

Appendix

SUMMARY OF FINDINGS (PDF)

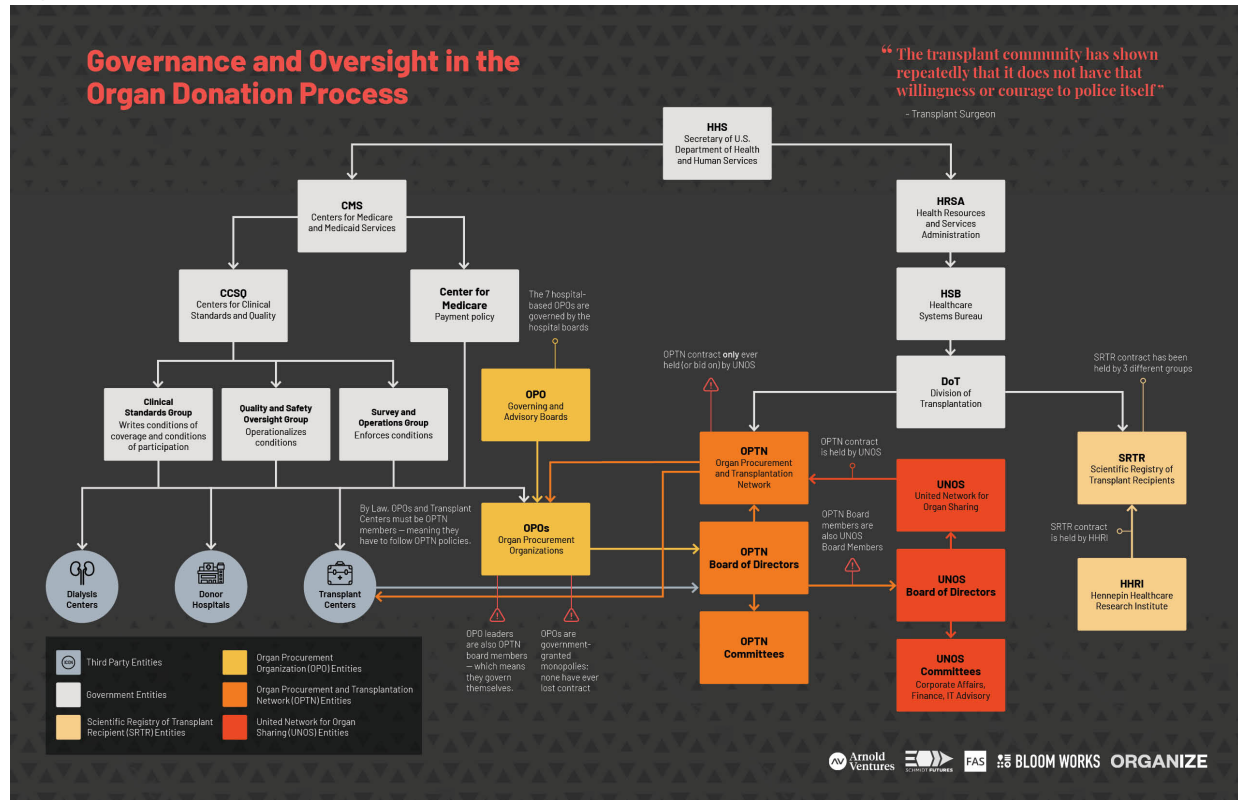
SUMMARY OF FINDINGS



[Read the printable PDF version here](#)).

GOVERNANCE AND OVERSIGHT IN THE ORGAN DONATION PROCESS (PDF)

Figure 1



[Download the “Governance and Oversight in the Organ Donation Process” PDF](#)

ORGAN DONATION POLICY CHART (PDF)

Figure 2

POLICY CHART

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

Policy Type	Name	Description	Affects	Alerts ⚠
Regulation	Final Rule	Lays out functioning of OPTN and SRTTR	OPOs, transplant centers and OPTN (written by HHS, currently delegated to HRSA)	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 .)
Regulation	Organ Procurement Organization (OPO) Outcome Measures	Creates criteria on which OPOs are evaluated for outcomes	OPOs (CMS enforces via CCSQ)	Self-reported, self-audited data means regulation currently unenforceable; no OPO has ever been decertified.
Bylaws	Organ Procurement and Transplantation Network (OPTN) Bylaws	Outlines requirements for OPTN membership	OPTN member institutions (i.e. OPOs and transplant centers), HHS must sign off	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.

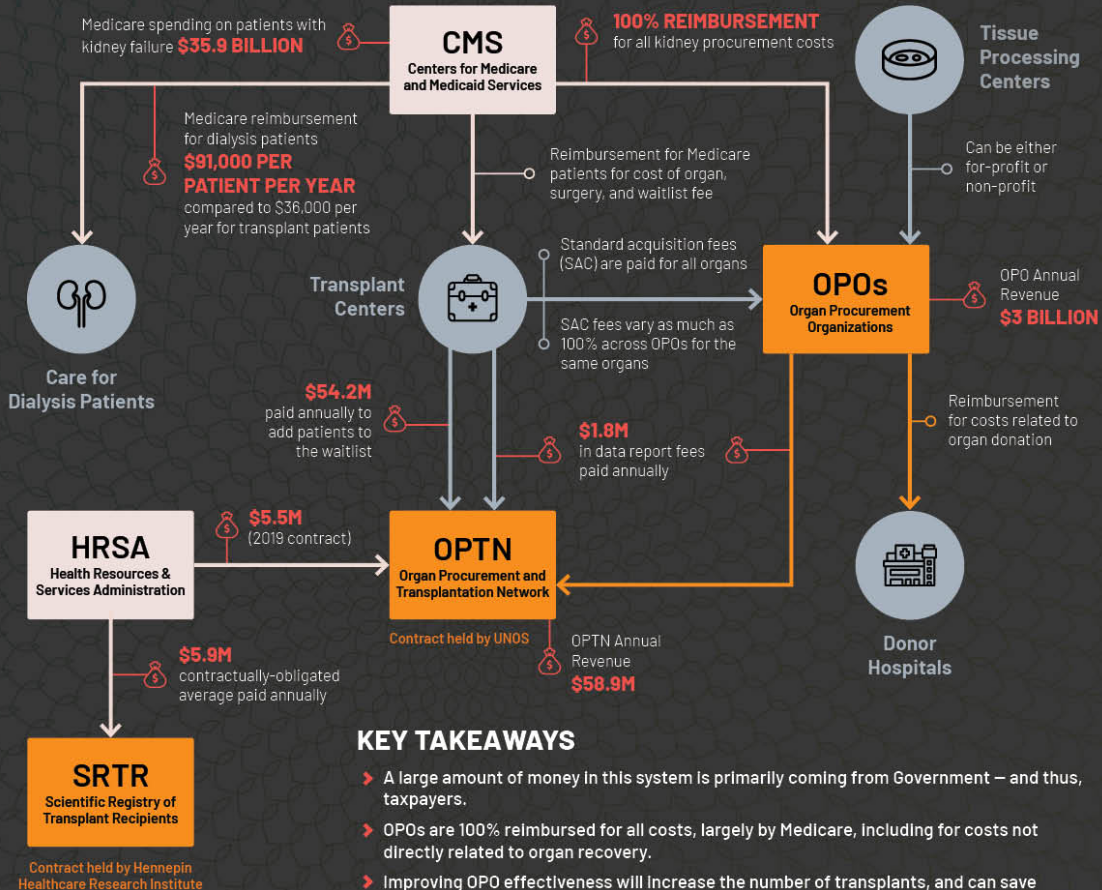
[Download the "Organ Donation Policy Chart" PDF](#) 

ORGAN PROCUREMENT MONEY FLOW (PDF)

Figure 3

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



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

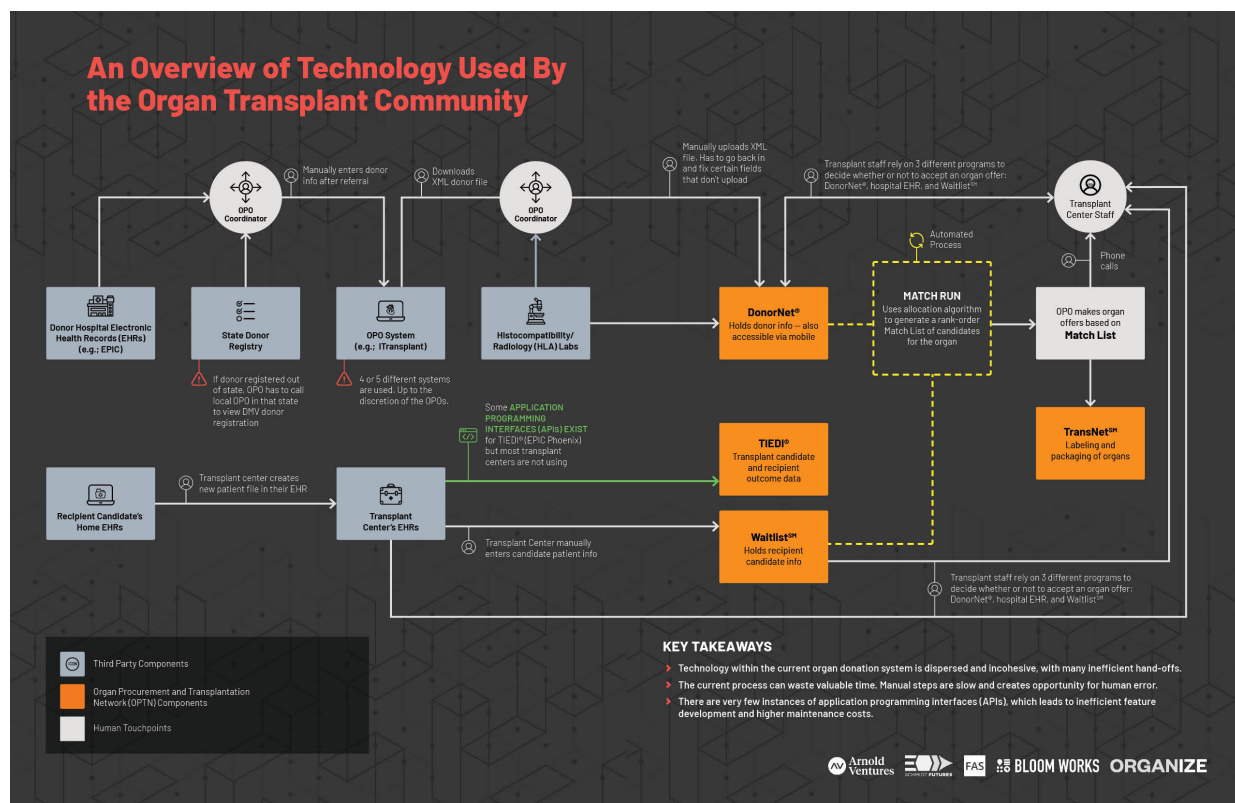
- <https://unos.org/wp-content/uploads/unos/2019-Audited-Financial-Statement.pdf>
- Federal Procurement Data System Record
- <https://optn.transplant.hrsa.gov/members>
- <https://usrds.org/media/2371/2019-executive-summary.pdf>
- <https://hifid-geoplatform.opendata.arcgis.com/datasets/hospitals>

- https://www.sttoday.com/business/local/mid-america-transplant-services-and-its-officials-move-into-for/article_f37bb65b-f000-5bf7-bc00-097b2f6341f5.html
- <https://onlinelibrary.wiley.com/doi/10.1111/ctr.13419>
- <https://www.hhs.gov/sites/default/files/cms-3380-p-ofr.pdf>



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Figure 5

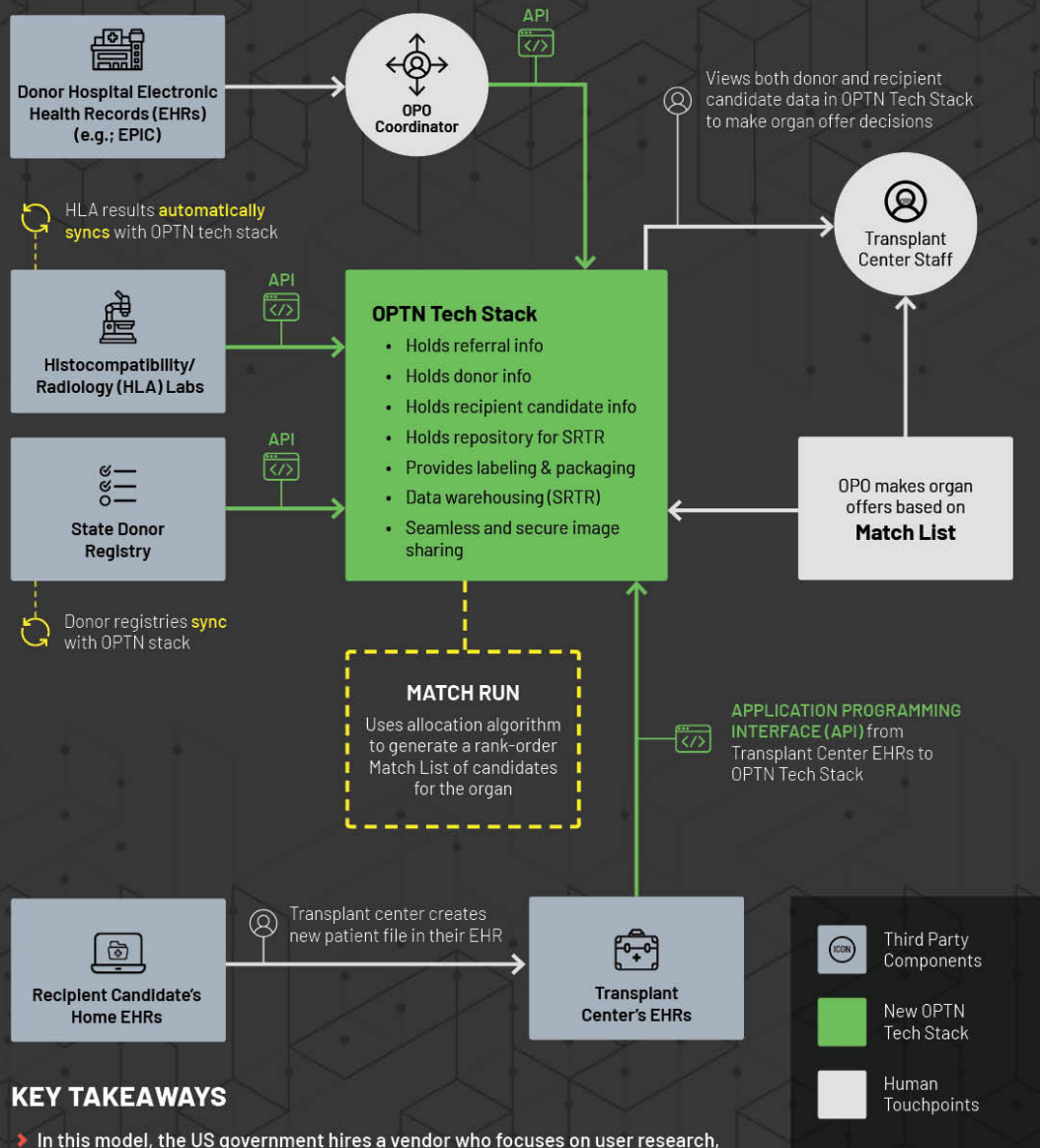


[Download the “An Overview of Technology Used By the Organ Transplant Community” PDF](#)

HOW ORGAN TECHNOLOGY COULD BE IMPROVED IN THE LONG TERM (PDF)

Figure 6

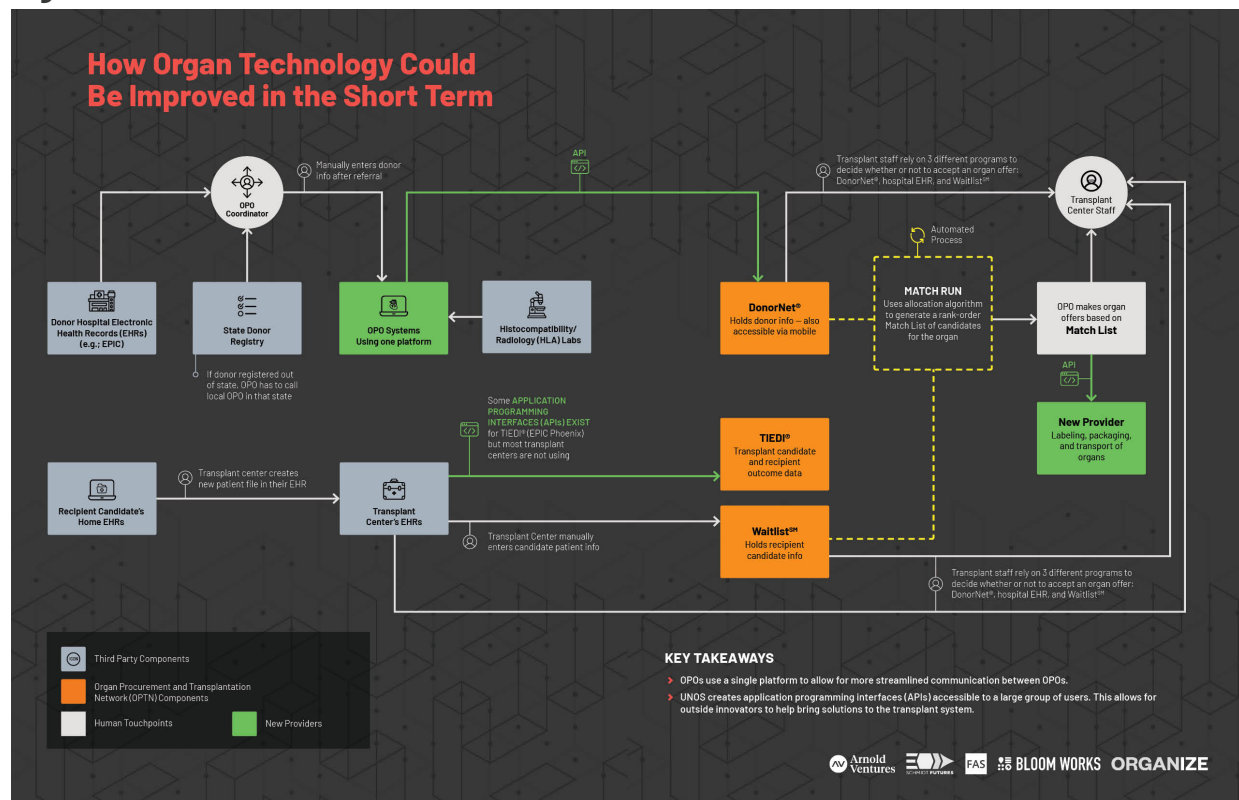
How Organ Technology Could Be Improved in the Long Term



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HOW ORGAN TECHNOLOGY COULD BE IMPROVED IN THE SHORT TERM(PDF)

Figure 7



[Download the "How Organ Technology Could Be Improved in the Short Term" PDF](#)

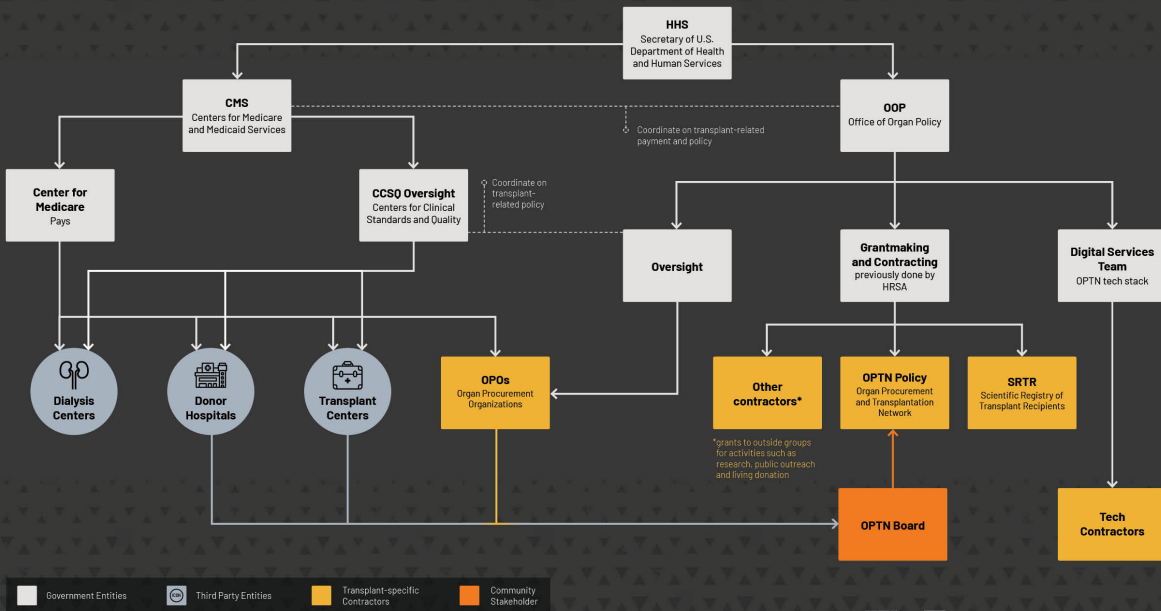
AN EXAMPLE ORGAN DONATION SYSTEM STRUCTURE WITH FEWER CONFLICTS(PDF)

Figure 8

An Example Organ Donation System Structure With Fewer Conflicts

“Creating an Office of Organ Policy [would] fix the fractured government-oversight system that has left tens of thousands of patients to die while waiting for organs.”

- Day One Project



[Download the “An Example Organ Donation System Structure With Fewer Conflicts” PDF](#)

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