The Costly Effects of an Outdated Organ Donation System

SUMMARY OF FINDINGS
As former Chief Technology Officers of the U.S. Department of Health and Human Services (HHS), we have seen first-hand the impact that thoughtful systems reforms can have on patient outcomes.

We have also all worked on organ donation reform, one of the very few issues that is so bipartisan that it has been supported by both the Trump and Obama Administrations. We are strongly motivated by data that show organ donation reform can save thousands of lives every year - as well as billions of dollars to the taxpayer - and help address racial disparities in our healthcare system.

The results of this discovery sprint make clear that reforms to governance, process, and technology can help thousands more patients receive life-saving organ transplants each year. Patients deserve the very best both from their government and from the government contractors tasked with managing the organ donation system.

To realize that basic errors in process (e.g., contractors never showing up to donor hospitals) and technology (e.g., organ offers going to deceased patients) are preventing tens of thousands of patients from receiving transplants, highlights exactly where we should focus.

Patients deserve accountability. Proposed reforms from HHS, once finalized, coupled with Congressional oversight, can transform the system. As a patient care issue, an equity issue, and an issue of the best use of taxpayer dollars, policymakers have every reason to get this right. With this thoughtful set of recommendations, there is a clear path forward that will save lives.

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Around 28,000 organs go untransplanted every year. Despite scientific advancements, the organ donation system is held back by poor management and performance. The U.S. government could save tens of thousands of lives and billions of dollars by holding contractors to more rigorous standards and modernizing the technology within the organ transplant ecosystem.

The effects of a broken system

Today, the medical community continues to make advancements in the field of organ donation and transplantation. Yet this life-saving science relies on an outdated system that has failed to scale up to modern day management and technology best practices.

How does this system hurt Americans? Imagine you need an organ and manage to join the 109,000 people on the waiting list — which in itself can be a challenge. Once you’re over the hurdle of getting on the list, you have only a 50% chance of receiving the organ you need within the next 5 years.

The problem is even worse for people of color, who are less likely to get on the waitlist and less likely to find a match once they’re on there. Black families are also less likely to even be asked about donation — and face lower quality interactions when they are approached — which contributes to the low match probability for Black recipients.

One might think with all the people on the waitlist, and with 90% of Americans supporting organ donation, that nearly all viable organs from deceased donors will get used. But disturbingly, that’s not the case. Less than half of people in the U.S. who meet established criteria for organ donation actually become donors.

That means around 28,000 life-saving organs every year, on average, are not transplanted. Additionally, taxpayers could save $40 billion in 10 years if more organs were recovered, according to research.

Without a transplant, patients with kidney failure have to rely on costly and painful dialysis. Medicare currently spends $36 billion every year on dialysis and treatment for people with End Stage Renal Disease — which is more than the annual budget for NASA and the CDC combined.

When people hear “organ donation,” they might only think about a box they checked off when renewing their driver’s license. While checking that box can be a helpful first step to saving lives through organ donation, most people don’t realize that there is a huge ecosystem behind what makes organ transplants happen — or not happen. People might assume because organ donation is so important, the system must be well-run. But in reality, it’s not. In fact, Americans are unnecessarily losing thousands of lives and billions of taxpayer dollars each year from what’s broken in this system.
After speaking with organ procurement organization (OPO) leaders, transplant centers, government officials, and other organ donation experts, our findings reveal a number of critical issues with how the organ transplant system has been built and continues to run. There are several root causes that illustrate the need for change.

A convoluted governance structure leads to problematic oversight

Responsibilities around organ donation and transplantation in the U.S. are diffused across several different government agencies and contractors (see "Governance and Oversight in the Organ Donation Process," Figure 1), leading to an unnecessarily complex — and conflicted — structure.

When Congress passed the National Organ Transplant Act (NOTA) of 1984, the government established the Organ Procurement and Transplantation Network (OPTN) and mandated that it be operated by a private contractor. The contract is currently overseen by Health Resources and Services Administration (HRSA) under Health and Human Services (HHS). The only contractor who has ever held the contract is the United Network for Organ Sharing (UNOS). (See Organ Donation Policy, Figure 2.)

While HRSA is responsible for the regulation and oversight of the OPTN, another HHS agency, Centers for Medicare & Medicaid Services (CMS), is stuck footing the bill. Government contractors who coordinate organ recovery, known as organ procurement organizations (OPOs), are 100% reimbursed for all expenses, and OPOs' failure to recover enough kidneys contributes to billions each year in taxpayer dialysis costs. CMS and the OPTN are also both responsible for overseeing OPOs, which we discuss more below.

Rather than working together to solve problems that arise, the existing governance structure enables each arm to pass accountability back and forth, resulting in issues falling through the cracks. As one interviewee explained, HRSA and CMS tend to pin problems on each other, and rely on the OPTN contractor, instead of working together to create a cross-HHS solution.

Little accountability contributes to poor performance

OPOs play the vital role of procuring organs, finding a matching recipient, and delivering those organs to transplant centers for the actual procedure. Each of the 58 OPOs in the U.S. operate without competition from any other organizations in their

58 OPOs, it is concerning that only 3 1/2 employees are tasked with effectively overseeing this massive responsibility.

It’s a perfect complexity; everyone is focused on their own problem, and ignoring the rot underneath.”

- Senior Government Official

There’s a sensitivity to addressing the controversies because then HRSA has to admit that there was a problem there in the first place that they allowed [or] didn’t fix. So they point instead to some other problem. It’s a conflict-avoidance strategy.”

- Senior Government Official

The HRSA team assigned to oversee the OPTN contract is roughly 3 ½ employees. Since the OPTN is responsible for the technology that connects the organ transplant ecosystem as well as overseeing the country’s

WHO’S WHO?

Government

- HHS
  - Health and Human Services
- CMS
  - Centers for Medicare and Medicaid Services
- HRSA
  - Health Resources and Services Administration

Contractors

- UNOS
  - United Network for Organ Sharing
- OPOs
  - Organ Procurement Organizations
- SRTR
  - Scientific Registry of Transplant Recipients

Healthcare

- DH
  - Donor Hospitals
- TxC
  - Transplant Centers

KEY FINDINGS & OPPORTUNITIES

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And 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.”

— New York Times Editorial Board
Despite massive underperformance, no OPO has lost its government contract in the nearly 40 years the system has operated.

“There is no provision for even random audits of the data submitted by OPOs to assess the accuracy of the data reporting. All data are self-reported and unverified.”

- Association of Organ Procurement Organizations

Misaligned incentives lead to fewer recovered organs

The current flow of money and costs (see “Organ Procurement Money Flow,” Figure 3) between agencies and federal contractors overseeing organ procurement and placement does not incentivize getting patients transplanted. The federal contractor in charge of overseeing the U.S. organ procurement system, UNOS, earns about $58 million a year, with the bulk of their revenue coming from transplant centers paying to add patients to the organ waitlist.

“Because most of that money comes from patient fees, there is more of an incentive to add patients to the waitlist than to secure organs for them.”

- New York Times Editorial Board

UNOS has held the contractor position exclusively since 1986. Since that time, the waitlist has grown considerably. The current system also does not incentivize OPOs to pursue all donation opportunities. For example, OPOs may de-prioritize ‘low-yield’ candidates, for lack of either financial or regulatory pressures to recover and place all transplantable organs. This can result in them rejecting, or simply not showing up for, older donors with only single organs available – even though those single organs could each save a life.

While not all patient referrals are clinically able to become donors, some OPOs fail to show up or decide not to pursue an organ. 

“Where OPOs ‘determine’ eligibility is a HUGE gap in the system. Many OPOs rule out patients that could be ruled in. Lack of training/knowledge, preconceived notions, pure laziness.”

- OPO Coordinator

OPOs fail to obtain family authorization. Many families report they would have donated if they had been approached correctly. However, poor interactions and poor training contribute to low authorization rates.

“Training keeps getting worse and worse...there’s no standard training, it’s very subjective...They’re setting [OPO staff] free before they’re really ready.”

- OPO Coordinator

OPOs do not place organs or get them where they need to be in time. Once an organ is recovered, OPOs rely on an inefficient matching technology from UNOS to place the organ while it is still viable. The algorithm can waste time by suggesting the wrong offers. For example, 17% of kidney offers go to deceased patients.

“What tends to happen is that sick people get offers for organs that they can’t tolerate because they’re too sick already. They’ll have too many complications. There IS a patient for that organ, but an offer never makes it to a patient who can accept the organ.”

- Researcher

Despite massive underperformance, no OPO has lost its government contract in the nearly 40 years the system has operated.
Core technology and software inhibits innovation and organ policy implementation

Many users we talked to stated that UNOS organ transplant technology felt dated and had frequent periods of downtime, or the system was extremely slow, where they had to rely on phone calls.

Further, the agency tasked with overseeing OPTN/UNOS has few tech staff to effectively audit or implement technical best practices. “We don’t have the in-depth IT staff to have an understanding of whether the things that are being built are good,” said one HHS official.

Another issue is the number of disparate software systems within the organ transplant tech community. Various contractors each handle their own system and data. This approach prevents a single overseer, like the OPTN, from collecting centralized data and making smarter, data-driven management decisions.

Most software used by UNOS is considered closed and proprietary, blocking any chance of innovation or competition from outside actors. This strongly goes against modern day best tech practices. (See Tech Recommendations.) And it has caused the organ donation system to miss the mark on moving the technology forward, blocking out a market of innovative technology options to tackle solvable problems.

The government’s current approach to contracting blocks progress

The government (HHS/HRSA) is extremely limited in its ability to select which vendors can be awarded the OPTN contract, due to overly prescriptive specifications within NOTA. Thus the same vendor, UNOS, has been awarded the contract during every recompete for the past 34 years. These constraints limit progress in developing digital products and services with modern best practices to truly support the system. (See Strategy for Buying OPTN Tech.)

Additionally, as mentioned above, in the past 40 years, none of the OPOs in the U.S. have lost their federally-funded positions, despite clear evidence of underperformance.

WHERE DO WE GO FROM HERE?

The good news is that many of these problems are solvable. We believe it is within reach to create a system that is less complicated and saves more lives and taxpayer dollars in the short and long term.

Below are key opportunity areas to increase the effectiveness of the organ transplant system:

Opportunities to modernize and remove conflicts from governance structure:

- Broaden options for HHS to more freely fulfill organ donation objectives without needing to designate as many functions to a contractor, and maximize competition for work done by the OPTN, so that HHS can access a much larger vendor pool.
- Centralize governance and oversight to contractors working on organ donation within one department, and staff it with a digital service team that can adequately manage and run technology services.
- Use modern acquisition strategies for technologies related to the OPTN. (See Strategy for Buying OPTN Tech.)

Opportunities for CMS to improve accountability in organ recovery and placement:

- Require objective, verifiable, and real-time data from OPOs on the number and timeliness of staff follow-up for all eligible donors, and whether follow-up was onsite.
Medical professionals save nearly 100 lives every day with organ transplants. People currently waiting for a heart, lung, kidney, liver, or pancreas face the painful reality that the science exists to save them, and yet it’s an outdated, bureaucratic system that’s getting in the way. Employing a few structural changes could have a massive impact on the number of lives saved.

2. *“The Terrible Toll of the Kidney Shortage,”* JASN. 2018.
4. There are fewer POC donors because of several factors, including: historical mistrust of the healthcare system, and POCS being less likely to be approached by Organ procurement organizations (OPOs), and more likely to receive a lower quality interaction from the OPs when they do get approached to be a donor refer. More donations are needed from every race... Hispanics, the nations largest minority, had a donation rate of 27.5 per million in 2017. And just 15.1 per million Asian-Americans are organ donors. Now a program helped solve the problem of far too few POC organ donors.” 2018.
7. *“Comparison of black and white families, experiences and perceptions regarding organ transplantation,”* Critical Care. 2003.
8. Although organs are not matched according to race/ethnicity, and people of different races frequently match one another, individuals waiting for an organ transplant will have a better chance of receiving one if there are large numbers of donors from their race/ethnic background. This is because compatible blood types and tissue markers - critical qualities for donor recipient matching - are more likely to be found among members of the same ethnicity. *Kidney Donor” 2018.
11. *“OPTN Deceased Donor Potential Study,”* OPTN.
14. *NACBS FY 2020 Budget is $1.362 billion.*
15. *“The Terrible Toll of the Kidney Shortage,”* Crit Care Med. 2012.
17. *“Medicare and Medicaid Programs: Donor Procurement Organizations Conditions for Coverage: Resident In the Outcomes Measure Requirements for Organ Procurement Organizations,”* CMS NPRM. 2018.
18. Ibid.
24. These typically come from donor hospital staff, or in very limited instances, through an electronic automated system.
25. *“Comparison of black and white families, experiences and perceptions regarding organ transplantation,”* Critical Care. 2003.
27. *See bipartisan oversight from the Senate Finance Committee, February 2020.*
Governance and Oversight in the Organ Donation Process

By Law, OPOs and Transplant Centers must be OPTN members — meaning they have to follow OPTN policies.

OPO leaders are also OPTN board members — which means they govern themselves. OPOs are government-granted monopolies; none have ever lost contract.

The transplant community has shown repeatedly that it does not have that willingness or courage to police itself.

- Transplant Surgeon
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<th>Name</th>
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<th>Affects</th>
<th>Alerts</th>
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<tbody>
<tr>
<td>Law</td>
<td>Social Security Act</td>
<td>Covers conditions of participation and payment</td>
<td>CMS, ESRD network, OPOs, transplant centers, donor hospitals</td>
<td></td>
</tr>
<tr>
<td>Law</td>
<td>Public Health Service Act: Amended by National Organ Transplant Act (NOTA)</td>
<td>Created OPTN; prohibits “transfer of valuable consideration” in exchange organs for transplant</td>
<td>HHS (CMS/HRSA), OPTN, transplant centers, OPOs</td>
<td>Established a requirement that the OPTN operates under contract, rather than mandate that HHS Secretary ensures that certain things happen. Does not restrict profiteering (e.g., from tissue) by government contractors or business partners</td>
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<tr>
<td>Law</td>
<td>Public Health Service Act: Amended by Organ Procurement Organization Certification Act</td>
<td>Called for the creation of OPO outcome and process measures</td>
<td>CMS, OPOs</td>
<td>Has been interpreted as closing the field to new entrants.</td>
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<tr>
<td>Law</td>
<td>Uniform Anatomical Gift Act</td>
<td>Model state law which sets framework</td>
<td>OPOs, donor hospitals, donors and donor families</td>
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### Regulation

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<tr>
<td>Regulation</td>
<td>Final Rule</td>
<td>Lays out functioning of OPTN and SRTR</td>
<td>OPOs, transplant centers and OPTN (written by HHS, currently delegated to HRSA)</td>
<td>Creates perverse incentives as OPTN fees derived from adding patients to the waitlist, rather than facilitating transplants for them. (See Money Map.) Allows stakeholders to self-regulate and has splintered oversight between CMS and OPTN. Despite documented underperformance, lapses in patient safety, and financial improprieties, no OPO has lost its CMS contract or OPTN membership. (See Governance Map.)</td>
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<tr>
<td>Regulation</td>
<td>Organ Procurement Organization (OPO) Outcome Measures</td>
<td>Creates criteria on which OPOs are evaluated for outcomes</td>
<td>OPOs (CMS enforces via CCSQ)</td>
<td>Self-reported, self-audited data means regulation currently unenforceable: no OPO has ever been decertified.</td>
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### Bylaws

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<tbody>
<tr>
<td>Bylaws</td>
<td>Organ Procurement and Transplantation Network (OPTN) Bylaws</td>
<td>Outlines requirements for OPTN membership</td>
<td>OPTN member institutions (i.e. OPOs and transplant centers), HHS must sign off</td>
<td>Mandates a large board (34-42 people), which can be operationally burdensome. Of note: board for OPTN and UNOS (OPTN contractor) are the same (see Governance Map) and UNOS has been criticized as “mired in bureaucracy and... resistant to change.” Self-regulated: OPTN bylaws are enforced by the UNOS Membership and Professional Standard Committee (MPSC), which is composed of OPTN members. Defines conflicts of interest so narrowly as to be functionally immaterial.</td>
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Organ Procurement Money Flow

“...the federal contract that grants control of the nation’s organ procurement system is valued at nearly $58 million per year. Because most of that money comes from patient fees, there is more of an incentive to add patients to the wait list than to secure organs for them.” — NYTimes Editorial Board

Medicare reimbursement for dialysis patients
$91,000 PER PATIENT PER YEAR
compared to $36,000 per year for transplant patients

Reimbursement for Medicare patients for cost of organ,
surgery, and waitlist fee

Standard acquisition fees (SAF) are paid for all organs
SAC fees vary as much as 100% across OPOs for the
same organs

$1.8M
in data report fees paid annually

Medicare spending on patients with
kidney failure $35.8 BILLION

HRSA
Health Resources &
Services Administration

OPTN
Organ Procurement and
Transplantation Network

OPOs
Organ Procurement
 Organizations

Care for
Dialysis Patients

Medicare reimburses patients with
kidney failure $35.8 BILLION

CMS
Centers for Medicare
and Medicaid Services

Tissue Processing
Centers

Donor
Hospitals

$5.9M
contractually obligated average paid annually

$5.5M
(2019 contract)

SRTR
Scientific Registry of
Transplant Recipients

Contract held by Hennepin
Healthcare Research Institute

Contract held by UNOS

OPTN Annual
Revenue
$58.9M

$1.8M
in data report fees paid annually

Reimbursement for costs related to
organ donation

OPOs
Annual
Revenue
$3 BILLION

UNOS is DOUBLE CHARGING transplant centers to add patients to the waitlist — as an “OPTN Registration Fee,” which is part of a mandate approved by HRSA, and a “UNOS Registration Fee,” which is not.

KEY TAKEAWAYS

► A large amount of money in this system is primarily coming from Government — and thus, taxpayers.

► OPOs are 100% reimbursed for all costs, largely by Medicare, including for costs not directly related to organ recovery.

► Improving OPO effectiveness will increase the number of transplants, and can save Medicare billions of dollars in dialysis costs - the largest value on this chart by far.

► Tissue processing is a multi-billion dollar industry, yet there are no prohibitions on OPO executives holding financial interests in their tissue processing partners. This has the potential to distort OPO priorities, including to divert resources away from organ recovery.

► UNOS is DOUBLE CHARGING transplant centers to add patients to the waitlist — as an “OPTN Registration Fee,” which is part of a mandate approved by HRSA, and a “UNOS Registration Fee,” which is not.

Sources
- https://optn.transplant.hrsa.gov/members
- https://hifld-geoplatform.opendata.arcgis.com/datasets/hospitals
- https://www.stltoday.com/business/local/mid-america-transplant-services-and-its-officials-move-into-for/article_f37bb65b-f000-5bf7-bc00-097b2f6341f5.html
How an Organ is Managed (Or Not) in Our Current Organ Donation System

**PHASE 1: Procurement**  
Donor Hospitals ↔ OPOs

1. **Recipient Candidate** is evaluated to be organ transplantable.

2. **Organ Procurement Organization Staff or Contractors** (OPO) requests medical records and donor information.

3. **Hospital staff** reviews donor record to determine if organ is available for donation.

4. **OPO staff** contacts family to discuss organ donation.

5. **Family** must authorize donation. In some cases, organ procurement organizations may start testing without family authorization.

6. **OPO staff** contacts transplant center to request organ.

7. **Transplant Center** (TxC) assesses organ viability and determines if organ is suitable for transplant.

8. **OPO** confirms organ viability and sends information to **Transplant Center**.

9. **Transplant Center** selects recipients for organ.

10. **Recipients** are notified and agree to transplant.

11. **Donor** undergoes organ recovery.

12. **Organ is shipped to transplant center**.


14. **Recipient** recovers from surgery and begins rehabilitation.

**DISCRETIONARY**  
OPOs have the discretion to accept organs within specific parameters. This may include factors such as organ viability, donor age, and donor history.

15. **Organ Donation System**  
- **FREQUENCY**  
- **MEDIUM/HIGH FREQUENCY**

**PHASE 2 CONTINUED: Match and Recovery**  
OPOs ↔ Transplant Centers

1. **Organ Donation System**  
- **PHASE 1 CONTINUED**

2. **Recipient Candidate** undergoes evaluation and is listed on transplant center's live donor or deceased donor list.

3. **Transplant Center** contacts **Organ Procurement Organization Staff or Contractors** (OPO) to request organ.

4. **OPO** sends information to **Transplant Center**.

5. **Transplant Center** selects recipients for organ.

6. **Organ Donation System**  
- **PHASE 2 CONTINUED**

**Organ Donation System**  
- **MEDIUM/HIGH FREQUENCY**

**PHASE 3: Transport and Transplant**  
OPOs ↔ Transplant Centers ↔ Organ Recipient

1. **Organ Donation System**  
- **PHASE 3 CONTINUED**

2. **Transplant Center** contacts next hospital on the list (OPOs go through local, usually regional matches). **Organ Center** does not have authority for kidney and pancreas.

3. **Recipient** undergoes transplant surgery.

4. **Recipient** recovers from surgery and begins rehabilitation.

5. **Organ Donation System**  
- **PHASE 3 CONTINUED**

**Organ Donation System**  
- **LOW FREQUENCY**

**DISCRETIONARY**  
OPOs have the discretion to accept organs within specific parameters. This may include factors such as organ viability, donor age, and donor history.
Organ Discarded