clinical history or healthcare values.

Even when a patient is able to be listed for transplant, they are often left in the dark about their status on the wait list. On average, transplant candidates receive 17 organ offers that are declined on their behalf without their knowledge or consent. While those organs are sometimes accepted by and transplanted into other patients with lower allocation priority, in many cases, those declined organs are not utilized at all.4 Increasing organ utilization is closely linked to reimbursement, transparency, and improved organ acceptance practices.[4] However, it begins with a patient-centered approach to understanding the wait-listed patient's goals and preferences (including preferences that might evolve as time is spent on the wait list). Transplant programs must always maintain sight of promoting shared decision-making with patients. Patient-centricity must always be a priority, and transplant programs should report on evidence of the inclusion of patients in the decision-making process.

NKF supports patient-centric process measures, including bi-annual reports to patients on organs offered and declined on their behalf and annual conversations between patients and their care team regarding patient preferences and tolerances for accepting or declining certain organs.

**The Importance of Equity in Access to Kidney Transplantation**

> As a Black patient who has collectively waited more than 14 years on the transplant list, the journey is daunting, and hope is diminished. Time is life when waiting for a lifesaving transplant.
>
> *M.B., NKF Kidney Patient Advocate*

All kidney failure patients must have a fair chance of receiving a lifesaving kidney transplant, regardless of their race or ethnicity. Unfortunately, people in underserved communities who want to pursue transplantation as a treatment for kidney failure often face racial, geographic, and socioeconomic barriers. Other hurdles include a lack of patient education and low health literacy which links to the substandard access to transplantation endured by people of lower socioeconomic status, which leaves them reliant upon dialysis instead of receiving the optimal treatment for kidney failure: transplantation.

NKF strongly supports efforts to improve data collection and transparency in the transplantation referral, evaluation, and wait-listing process. The absence of data on the pre-wait list experience makes it challenging to determine where problems exist. Better data collection would shed light on individual transplant center performance, identify gaps in the system, and would inform policy development to assure that all

[4] Husain, S.A., King, K.L., Pastan, S., et al. Association Between Declined Offers of Deceased Donor Kidney Allograft and Outcomes in Kidney Transplant Candidates. *JAMA Netw Open.* 2019;2(8):e1910312. doi:10.1001/jamanetworkopen.2019.10312.

candidates have equitable access to transplantation. Congress and the OPTN could advance this objective by advancing policy that develops a standard definition of a transplant referral and promoting a nationwide system for tracking racial and ethnic disparities in transplant referral, evaluation, and wait-listing.

**Saving More Lives by Reforming the U.S. Transplant System**

> [Receiving a] Transplant means everything to me. Living on dialysis is very hard. Dialysis is surviving. Transplant is living.
>
> *A.H., NKF Kidney Patient Advocate*

NKF supports reforming and modernizing the U.S. Transplant System to increase and enhance kidney transplantation by upholding patient-centricity, transparency, and equity. We believe that the Health Resources and Services Administration (HRSA) has a responsibility to the American people to create, maintain, and support a high-quality, high-performing transplant system. We look forward to its Organ Procurement and Transplantation Network (OPTN) Modernization Initiative. With increased kidney non-utilization rates, lack of innovation in a world that now has cutting-edge technology, and wide disparity gaps in access to kidney transplantation, we are eager for HRSA to take action to revitalize the transplant system to mitigate the life-threatening consequences of antiquated practices and poor regulatory oversight and accountability.

**Conclusion**

The National Kidney Foundation applauds the Senate Finance Committee for endeavoring to improve transplantation in the United States. We firmly believe in the achievement of a transplant system that prioritizes patients; it is long overdue. We welcome any questions or comments and stand ready to support Congress in its effort to reform transplantation. Please contact Morgan Reid, Director of Transplant Policy and Strategy (morgan.reid@kidney.org), or Lauren Drew, Director of Congressional Relations (lauren.drew@kidney.org).

Thank you for your consideration.

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ORGAN DONATION CONSORTIUM
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July 28, 2023

Honorable Benjamin Cardin, Chair
Honorable Steve Daines, Ranking Member
U.S. Senate
Committee on Finance
Subcommittee on Health Care
219 Dirksen Senate Office Building
Washington, DC 20515

Re: Hearing of the Subcommittee on Health Care "The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System," Thursday, July 20, 2023 at 10:00 a.m.

Dear Chair Cardin and Ranking Member Daines,

We, the members of the Organ Donation Consortium, offer this statement for the record for the Health Subcommittee Hearing—"The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System." As Senator Grassley noted at the hearing, failures in the transplant system result in deadly costs not only to those who await a transplant but also to the generous donor families who make the gift of life possible. As organ donation professionals, and on behalf of those donor families we have the privilege of serving every day, we thank you for making reforms to the entire system a priority.

*Who We Are.* The Organ Donation Consortium, or ODC, is comprised of five of the nation's leading Organ Procurement Organizations (OPOs) and collectively represents almost 38 million Americans—over 10% of the U.S. population stretching from California to Florida. The ODC was formed in part to promote collaboration, transparency, and accountability among all stakeholders, to decrease disparities in

the transplantation ecosystem, and to modernize technology and systems among all institutions engaged in this work.

*Support of S. 1668.* We fully support S. 1668—the Securing the U.S. Organ Procurement and Transplantation Network Act, which would allow the Health Resources and Services Administration (HRSA) to run a competitive process to choose from the best contractors for different functions of the national Organ Procurement and Transplantation Network (OPTN). This bill would bring important, needed improvements to the organ donation and transplantation ecosystem and would make for a more equitable and accountable system.

*OPTN Governance.* We support a governance structure for the OPTN that is wholly independent from the organizations it engages to conduct its work. This will lead to greater oversight and accountability of the entire transplant ecosystem for years to come and should be a top priority of HRSA and its Modernization Initiative.

*For-Profit Contractors.* While the OPTN itself should continue to function as a board operated solely as a non-profit organization, we believe for-profit contractors should be allowed to bid for the operational portions of the OPTN contract. The organ donation and transplantation system should be allowed to benefit from best-in-class services regardless of the exempt status of the organization at hand. The current OPTN contractor as well as every OPO in the country already relies on for-profit entities to provide services in this work, and some transplant centers themselves are for-profit hospitals. There is simply no reason why the donation and transplant system should be prohibited from working with entities deemed best able to provide a given service.

That said, we firmly believe that only non-profit organizations should be allowed to serve as OPOs, just as the OPTN board itself must be non-profit. OPOs are frontline organizations working directly with donor families in the most tragic of circumstances as they make the selfless decision to donate their loved one's organs. The public's trust in the donation and transplant system is sacrosanct, and no one should fear that the system itself is an attempt to profit from the gift of life.

*Need for Data Collection, Performance Metrics, and Transparency.* We support the adoption of performance metrics for all stakeholders throughout the system—donor hospitals, OPOs, and certified transplant centers—with common definitions and guidelines at their core. With the collection of uniform process data, each stakeholder can be compared, benchmarked, and evaluated as a participant in the donation and transplantation system. We also support the public disclosure of system-wide performance data to drive accountability and improvements. Doing so could be accomplished without jeopardizing patient privacy, which today is routinely realized through medical research leading to evidence-based best practices.

*The OPO Final Rule.* We support the enforcement of the OPO Final Rule to ensure every community is served by a high-performing OPO, although we recommend the rule be implemented in a way that does not disrupt the system irresponsibly. We support the immediate publication of interpretive guidelines to provide clear direction on the impending recertification process. We also support a revision to the OPO Final Rule that would remove the inclusion of research pancreas in the OPO performance metrics.

We look forward to working with you to improve the efficiency and effectiveness of the organ transplantation process. Thank you again for your leadership on this issue.

Sincerely,

Janice F. Whaley
President and CEO
Donor Network West
San Ramon, California

Ginny McBride
Executive Director
Our Legacy
Orlando, Florida

Bradley L. Adams
President and CEO
Southwest Transplant Alliance
Dallas, Texas

Kevin Lee
President and CEO
Mid-America Transplant
St. Louis, Missouri

Kelly Ranum
President and CEO
Louisiana Organ Procurement Agency
Covington, Louisiana

cc: Senator Ben Cardin, Senator Todd Young, Senator Bill Cassidy, Senator Elizabeth Warren, Senator Cory Booker

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SCIENCE IN DONATION AND TRANSPLANT
791 Alexander Road
Princeton NJ 08540

U.S. Senate
Committee on Finance
219 Dirksen Senate Office Bldg.
Washington, DC 20510-6200

August 1, 2023

Re: Subcommittee Hearing "The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System," Subcommittee on Health Care, Date: Thursday, July 20, 2023

Thank you for this opportunity to respond to the issues raised during July 20, 2023, Senate Finance Committee Health Subcommittee Hearing on Organ Transplantation Reform and the United States's Organ Procurement and Transplantation Network. Our non-profit organization, Science in Donation and Transplant (SID&T), supports evidence-based donation and transplant policy-making. Donors and transplant recipients alike deserve a well-aligned, science-based system. We advocate reform with leading medical practitioners for enhanced coordination and alignment among Organ Procurement Organizations and transplant centers. We aim to ensure that the metrics and measures used to credential and designate donation and transplant organizations are grounded in science and protected from political whim and private financial influence. SID&T understands that public trust is the foundation of a system based on altruism. We are concerned that statements of the Senate Finance Committee threaten the world's leading donation and transplant system.

***Mass Closure of OPOs does not lead to system improvement, but instead destabilizes the donation and transplant system:*** System improvement requires that there be evidence-based quality-enhancing processes. The hearing rehashed outdated data and doubled down on the extremely poorly conceived metrics governing organ donation. Committee members advocated that the Centers for Medicare and Medicaid Services (CMS) demand that Tier 1 Organ Procurement Organizations immediately take over Tier 3 OPOs. This demand is both unachievable and downright dangerous. Was the Committee aware, leaving aside for a moment the medically flawed metrics that established Tiers in the first place, that the data used for current standing is two years old at the time that of? The real-life impact, therefore, of the "immediate closure" could well be that an OPO currently performing as a Tier 3 might be required to take over an OPO presently functioning as a Tier 1. Additionally, since adopting the Rule over 31 months ago , CMS has yet to establish any mechanism for avoidance of the inevitable chaos that would follow mass unwarranted decertifications.

The focus on system closure rather than data-based system improvements, underscores the source of the current rule: *i.e.,* special interests intent on shutting and privatizing OPOs and monetizing what's left of the world's leading procurement system without the donor or recipient in mind. No other health entity or hospital is regulated in this manner; accountability is measured by adherence to standards, and data which reflects current performance, rates of improvement, and adherence to best practices. No other health care entity participating in the federal system of reimbursement is required to compete in a "hunger games" race, pitted against one another. HHS does not arbitrarily shut 42% of the nation's so-called underperforming hospitals by pitting the performance of urban and poor rural facilities against those located in wealthy and homogenous suburban locations; no data would assume that health care access is the same in every community. Achieving high quality is a goal, one that is achieved through researching and understanding best practices and processes. Quality and community service is not a win/lose, live/die proposition.

***The Committee ignored Congress' own analysis of the donation and transplant system:*** The Senate Finance and Senate Budget Committees would be better served by investigating why Health and Human Services and CMS ignored the will of Congress. Congress charged the National Academies of Sciences, Engineering, and Medicine (the National Academies) to examine and recommend improvements to research, policies, and activities related to deceased donor organ procurement, allocation, and distribution. The congressional language requested that the report in-

clude recommendations to update the Organ Procurement and Transplantation Network's (OPTN's) policies and processes. Shortly before the problematic OPO performance rule was promulgated Congress mandated an in-depth peer-reviewed scientific study of organ donation and transplant by the National Academies of Sciences, Engineering, and Medicine (NASEM). The rule was promulgated without reference to the report, and to date, has not incorporated its findings.

Beginning in 2020, NASEM held 17 discussions, meetings, listening sessions, and webinars ending in February 2022, with the release of their report: **A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution. Nevertheless,** in November 20, 2020, amid data gathering for a scientific study still underway, powerful lobbyists convinced federal regulators at CMS to finalize rules governing Organ Procurement Organizations (OPOs) despite warnings from healthcare and science professionals on its potentially devastating impact. While, in late 2021 Health and Human Secretary Becerra called for subject matter experts, science professionals, and others to respond to a CMS Request for Information on opportunities to improve and grow the organ donation and transplant system, even this effort ignored the pending release of the Congressionally-sponsored NASEM study. Prior to receipt of either Congress' report, or digestion of its own data, some Federal officials proposed allowing federal bureaucrats to delegate for-profit organ management companies to replace current community-based, nonprofit Organ Procurement Organizations. This effort was fortunately never acted upon, allowing for the February 2022 release of the landmark NASEM study authorized by Congress, which highlighted significant flaws in regulations recently enacted by federal regulators.

We, and many peers in the field, know from fact-based experience that improving accessibility and outcome for patients and the overall efficiency and effectiveness of the donation and transplant system requires specific CMS-encouraged goals:

- Encouraging the proper alignment and cooperation among Organ Procurement Organizations, Transplant Centers, Hospitals, and community partners.
- Recognizing that the certification and decertification metrics for OPOs need revision. Measuring OPOs based on transplant rates fails public policy and basic logic tests. Transplant decisions are made by transplant centers, not OPOs.
- The many questions raised by the Rule's failure to address all of the critical criteria and timeframe questions of potential decertification of up to two-thirds of existing OPOs, and the potential negative impact this poses to the most at-risk populations demand the establishment of a National Task Force of science-based experts and community stakeholders to study the issues and make recommendations.
- The compassionate nature of organ donation and procurement begs for CMS to protect, nurture and improve the community-based nonprofit system and not be the instrument of the system's destruction.

***Proposed Decertification has inequitable impact:*** We are concerned that most entities headed for decertification under the latest data publication from CMS are OPOs whose service area demographics are disproportionately underserved communities. First, the research has yet to be done to determine if these OPOs are being fairly evaluated, given the impact of their certification on factors they cannot control, such as transplant rates. As stated in the NASEM report: From the NASEM report:

> While waiting lists remain long and many listed individuals die while awaiting an organ every day, too many donated organs procured and offered to patients at transplant centers are not accepted—leaving thousands of potentially lifesaving donated organs unused yearly. Evidence indicates that many, if not a large majority, of unused organs could be successfully transplanted and benefit patients. This problem is much more prominent in the United States than in many other countries. For example, the overall nonuse rate in the United States is twice that in France. In the United States, on average, patients who die waiting for a kidney had offers for 16 kidneys that were ultimately transplanted into other patients. This indicates that many transplant centers refuse viable kidney offers on behalf of those on the waiting list.

This clearly must improve through better alignment.

Second, given the unknown impact, and tremendous complexity of closing, merging or reorganizing OPOs, frightening questions about how those populations will be served are raised. Given CMS' one-year timeframe for improvement, what high-

performing OPO will take over a lower-performing service area? There is a tremendous cost associated with decertification. Who will be responsible for the fiscal issues related to physical facilities, buildings, labor, affiliates, and contractors? The uncertainty around these issues, and the process of this rule making and decertification itself opens the door to an avalanche of lawsuits? Federal judges, not experts in quality improvement or the delivery of scarce services, will determine the future of organ procurement.

In closing, the current special interest political movement to accelerate the full force of the Rule governing donation and transplant is not a plan. It is a roadmap to chaos which will inordinately impact patients of color and lower economic standing. The sensitive nature of organ donation and procurement begs Congress and HHS/CMS to protect, nurture and improve the community-based nonprofit system based on evidence-based science, not special interest politics. In support of the efforts of policy-makers, Science in Donation and Transplant commissioned a literature review by Healthcare Management Associates, providing important resources for those who are concerned with quality improvement. The result of this research, much of which belies the arguments made by the hand-chosen witnesses placed before the Committee is attached for your edification.

Thank you for the opportunity to respond.

(1) Realizing the Promise of Equity in the Organ Transplantation System (The National Academies of Sciences, Engineering, and Medicine Consensus Study Report, 2022), *https://nap.nationalacademies.org/catalog/26364/realizing-the-promise-of-equity-in-the-organ-transplantation-system.*
(2) *https://unos.org/about/fast-facts/.*
(3) Prior rule projections calculated by Donate Life America. CMS rule projections based on CMS new rule goal.

The following is the full report of Health Management Associates *(https://sidandt.org/the-science/hma-executive-summary-and-report).*

Health Management Associates was engaged to review the November 2020 RULE based on sound science and research.

**Health Management Associates (HMA)**

Founded in 1985, HMA is a leading independent, national research and consulting firm that provides technical assistance and training, facilitation and strategic planning, research and evaluation, policy development and recommendations, technical report writing, and analytical services with a focus on improving the administration and delivery of public health, healthcare, and social services programs.

**Introduction**

The United States has one of the highest-performing donation and transplant systems in the world and is continually improving to increase organ donation and transplant.[1] Based on data from the International Registry in Organ Donation and Transplantation, the U.S. has the highest number of organ donors per million population and the highest number of kidney, liver, and heart transplants per million population. In 2022, 42,887 organ transplants were performed in the country, which reflected a 3.7% increase over the previous year. to further reduce the wait list for organs, CMS issued the final rule, "Medicare and Medicaid Programs: Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measures Requirements for Organ Procurement Organizations: Final Rule." The new rule includes the following provisions: (1) donation rate measure, (2) transplantation rate measure, (3) performance benchmark, (4) 12-month review periods, (5) performance tiers, (6) increased competition, (7) transparent OPO performance, and (7) implementation timeline.

**Reliable and Timely Data for Evaluation**

Both the donation rate and transplant rate measures utilize "donor potential" in measuring the OPO performance. Under the new rule, "donor potential" is defined as "the number of inpatient deaths within the DSA among patients 75 and younger with a primary cause of death consistent with organ donation." Donor potential will be calculated utilizing state death certificate data which is an unreliable source of

[1] International Registry in Organ Donation and Transplantation (IRODaT). (2023, May 15). Database. International Registry in Organ Donation and Transplantation (IRODaT). *https://www.irodat.org/.*

data. According to the CDC, approximately 20–30% of death certificates have issues with completeness.[2] A recent study sought to compare the accuracy of using death certificate data in calculating the potential donor as defined under the new rule versus the true potential as determined by an OPO in the real-time disposition of donor referrals. Utilizing death certificate data, approximately 55% of the 140 deaths reviewed were deemed "potential donors." Whereas an analysis applied OPO evaluation of clinical exclusion characteristics to determine donor potential determined that only 10% were truly eligible donors.[3] It is vital to utilize a data source to evaluate OPOs; however, utilizing death certificate data does not provide the level of clinical detail needed to accurately reflect the number of viable organs that can be transplanted. In accordance with the National Academies of Science, Engineering, and Medicine (NASEM), SID&T urges that patient-level data be collected and used as the measure denominator. The patient-level data should be granular enough to contain essential information about referrals of ventilated deaths, medical suitability of donors, and other key information.

**Metrics for Evaluation**

CMS proposed to revise the definition of "donation rate" from "eligible donors as a percentage of the eligible deaths" to "the number of donors as a percentage of the donor potential." The inclusion criteria for donor potential are ICD–10–CM codes I20–I25 (ischemic heart disease); I60–I69 (cerebrovascular disease); V–1–Y–89 (external causes of death): Blunt trauma, gunshot wounds, drug overdose, suicide, drowning, and asphyxiation. Donor potential will be adjusted using the proportion of Medicare beneficiary inpatient deaths in the hospital compared with the total Medicare beneficiary inpatient deaths in the county for OPOs servicing a hospital within a waiver under § 486.308. Currently, the donation rate measure fails to take into account various factors, such as gender, race/ethnicity, and BMI. These factors have been found to significantly affect donation metrics (*i.e.,* donors per death,[4] donors per eligible death,[5] and eligible donors per eligible death).[6] According to an assessment of national organ donation rates, male donor subgroups, compared with female donors, had higher donors per death, donors per eligible death, and eligible donors per eligible death.

In comparison to other racial/ethnic groups, it was found that White individuals had the highest likelihood of donation across these three donation metrics. The study also found that body mass index greater than 30, compared with BMI less than 30, was significantly inversely associated with all donation metrics. It is vital to take into consideration BMI since the prevalence rate of obesity among adults aged 20 is over nearly 42 percent. Additionally, obesity is an important risk factor for ischemic heart disease.[7,8] SID&T recognizes the value of the donation rate; however, we agree with NASEM that a consensus-based process be utilized to develop the donation rate measure and that it be one of many measures in a dashboard of metrics to assess OPO performance. We urge that the dashboard include elements to address disparities, referrals responded to, and others. SID&T also recommends that the dashboard be available to patients.

Under the new final rule, CMS is also changing the transplantation rate measure to the number of transplanted organs from an OPO's DSA as a percentage of inpatient deaths among patients 75 years old or younger with a primary cause of death that is consistent with organ donation. The transplant rate does not take into consideration regional differences. According to a study published in the *Journal of the*

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[2] Department of Health and Human Services, Understanding Death Data Quality: Cause of Death from Death Certificates. Centers for Disease Control and Prevention. Retrieved May 15, 2023, from *https://www.cdc.gov/nchs/data/nvss/coronavirus/cause-of-death-data-quality.pdf.*

[3] Gunderson, S., Kemink, J., Topp, C., Payne, W., Brown, T., Welsch B. Can Organ Donor Potential Be Determined from Death Certificates? A Case Report [abstract]. *Am J Transplant.* 2020; 20 (suppl 3). *https://atcmeetingabstracts.com/abstract/can-organ-donor-potential-be-determined-from-death-certificates-a-case-report/.* Accessed January 6, 2023.

[4] Donors per death measures the percentage of the population who become donors of 1 or more organs when deceased.

[5] Donors per eligible death is an adjusted metric that accounts for the number of deaths meeting the predefined eligibility criteria.

[6] Eligible donors per eligible death represents the eligible deaths that are converted into donors.

[7] Bryan, S., Afful, J., Carroll, M., Te-Ching, C., Orlando, D., Fink, S., and Fryar, C. (2021). National Health and Nutrition Examination Survey 2017—March 2020 Prepandemic Data Files Development of Files and Prevalence Estimates for Selected Health Outcomes. National Health Statistics Reports. *https://doi.org/10.15620/cdc:106273.*

[8] McPherson, R. (2015). Obesity and ischemic heart disease. *Circulation Research,* 116(4), 570–571. *https://doi.org/10.1161/circresaha.115.305826.*

*American Medical Association (JAMA),* heart, liver, and kidney transplantation rates in rural/small towns are lower than those in urban areas despite their waiting list registration rates being lower.[9]

It is also important to highlight the organ procurement and transplant system relies both on OPOs and transplant centers to work collaboratively to ensure the recovery and transplantation of organs to individuals in need. OPOs are responsible for coordinating the procurement, preservation, and transportation of organs, as well as maintaining a system for locating prospective beneficiaries for available organs. However, this measure will hold OPOs accountable for transplant centers which are responsible for determining whether a patient is added to the national waiting list that UNOs manages and whether to accept or decline organ offers for their patients. This measure puts the OPOs and transplant centers at odds while compromising patient care. It is essential that CMS develop and design measures that align and appropriately hold OPOs and transplant centers for their performance.

This was seen in 2007 when CMS established that if the total number of patient deaths or graft failures that occur within one year of transplant exceeds 150% of the risk-adjusted expected number (*i.e.,* 1.5 times the expected number) for a 2.5-year period, and the result is both statistically significant ($p<0.05$) and numerical meaningful ($O-E \geq 3$), then the program is not in compliance.[10] A study by Dr. Adel Bozorgzadeh, a transplant surgeon at UMass Memorial Medical Center, found transplant centers dropped a large number of patients from organ transplant waiting lists following the implementation of this policy. Since surgeries involving imperfect organs and extremely ill patients were riskier, transplant centers would perform less high-risk procedures that could affect their federal hospital ratings and Medicare funding. Additionally, the research referenced in the rule analyzed the untapped potential of organs during a time period in which organ transplant rates were lower given transplant surgeon's hesitancy to undertake high risk transplant procedures. For example, in calendar year 2015, a total of 3,159 adult kidneys were recovered from deceased donors but not used (out of a total of 16,410 deceased donor adult kidneys recovered for transplant). This represented an increase from 2,889 such adult kidneys that were donated and recovered but not used for transplant in CY2014, and 2,632 in 2007 and 2,084 in 2004.

With the addition of the transplant measure, SID&T recommends that HHS update the OPTN contract to require increased transparency around organ offer declines and require transplant center accountability for patient engagement and partnership between transplant center professionals and patients in deciding whether to accept or reject an offered organ. It is also vital that HHS make it easier for transplant centers to accept organ offers and work with OPTN to enhance organ allocation and distribution policies and processes to reduce nonuse of deceased donor organs.

**Decertification**

There are concerns regarding the unintended consequences of the decertification process of OPOs. CMS may not voluntarily renew its agreement with an OPO if it fails to meet the requirements for certification which includes criteria based on both the donation rate and transplant rate. As previously mentioned, these metrics do not take into consideration the myriad of factors that are out of the control of the OPOs which may put them at risk for decertification. An analysis of the 2023 OPO Interim Annual Public Aggregated Report revealed that 42.0% of 52 OPOs were in Tier 3 in 2021. Based on the new rule, these OPOs would be at-risk for decertification.

The rule does not provide a plan for a seamless transition should an OPO become decertified. Additionally, should CMS choose to renew its agreement with an OPO, it leaves the DSA open for competition to only OPOs that fall within Tier 1 and Tier 2. Given the limited number of OPOs, there are legitimate concerns regarding whether another OPO will even apply to complete for the open DSA or an existing OPOs ability to provide adequate services which may create a massive disruption

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[9] Axelrod, D.A., Guidinger, M.K., Finlayson, S., et al. Rates of Solid-Organ Wait-listing, Transplantation, and Survival Among Residents of Rural and Urban Areas. *JAMA.* 2008;299(2):202–207. doi:10.1001/jama.2007.50.

[10] Center for Clinical Standards and Quality/Survey and Certification Group. (2016). (rep.). Solid Transplant Programs—Outcome Thresholds—Revised Guidelines. Department of Health and Human Services—Centers for Medicare and Medicaid Services. Retrieved May 15, 2023, from *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-24.pdf.*

in the DSA and population being served similarly to what occurred to transplant centers.

In the example above, CMS inevitably issued a memo in 2016 revising its policy to relax the transplant standards. Unfortunately, in the eight years the policy was in place, 145 transplant centers were cited for deficiencies and 17 programs lost their Medicare funding. Unlike the example above, there are far fewer OPOs and they have limited control in the number of organs actually transplanted as the transplant surgeons determine on patients' behalf whether to accept an organ. It is also important to highlight that transplant centers that have lost their Medicare approval may seek to re-enter the program; whereas, OPOs that become de-certified cannot compete for any open DSA.[11]

SID&T stresses the importance NASAM's recommendation that HHS take actions to reduce variations in the performance of donor hospitals, OPOs, and transplant centers and increase the reliability, predictability, and trustworthiness through implementing and sustaining continuous quality improvement efforts across the system. Additionally, HHS should hold the appropriate entities of the organ transplantation system accountable for achieving demonstrable performance improvement. The government should facilitate quality improvement efforts that fosters greater systemness and accountability for the highest possible performance among all donor hospitals, OPOs, and transplant centers. Lastly, it is essential that special attention be given to spreading best practices in organ procurement and transplantation that reduce and eliminate inequities and disparities.

**Conclusion**

Recognizing the inherent challenges within the organ procurement and transplant system, SID&T encourages CMS to re-evaluate and revise the rule to both increase access to lifesaving organs, while ensuring the success of the entities within the organ procurement and transplant system. It is essential that a reliable and timely data infrastructure be created to adequately evaluate the performance of OPOs in a way that fosters quality improvement. Additionally, a consensus-based approach is needed to develop standardized performance metrics based on peer reviewed, evidence-based research to foster the improvement throughout the organ procurement and transplant process. These metrics should properly hold both OPOs and transplant centers for their roles within the transplant process while driving collaboration and the development of best practices to improve their performance.

Given the CMS rule does not provide guidance around the decertification of OPOs, SID&T urges that HHS provide guidance and for Congress to take action to ensure there is no disruption with the organ donor transplant ecosystem by legislating NASEM's recommendations implementing continuous improvement efforts across the entire system.

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SOCIETY OF PEDIATRIC LIVER TRANSPLANTATION
7916 Birmingham Drive, 2nd floor, Gastro
San Diego, CA 92123

**Statement of Amber Hildreth, D.O., FAAP, Vice Chair, SPLIT Advocacy Committee**

The Society of Pediatric Liver Transplantation has written the following statement as an initial community response to the Health Resources and Services Administration's OPTN Modernization Initiative. We look forward to engaging with HRSA, the OPTN, and the transplant community on initiatives to modernize and improve transplant in the U.S.—particularly for children awaiting and after lifesaving liver transplant.

The Society of Pediatric Liver Transplantation (SPLIT), as the largest consortium of pediatric liver transplant centers in the United States and in close collaboration with our Patient, Family, and Engaged Partners (PFEP), supports meaningful innovation initiatives that tangibly improve equitable access to pediatric liver transplant, ongoing research to improve wait list and post-transplant outcomes, provisions for living donation, diversity of the workforce, and sustainable health for organ donation and transplant institutions.

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[11] 42 CFR part 486 subpart G.

To ensure that our transplant system successfully serves children, a persistently vulnerable transplant population, we need the following:

- A modernization effort that recognizes and considers pediatric-specific concerns at every stage, in parallel to concerns that primarily impact adult candidates.
- Pediatric provider and patient representation in every step of the planning process.
- A well-organized national system that ensures nationwide sharing of pediatric organs prioritized for pediatric recipients, acknowledging that these children are vulnerable with more limited donor options.

It is imperative that our society and government take all available action to urgently prioritize optimal health care delivery to children, especially in focused initiatives that explore improvements to the organ donation and transplant system. SPLIT, as a society of multidisciplinary experts on pediatric transplant, is poised and compelled to serve as a resource for the proposed modernization agenda.

We recognize there are significant improvements needed in our organ transplant system. In 2019, the pediatric wait list mortality rate for liver candidates less than 1 year of age exceeded that of adults of all ages, with a peak rate of 12.1 deaths per 100 wait list years (SRTR Annual Report, Liver 2018, SRTR Annual Report, Liver 2019). However, we also need to acknowledge the significant advances and improvements that have been made. In 2020, after implementation of the new acuity circle allocation policy, deaths on the pediatric liver wait list reached its lowest since 2011, at 4.9 deaths per 100 wait list years. For pediatric liver recipients, we have achieved greater than 90% patient survival rate at 5 years post-transplant (SRTR Annual Report 2020)—but this means that transplant was available too late, or that complications were too overwhelming, to save 1 in 10 of these children. UNOS allows for data- driven tracking of every U.S. transplant, which is more comprehensive than tracking for any other medical condition. Access to this data has allowed for research aimed at improving outcomes in pediatric transplant patients.

While much recent press has focused on UNOS, improvements are also needed in individual transplant programs to optimize outcomes for children. All patients, regardless of geographical location or resources, need to have equal access to transplant. This includes access to all graft types—with the surgical expertise and team willingness to include split and living donor transplant.

A nationally organized system is critical to ensuring equitable access to organs for children and other difficult to match candidates. It is important to ensure that this system provides oversight for all transplant centers and Organ Procurement Organizations to optimize organ distribution and lives saved. This is not about creating a monopoly or having one entity run every aspect of organ transplant but creating shared accountability with adequate oversight.

We implore new entities interested in managing the OPTN to engage with pediatric groups such as SPLIT. The United Network for Organ Sharing (UNOS) has made substantial efforts to engage and involve the pediatric community since its inception, and particularly in the last half-decade. There is significant risk of losing ground towards the goal of eliminating pediatric wait list mortality in this modernization effort. The Health Resources and Services Administration (HRSA) does not address pediatric patients at all in the modernization announcement nor in the aims of the initiative.

We strongly encourage including pediatric-focused advocates in any modernization initiatives proposed by the HRSA, and SPLIT welcomes the opportunity to participate in all phases of this proposal.

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**EXECUTIVE SUMMARY:** TransMedics, Inc. applauds the bipartisan leadership of the Senate Finance Committee for convening this hearing today and continuing the Committee's longstanding focus on improving implementation of our national Organ Procurement and Transplantation Network (OPTN) for the benefit of patients and their families. We appreciate the Committee's persistent focus on solid organ transplantation and the impending Health Resources and Services Administration (HRSA) reforms of the OPTN, and we submit testimony to kindly urge the Com-

mittee to ensure that HRSA preserves flexibility in the OPTN system to allow innovation, such as the TransMedics' National Organ Care System Program ("NOP"), to continue to increase the number of organ transplants in the U.S. working within the OPTN structure.

TransMedics is a medical device company founded by a surgeon two decades ago to address the unmet need for more and better organs for transplantation, with a current focus on heart, lung, and liver transplants. For decades, cold storage (literally ice storage in a suspended animation state) has been the only option for organ preservation, dictating strict limits on transportation, timing, and viability of organs for transplant. However, beginning in September 2021 with its first FDA approval, TransMedics' Organ Care System (OCS) introduced an entirely new approach to organ transplantation, utilizing oxygenated blood perfusion technology to keep human organs alive and functioning (hearts beating, lungs breathing, livers producing bile) outside of the human body. This technology was validated in large FDA clinical trials to increase the rate of donor organ utilization for transplants.

Remarkably, perfusion technology has eliminated the historical time and distance limitations imposed by cold storage, enabling previously unutilized organs to reach record numbers of patients in geographic areas previously unreachable, in better condition, and with better outcomes. Equipped with FDA approvals for heart, lung, and liver perfusion devices to facilitate transplants, TransMedics developed the first national organ surgical recovery and organ clinical management model using dedicated surgical and clinical expertise to remove logistical barriers to maximize organ utilization and has dramatically increased recovery and transplant of lung, heart, and liver donations—organs that are massively underutilized today in the US. As a result of these innovations, TransMedics has facilitated more than 2,000 transplants of hearts, lungs and livers that might not have otherwise been used over the past year and a half.

TransMedics appreciates that transplantation has always been a collaborative effort, requiring coordination and contribution from multiple parties, including donors, their families, skilled surgeons and transplant programs, technology systems, Organ Procurement Organizations (OPOs), the OPTN, and many other healthcare providers. TransMedics' innovative approach to organ recovery and transplantation is already delivering meaningful improvements in heart, lung, and liver transplants alongside the current OPO/OPTN system and offers tremendous potential as Congress and HRSA modernize this system.

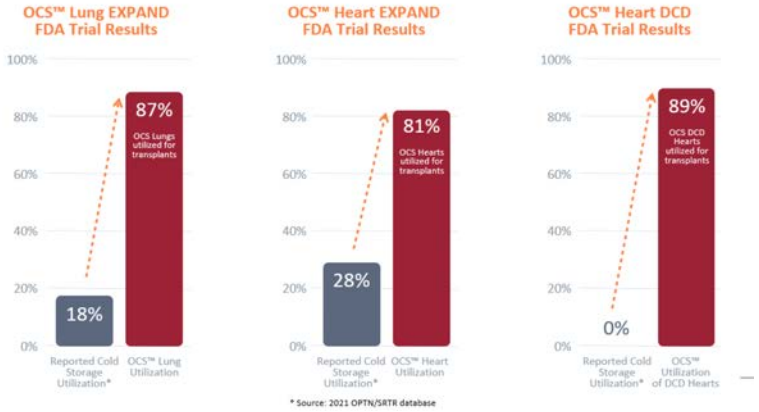
We share the goal of this Committee and the OPTN, to dramatically increase organ transplants and facilitate broader utilization and equitable distribution of these precious lifesaving donor organs. We support HRSA's OPTN Modernization Initiative as well as the pending OPTN Modernization legislation. We commend the Senate Finance Committee and the individual Senators that have worked for years, even decades, to improve our system to benefit patients and their families, and urge the Committee to ensure that any reforms implemented in the coming weeks and months retain the necessary flexibility to permit innovative technology and programs like the NOP program to continue to thrive and succeed in increasing transplants across the United States.

**BACKGROUND: TRANSMEDICS AND THE OCS SYSTEM**

TransMedics has developed the FDA-approved OCS to replace the decades-old static cold storage standard of care that is significantly limiting access to lifesaving transplant therapy for hundreds of thousands of patients worldwide. Since receiving FDA approval in 2021, we have initiated a national program to provide an end-to-end clinical service and technology solution for donor organ surgical retrieval, OCS perfusion, and clinical assessment in collaboration with leading transplant programs and select OPOs across the U.S. with the primary goal of increasing utilization of donor organs for transplant.

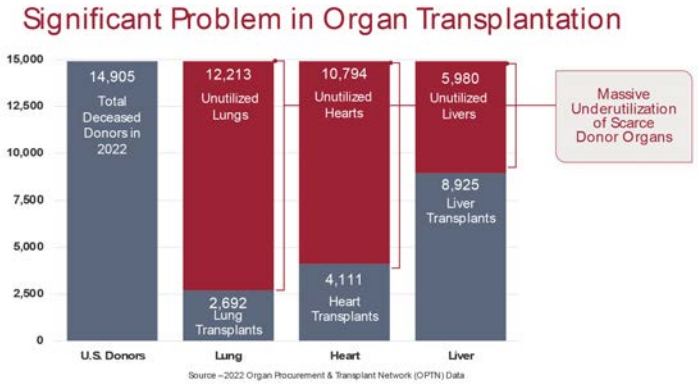
The OCS technology is the first, and currently the only, portable, multi-organ platform for extracorporeal, oxygenated blood perfusion of solid donor organs in a living and functioning state (heart beating, lungs breathing, and liver producing bile), outside of the human body for eventual transplantation into recipients who suffer from end-stage heart, lung, and liver failure. Unlike historic and traditional cold static-storage methods for solid organ preservation for transplants (ice coolers and ice to preserve precious vital human organs), the OCS technology replicates many aspects of the organ's natural living and functioning environment outside of the human body, which significantly reduces damage that occurs using cold-storage, enables optimization and clinical assessment of the donor organ viability for transplantation to maximize clinical confidence to transplant organs to recipients in need. The re-

sults of clinical trials demonstrate a significant increase in capacity to preserve transplantable organs and ensure that they could be used over greater time and distance than had been the case historically:




Given these results, the OCS held the potential to create a fundamental paradigm shift in organ preservation by allowing more organs to remain usable for longer and reach patients in better condition. In fact, that is precisely what has happened—the OCS was able to transform the standard of care in transplantation by increasing donor organ utilization, improving patient outcomes, and reducing transplant costs. To date, and as discussed in more detail below, use of the OCS has resulted in more than 2,000 organs transplanted.

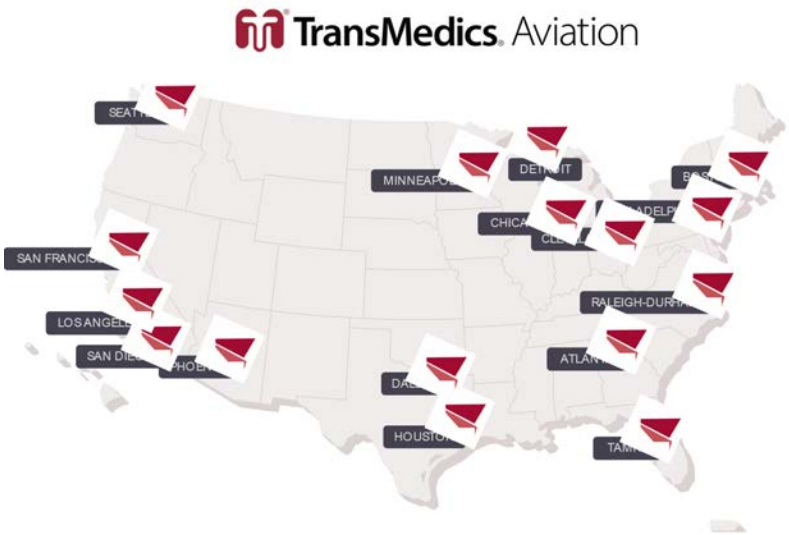
The OCS system was particularly timely given that there was a massive underutilization of hearts, lungs, and livers across the transplant program. As demonstrated below, in 2022 there were nearly 15,000 deceased donors who were able to contribute a solid organ for transplant. Yet, while nearly 20,000 kidneys were recovered for transplant, only 2,700 lungs, 4,100 hearts, and 8,900 livers were recovered from these same donors. While TransMedics acknowledges that not every deceased donor was eligible to donate a heart, lung, or liver, many of these organs that could have been recovered were not, exacerbating the wait list and impacting both patient care and cost to the Medicare program.




Securing FDA approval for the OCS system, however, was not enough. TransMedics quickly recognized that it would need to innovate in several ways to ensure that its OCS solution would have a material impact on increasing heart, lung, and liver transplantation nationally. First, TransMedics built a team of clinical experts who had the training and experience to recover hearts, lungs and livers from deceased donors, utilize the OCS system to expand the quality and duration of the organs itself, and ensure that these revered organs could reach those on the waiting list

for transplantation. TransMedics worked closely with both UNOS and the OPOs all across the country to ensure that the benefits of the OCS system could work for transplant patients. As a result, in 2022 TransMedics was able to facilitate nearly 1,000 additional heart, lung, and liver transplants above 2021 levels—all at no separate charge to the Medicare program. As importantly, because of the OCS system, these additional organs were able to travel farther and last longer on the OCS system than had ever been the case before, eliminating the historic limitations in transplanting these fragile organs. The chart below speaks for itself—and could never have occurred without the OCS perfusion technology.


TransMedics also learned through its work that the significant limitations of chartered flights transport of solid organs, with which this Committee is well familiar, simply were not sufficient to support the increase in hearts, lungs and livers that needed to be shared across the country due to UNOS matching. As a result, TransMedics is building its own network of dedicated aircraft to be available upon demand and with the capacity to fly the necessary distances needed to transport needed organs for transplant. The aircraft network is still growing, and is currently configured as follows:



We highlight these features to bring to light the innovation that can, and has, occurred within the transplant system today. Three years ago, hearts, lungs, and livers were barely being recovered, and were unable to be used due to highly restricted time and distance limitations. Due to the innovation described above, in the first quarter of 2023 alone an additional 430 transplants were performed though the NOP program, using the specialized organ recovery clinical team, the OCS perfusion system, and the dedicated transportation network. And this system was built in partnership with the existing UNOS infrastructure that helped make the national donor-recipient "matches" to ensure that recovered organs got to those in greatest need notwithstanding the distance, and with the OPOs who partnered with TransMedics to facilitate the organ recoveries.

**RECOMMENDATIONS FOR THE COMMITTEE'S CONSIDERATION**

TransMedics appreciates that transplantation has always been a collaborative effort. Successful organ transplantation requires significant coordination and contribution from multiple parties including donors, their families, skilled surgeons and transplant programs, technology systems, OPOs, the OPTN, and many other healthcare providers. As reflected in our comments above, TransMedics is committed to working with all current U.S. transplant stakeholders to develop and provide the best possible outcomes to those in need of organ transplantation.

As the February 2022 National Academies of Science, Engineering, and Medicine ("NASEM") report titled, "Realizing the Promise of Equity in the Organ Transplantation System," recognized—components of the transplantation system suffer from significant variations in performance, which leads to a system containing inefficiencies and inequalities. While many of the NASEM conclusions relate to kidney transplant access (an issue that TransMedics is working on), the Committee's work also included an examination of heart, lung, and liver transplants. Historically, the program for heart, lung, and liver transplants has been limited in its ability to improve the number of transplants for patients with end-stage organ failure. For the past decade or longer, donor lungs and hearts have been limited to 20%–30% of the available deceased donors annually. This significant waste of valuable and precious resources is now being reversed, thanks to innovation at multiple levels—the FDA approval of the OCS systems; the development of specialty teams able to recover hearts, lungs, and livers, and connect them to the OCS devices; the transportation network dedicated to ensuring that organs get where they need to be on time and healthy; and the logistical infrastructure to work with the OPTN and the OPOs to make it all happen. This innovation has been difficult to build, and we urge the Committee to ensure that it is preserved and given the opportunity to thrive.

For these reasons, TransMedics has three recommendations that we ask the Committee to urge HRSA to adopt:

- HRSA's OPTN Modernization Initiative presents an ideal opportunity to dramatically increase heart, lung, and liver transplants using latest FDA approved perfusion technologies and a first-of-its kind national surgical procurement service model to facilitate broader utilization of precious donor organs for transplants.
- Congress should ensure that HRSA considers the option of contracting or allowing the establishment of a national independent clinical procurement and medical technology entities focused exclusively on procurement, clinical management and transportation of donor heart, lung, and liver for transplants. The current model enables these national entities to charge transplant programs for the service directly, rather than charge HRSA for serving as contractor.
- At a minimum, the Committee should ensure that HRSA's upcoming reorganization of the OPTN accommodates this type of creative NOP model that is demonstrating significant promise in the field today.

We appreciate the Committee's time and attention to this crucial issue, and we look forward to continuing to partner with the Committee on this important work.

UNITED NETWORK FOR ORGAN SHARING
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The United Network for Organ Sharing (UNOS) appreciates the opportunity to submit a statement for the record on the Senate Finance Committee's Health Subcommittee hearing titled "The Cost of Inaction and the Urgent Need to Reform the U.S. Transplant System," held on July 20, 2023.

UNOS is the mission-driven, non-profit organization that serves as the nation's organ donation and transplant system—the Organ Procurement and Transplantation Network (OPTN)—under contract with and oversight by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS). We are committed to working with policymakers to help ensure that the United States continues to be the leader in successful organ donation and transplant.

UNOS has heard calls from policymakers and stakeholders urging reforms to the organ donation and transplant system and is embracing change. In support of a more competitive bidding process, UNOS welcomes HRSA's modernization initiative [1] and does not oppose the Securing the U.S. Organ Procurement and Transplantation Network Act.[2] As the current OPTN contractor, UNOS is committed to being an invaluable partner to HRSA as reforms are implemented.

In keeping with UNOS' goal of seeking to improve the system, under the new leadership of Maureen McBride, Ph.D., UNOS released an Action Agenda [3] in January 2023, which is a set of collaborative reforms that will strengthen the system and address concerns shared by Members of Congress and other stakeholders. The Action Agenda also aligns with the reforms that HRSA announced in March, including a focus on quality improvement, data transparency, governance and technology. Every aspect of the agenda is focused on serving patients, and these reforms will help to bolster and streamline the nation's system.

UNOS is actively identifying areas for improvement so that we can adopt changes that strengthen the system to better serve the patients who rely on us every day. Being transparent about systemic challenges is critical because addressing these areas will require action and collaboration from the entire organ donation and transplant community as well as policymakers.

Consistent with its Action Agenda, UNOS is working to drive change in key areas including: (1) increasing direct services, tools and resources to patients, donors, caregivers and their families to more easily navigate the transplant journey, which could provide information to candidates about their status on the wait list; (2) reducing the organ non-use rate (non-use refers to organs recovered for transplant but ultimately not transplanted); (3) improving equity in access to the transplant healthcare system; (4) ensuring access to OPTN data; (5) maintaining safe, modern, and reliable information technology (IT) systems and infrastructure; (6) reforming the OPTN Membership and Professional Standards Committee (MPSC) processes; and (7) restoring trust in the organ donation and transplant system by establishing an independent OPTN board of directors.

**I. Increasing Patient Resources to Navigate the Transplant Journey**

A key component of the Action Agenda is patient empowerment through additional services, tools and resources for patients, donors, caregivers and their families. Our aim is to help patients and their families navigate their transplant journey, which can be complex and burdensome, especially to those already struggling with a difficult diagnosis, ongoing illness and other sources of stress. HRSA has the opportunity, as it undertakes OPTN modernization, to ensure patients have the information they need, including about their status on the wait list, in an accessible format.

Given the importance of ensuring a patient-centered organ donation and transplant system, UNOS is advocating that HRSA require the OPTN to offer more expansive consumer empowerment tools to enable patients to make choices regarding their

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[1] UNOS Statement Supporting Improvements to the National System, March 22, 2023, *https://unos.org/news/unos-welcomes-competitive-bidding-process-for-next-optn-contract/*.

[2] UNOS Position on the Securing the U.S. Organ Procurement and Transplantation Network Act, June 30, 2023, *https://unos.org/wp-content/uploads/UNOS-letter-securing-US-Organ-Transplantation-Network-Act-063023.pdf*.

[3] UNOS Actions to Strengthen the U.S. Organ Donation and Transplant System, January 30, 2023, *https://unos.org/wp-content/uploads/Actions-to-strengthen-the-US-organ-donation-and-transplant-system-30-Jan-2023.pdf*.

care, as well as education and resources for patients, donors, caregivers, parents, and their families. The next contract should require, in collaboration with the patient community, the development of consumer choice tools that include information to assist patients in finding appropriate care for their needs, timely updates about new patient benefits or care programs, emerging medical innovations, and a candidate's status on the wait list to help patients navigate through the donation and transplant process. Including these enhanced offerings as part of the OPTN Contract would ensure that the OPTN serves as a centralized resource to patients and their loved ones during their journey.

Patients have shared concerns about the lack of clear and readily accessible information regarding their status on the wait list. Transplant hospitals, which know their patients best, make the decision about whether to temporarily inactivate a transplant candidate, meaning that the candidate will not receive organ offers while in that status. Neither UNOS nor the OPTN are involved in any decision to inactivate or reactivate an individual candidate. UNOS does not communicate with patients about their placement or status on the wait list. The transplant hospital is responsible for all phases of the patient's treatment and serves as the first and most authoritative source of information for patients and their caregivers.

At the direction of a transplant program or by individual choice, a candidate may have an inactive status on the wait list for a variety of reasons. In many cases, a transplant team changes a candidate's status to inactive due to medical factors that would decrease the likelihood of a successful transplant. For example, a patient may develop a medical condition, such as cancer, that requires treatment before that person is healthy enough to receive a transplant. Other reasons that a transplant hospital may make a candidate inactive include lack of health insurance, noncompliance with required transplant medical evaluations, or that the candidate is waiting for a living donor. Transplant hospitals have the ability to modify a candidate's waiting list status from active to inactive, and they must also report to the OPTN a reason for inactivation. Data regarding the number of candidates who are active or inactive are publicly available on the OPTN website.

**II. Reducing the Organ Non-Use Rate**

Any organ not ultimately transplanted represents a profound loss, both for the selfless donor's family and the patient waiting. Between 2011 and 2020, the annual non-use rate for kidneys was between 18 and 20 percent. Liver non-use since 2011 has been between 8 and 10 percent. The non-use rate for kidneys increased following a change in kidney allocation policy and was approximately 25 percent as of March 2022.

The number of deceased-donor organs recovered has increased annually over the past decade. As the medical criteria for deceased organ donation continue to broaden, increasing numbers of organs come from older donors and people who died of circulatory death. The increase in the number of medically complex donor organs that are recovered and offered to transplant hospitals corresponds to an increase in the non-use of organs but also the number of transplants performed and lives saved.

Livers and kidneys are viable outside of the body longer than hearts and lungs, so an organ may be recovered before a recipient is identified or biopsy results of the donor are known, both in the interest of the patients in need and to best honor deceased donors. The primary issue for non-use reported to the OPTN is that the wait list has been exhausted, meaning that all transplant hospitals declined the organ for their patients. Sometimes, post-recovery biopsy findings may determine that an organ is not suitable for transplant. As a result, livers and kidneys that were initially recovered for transplant but were ultimately determined to not be medically suitable are likely to have a higher rate of non-use.

UNOS, working in collaboration with members of the organ donation and transplant community, is pursuing a variety of innovative strategies to improve organ acceptance rates at hospitals, make it easier to say "yes" to organ offers, and save more lives. The OPTN and UNOS are working to improve acceptance through kidney offer filters, predictive analytics, an offer acceptance collaborative, transplant hospital performance metrics, and improvements in the efficiency of transportation of organs by commercial air. Additionally, the OPTN Board is establishing a task force to identify additional ways the community can work together to reduce the non-use rate.

*Kidney Offer Filters*

The kidney offer filters tool creates a more efficient offer process and reduces the risk of non-use. The tool enables transplant hospitals to avoid receiving offers that

they would not accept. For example, a hospital may have a filter that would prevent it from receiving offers for any donor over a specified age or other medical criteria. The OPTN recommends filters to hospitals based on offers that they have historically received but never accepted, and hospitals may design their own filters as well. With these filters enabled, offers can then reach programs more willing to accept them sooner.

The tool also shows hospitals data on offers that were filtered from their program but transplanted at other programs, allowing them to review and adjust their own acceptance practices and filters. More than half of kidney transplant programs have elected to use the tool. The OPTN Board adopted a policy in June 2023 that would automatically turn on offer filters in all adult kidney transplant programs with the ability for them to modify or opt out of the offer filters.

*Predictive Analytics*

In 2023, the OPTN launched the predictive analytics tool, which is available to all adult kidney programs, with the aim of increasing organ use rates by providing information about the impact that accepting or declining an offer could have on a patient. At the time of an organ offer, the tool uses statistical models to display: (1) the time-to-next offer, which predicts the length of time the candidate could wait for another high-quality organ offer; and (2) a mortality prediction, which offers a visualization of the candidate's likelihood of survival over the next three years without a transplant. During a pilot test, participating programs showed a 2.9 percentage point increase in offer acceptance compared to the previous period, while programs in the control group did not show an increase.

*Offer Acceptance Collaborative*

Earlier this year, UNOS brought together 83 transplant hospitals to participate in the OPTN Offer Acceptance Collaborative. The 6-month project, launched on January 31, 2023, supports OPTN members as they work together to improve offer acceptance practices and processes at their respective transplant programs. The transplant community and other stakeholders have access to recorded sessions from the kickoff conference as well as webinars hosted throughout the collaborative.

*Transplant Hospital Performance Metrics*

In December 2021, the OPTN Board of Directors approved new metrics for monitoring the performance of transplant programs. The OPTN began to evaluate transplant programs' offer acceptance rates in July 2023. The collection of these data will help inform future initiatives to reduce non-use.

*Efficient Transportation of Organs*

The current OPTN Contract does not include a task for facilitating, tracking, or collecting data on the transportation of organs. However, our Action Agenda includes recommendations to improve the efficiency of the transportation of organs. UNOS supports provisions in the Federal Aviation Administration (FAA) reauthorization legislation that would enable the transportation of donated organs, primarily kidneys and livers, in the passenger cabin instead of in the cargo hold of an airplane. Transporting organs through cargo involves more logistical challenges including restricted schedules, gaps in handling, and less flexibility. Cargo does not lend itself to the nature of organ transplant, where organs are viable outside of the body for a limited amount of time and must be transported at all hours of the day and night.

Additionally, UNOS developed a travel application to make it easier for Organ Procurement Organizations (OPOs) to select the most efficient option to transport organs on commercial flights. It aggregates real-time flight schedules, driving directions, and critical logistics data like cargo hours to give users a comprehensive understanding of an organ's projected travel time and path. The tool is being pilot tested by a limited number of OPOs. It is expected to be available to all OPOs later this year.

**III. Improving Equity in Access to the Transplant Healthcare System**

UNOS is striving for increased equity in access to transplant through the continuous distribution allocation framework and changes to the estimated glomerular filtration rate (eGFR) equation and soon to the kidney donor profile index (KDPI) score. Previously, transplant hospitals sometimes used a race-inclusive calculation of eGFR to estimate a candidate's level of kidney function. The KDPI is used to evaluate every kidney offered for transplant from a deceased donor. It estimates how long a kidney from that donor may function after a transplant. UNOS is also seeking authorization for the OPTN to collect pre-wait list data to understand the

burden of end-stage organ failure, including the prevalence, incidence, and mortality, and barriers that patients face to being included on the wait list.

*Continuous Distribution Allocation Framework*

As established by federal law, explicated in what is known as the OPTN Final Rule,[4] the OPTN has an obligation to design policies to achieve equitable organ allocation by distributing organs over as broad a geographic area as possible and with the sickest patients being served first regardless of location. In 2010, the Secretary's Advisory Committee on Organ Transplantation (ACOT) explicitly recommended that the OPTN develop evidence-based allocation policies not determined by arbitrary administrative boundaries such as donation service areas (DSAs), OPTN regions or state borders. Where people live and receive treatment does not determine the severity of their illness nor priority for a lifesaving organ.

Continuous distribution is a new organ allocation framework aimed at making the national system even more equitable and the organ allocation policymaking process more accessible. This new approach will ensure more meaningful engagement with patients and the public about the values that should guide organ allocation in the United States.

As a result of HRSA's July 2018 directive that the OPTN remove the use of DSAs in organ allocation policies, the OPTN approved allocation policies that consider distance between donor and recipient for liver and kidney transplants as a bridge to the continuous distribution allocation framework. The liver acuity circles allocation policy ensures that the sickest patients and children are getting transplants more quickly than ever before. The kidney allocation policy has resulted in a 29 percent increase in overall transplant rates and improved equity in access to transplants for key populations including Black candidates, Hispanic candidates, Asian candidates, highly-sensitized candidates, and pediatric candidates.[5]

In December 2018, the OPTN Board of Directors approved the continuous distribution framework for future policy development. Continuous distribution will consider all patient factors together to determine the order of an organ offer, and no single factor will decide an organ match. The score will consider factors like patient medical urgency, outcomes and biology, in balance with the efficient management of organ placement, providing the sickest patients with even better access to lifesaving organs. The goal is to increase fairness by removing all the hard boundaries that are part of the classification-based system. All organ systems are transitioning to the continuous distribution model. The framework was first implemented on March 9, 2023, for lung. In July, the OPTN published its three-month lung allocation policy monitoring report[6] presenting data describing the U.S. transplant system before and after the allocation policy change. The report showed an overall decrease in wait list removals due to death or too sick to transplant.

*Elimination of Inclusion of Race in eGFR Equation*

In December 2022, the OPTN Board approved a process to improve transplant equity by backdating the waiting times of Black kidney transplant candidates who were disadvantaged by previous use of a race-inclusive calculation to estimate their level of kidney function. The Board action requires all kidney transplant programs, starting January 5, 2023, and within one year, to identify those Black kidney candidates whose current qualifying date was based on the program's use of a race-inclusive eGFR calculation, and to determine whether a race-neutral eGFR calculation shows the candidate should have qualified sooner to start gaining waiting time for a transplant. Programs must then apply to the OPTN for a waiting time modification for such candidates.

As of July 31, 2023, UNOS, as the OPTN contractor, has completed 7,733 waiting time modifications for kidney transplant candidates who qualify, submitted by 116 of the 230 kidney transplant programs.

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[4] 42 CFR 121.

[5] OPTN Kidney Transplantation, Eliminate Use of DSA and Region from Kidney Allocation Two Year Post-Implementation Monitoring Report, June 22, 2023, *https://optn.transplant.hrsa.gov/media/4mhfm3oq/eliminate_use_of_dsa_and_region_from_kidney_allocation_two_year_post_implementation_monitoring_report_2yr.pdf*.

[6] OPTN Lung Transplantation Committee, Lung Continuous Distribution Three Month Monitoring Report, July 13, 2023, *https://optn.transplant.hrsa.gov/media/fzhh1e5r/data_report_lung_committee_cd_07_13_2023.pdf*.

*Elimination of Race in KDPI Score*

During its June 2023 meeting, the OPTN Executive Committee approved a new project sponsored by the Minority Affairs Committee to revise the KDPI score to eliminate the consideration of race and exposure to the hepatitis C virus (HCV). The KDPI is used to evaluate every kidney offered for transplant from a deceased donor and estimate how long a kidney from that donor may function after a transplant. An OPTN working group that includes key stakeholders from the kidney community has been established to identify how to revise the KDPI calculation without race and HCV. UNOS has been working with the Scientific Registry of Transplant Recipients (SRTR) to develop a simulated allocation model to evaluate the effects of potential changes to the KDPI score formula. The OPTN will issue a proposed revision to the KDPI score for public feedback during the OPTN Winter 2024 comment period.

*Collection of Pre-Waitlist Data*

The OPTN is currently charged with developing and maintaining equitable organ allocation policies that apply to wait-listed patients. The OPTN has been able to continually monitor and adjust organ allocation policies to improve equity in access to transplants among wait-listed patients. The OPTN maintains an Equity in Access dashboard [7] to enable public research and review of these ongoing efforts and publishes organ allocation policy monitoring reports for the public. These resources include data on key equity indicators such as race and ethnicity, rural vs. urban, insurance type, and education level.

True access to transplant, however, not just the wait list, cannot be measured without understanding the national disease burden. UNOS calls for government action to seek broader equity in access to transplant health care. UNOS seeks authorization for the OPTN to collect data to identify barriers to equitable access to the wait list and quantify the national disease burden. More data collection on patients before they are added to the wait list is necessary to eliminate inequities in access to the transplant wait list. Such data are important to understanding patient, population, and transplant program-level factors that may contribute to inequities in wait list and transplant access, which could drive research, quality improvement, and other initiatives for OPTN members to address these inequities.

**IV. Ensuring Access to OPTN Data**

UNOS is committed to data transparency and accessibility. As the OPTN contractor, UNOS is required by the OPTN Final Rule to provide data for research and analysis of the performance of the OPTN or individual transplant programs. UNOS and the OPTN are similarly required by the OPTN Final Rule and the OPTN Contract to provide to the Secretary of HHS or their designees any OPTN data or information that the Secretary requests.

UNOS responds to formal requests for OPTN data from the public and OPTN members. Like OPTN members and the public, UNOS must similarly submit formal requests to obtain OPTN data for the work it performs outside of its support for the OPTN. In 2022, UNOS received more than 1,400 formal requests for OPTN data. Anyone can submit a data request through the OPTN website [8] and OPTN members can request data through UNetSM, UNOS' IT system. OPTN members may request data they have previously submitted to the OPTN at any time, and the OPTN will provide that data to the OPTN member without charge. Information can be provided in datasets, so that requesters can perform their own analysis, or in static reports.

Pursuant to the OPTN Final Rule and the OPTN Contract, patient-identified data requests require that the requester submit a signed data use agreement (DUA), a plan to secure the data, a research plan, and documented approval by an Institutional Review Board (IRB). Requests for patient-identified data must be approved by HRSA before UNOS can release the information to the requester. UNOS also has an obligation as the steward of OPTN data under the OPTN Contract to secure all OPTN data, and therefore all OPTN data requests are subject to restriction on how OPTN data can be stored and used.

Our goal is for the organ donation and transplant community to leverage data for performance improvement. To that end, UNOS has expanded our online self-service tools, enhanced and built new public-facing dashboards, and has a data analytics department to assist with inquiries.

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[7] Equity in Access to Transplant Dashboard, *https://insights.unos.org/equity-in-access/*.

[8] Organ Procurement and Transplant Network, Request Data, *https://optn.transplant.hrsa.gov/data/request-data/*.

**V. Maintaining Safe, Modern, and Reliable IT Systems and Infrastructure**

UNet has been the focus of significant discussion, especially in the wake of reports from the National Academies of Sciences, Engineering, and Medicine (NASEM) and the United States Digital Service (USDS) last year. UNet is the system that helps match donor organs to candidates on the transplant wait list. In January, UNOS engaged an independent consulting firm to assess our technology and modernization efforts against industry best practices and the USDS Digital Services Playbook. This assessment is in progress. Security, reliability, and modernization have deservedly received much attention. UNOS has also focused many of our improvement efforts on the IT system and security.

*UNet Improvements*

UNOS is making improvements to UNet, including steadily moving the platform into the cloud, as recommended by our own experts as well as by NASEM and USDS. The OPTN's predictive analytics tool, which enables all adult kidney transplant programs to evaluate organ offers through predictive analytics data, was born in the cloud. Other functions of UNet are being transitioned to Microsoft Azure and should be in the cloud next spring. This work will not complete our modernization, but it is an important step in what is and should be continuous momentum for improvement. And it will make our system even more secure. As we work, UNOS is building to the highest industry and federal government security standards.

*Cybersecurity Defenses*

HHS Office of Inspector General (OIG) contractors recently conducted rigorous penetration tests of UNOS' IT security and have told us we already have established strong defenses against cyberattacks that exceed what most similar organizations have in place. Nonetheless, we continue to press for ongoing improvement in this quickly evolving environment.

*Network Reliability*

In February, the IT system experienced a 51-minute outage. However, during the last 15 years, the network has been up and running 99.9 percent of the time, consistent with the target service level agreement (SLA). By that measure, reliability is good, and getting better, but we believe we can make additional improvements.

UNOS shares policymakers' concern about patient safety, and UNOS can confirm that during the February service outage, there were no reported negative effects on any donor or recipient activity taking place within the entire organ donation and transplant network. UNOS staff conducted prompt outreach to all OPTN members who contacted us during the outage and confirmed that all donor and recipient functions being performed within UNet before the interruption were completed successfully once service was restored. We understand that no transplants were put in jeopardy despite the outage.

As we have shared with HRSA and staff for Chair Ron Wyden (D–OR) and Sen. Chuck Grassley (R–IA), UNOS has taken and will continue to take actions to safeguard against future system disruptions. Most significantly, UNOS implemented additional monitoring and alerts to ensure visibility of all database conditions that could lead to a system failure and has accelerated plans to transition the UNet database into one of the Azure public cloud database platforms.

**VI. Reforming MPSC Member Compliance Investigations Processes**

In response to concerns that investigations examining compliance with OPTN membership requirements were not forwarded to the OPTN MPSC for review, the MPSC implemented improvements in October 2022 to increase transparency.

Specifically, the MPSC established a new process to review all investigative activity assessing member compliance with OPTN requirements and policies. Previously, the MPSC reviewed reports when investigations revealed potential noncompliance with OPTN obligations. Staff would consult with MPSC members during the investigation, particularly for guidance on clinical matters pertaining to medical judgement and patient safety; however, the full Committee did not receive information about investigative activity that was not identified as a potential noncompliance or safety issue.

This process has been reformed to provide the MPSC with greater information and to aid in its decision making and compliance function. Now, the MPSC will regularly receive information including but not limited to:

- The number of reports submitted;
- The method of receipt, such as the Improving Patient Safety Portal, Member Reporting Line, and referrals from Patient Services;
- Whether the reporter was an OPO, transplant program, histocompatibility laboratory, patient or donor family member, or anonymous;
- Whether the report was a self-report or about another organization;
- The number of reports that are still pending review, referred to the MPSC for action, or are not forwarded for an MPSC action; and
- For cases not referred to the MPSC for formal action, the MPSC will receive a brief summary of the nature of the reports and investigative findings that led to staff's determination not to forward for MPSC review.

Staff have implemented revised processes and documentation so that cases are not formally closed until the MPSC has received the information described above about a case. When the MPSC learns of issues that are outside of OPTN purview, it informs our HRSA colleagues.

**VII. Restoring Trust in the System by Establishing an Independent OPTN Board of Directors**

Governance of the OPTN has been an area of ongoing attention. UNOS has requested HRSA engagement since May 2021 to create an independent OPTN board of directors distinct from the OPTN contractor's board of directors.

On July 14, 2023, in response to a contract task added by HRSA on May 12, 2023, UNOS submitted an in-depth plan to HRSA for creating an independent OPTN board. This would clearly establish an OPTN board with distinct priorities, providing greater role clarity and ensuring trust in the national system. UNOS recommended to HRSA that this separation will require the formation of an OPTN corporate entity as required by the National Organ Transplant Act (NOTA), affirming its establishment as a private, non-profit entity among other steps.

To ensure seamless continuity, according to this plan, the separation will occur prior to or coinciding with the end of the current OPTN Contract. UNOS is committed to working with HRSA to ensure the successful and timely implementation of any OPTN governance restructuring plan under the current OPTN Contract to ensure the OPTN board is independent from the governance of any OPTN contractor.

UNOS appreciates the engagement of Congress, HRSA, and the Centers for Medicare and Medicaid Services (CMS) on these complex issues. All stakeholders, including UNOS, share a common mission: Identify, allocate and transplant as many suitable organs as safely, equitably and efficiently as possible. We must hold all parts of the system accountable for making sure that this happens. UNOS extends our gratitude to Chair Wyden and the other Senators on the Senate Finance Committee who have worked with UNOS. We look forward to your ongoing collaboration to improve the system for the benefit of patients, donors, and their families.