**U.S. DIGITAL SERVICE**

# LIVES ARE AT STAKE

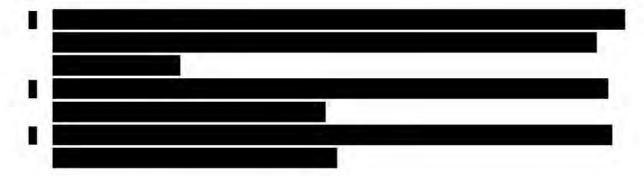## The Government's Role in Modernizing the OPTN

**U.S. Digital Service**

January 5, 2021

## EXECUTIVE SUMMARY

Through discovery work and market research, 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 life-saving transplants. In order to properly and equitably support the critical needs of these patients, the ecosystem needs to be vastly restructured. There are little to no incentives for the United Network for Organ Sharing (UNOS), the current and only Organ Procurement and Transplantation Network (OPTN) contractor, to ever modernize the operations of the OPTN and improve the current processes or technology, and the government has very little leverage to enact, or even encourage, change.

In order to create a better organ transplant system and enable better patient outcomes, the government needs to:

- ██████████████████████████████████████████████████
  ████████████████████████████████████████████
  █████████████████
- ██████████████████████████████████████████████████
  ███████████████████████████████████
- ██████████████████████████████████████████████████
  ████████████████████████████

## USDS ENGAGEMENT

During summer 2020, a team from the U.S. Digital Service was engaged by the Health Resources & Services Administration (HRSA) Office of Acquisitions Management and Policy (OAMP) to review the responses to the Request for Information (RFI), "Modern National Resource Allocation System" (MNRAS)[1] issued in fall 2019. ████████████████████
████ and our initial assessment was delivered to HRSA's OAMP, Health Systems Bureau (HSB), and Office of Information Technology (OIT).

As we engaged for the initial RFI response review, we also began our own background research efforts, including a review of the relevant statutes[2], reading published reports and

---

[1] MNRAS RFI: https://beta.sam.gov/opp/69bd972384b8480283bd2599fc8805a9/view
█ ████████████████████████████████████████████████████
████████████████████████████

papers from both government agencies and interest groups[3], as well as speaking to staff at the Centers for Medicare and Medicaid Services (CMS), the Office of Management and Budget (OMB), lawyers at the HHS Office of General Counsel (OGC), former federal employees with experience in the organ transplantation space, and outside groups who were doing research into the issues around the OPTN.

Additionally, we began to have regular meetings with the program leadership and staff at HRSA to learn more about the history of the program, the problems they were facing in the administration of the program, and the things they had tried in the past to overcome those issues. In lieu of being able to access the current IT systems that support the OPTN, we requested the Authority to Operate (ATO) documentation from HRSA in an attempt to get basic learnings about what is currently in place, as this would have been very informative for our vendor capabilities assessment.

Our initial review of the written RFI responses concluded that there were a variety of vendors in the marketplace who seemed to possess the capabilities to compete for a future procurement to modernize the technology for the Organ Procurement and Transplantation Network (OPTN). We followed the delivery of our assessment with a recommendation that HRSA proceed with continued market research by inviting the top responders and the incumbent OPTN contractor, UNOS, to demonstrate and discuss their capabilities for meeting the requirements of an MNRAS. The sessions for those vendor demonstrations took place December 1-15, 2020.

Despite not having a top response to the RFI, we strongly recommended that UNOS be invited to demo the current systems and discuss their efforts around systems modernization. UNOS demoed the current system for HRSA and the U.S. Digital Service for the first time on Thursday, December 10, 2020.
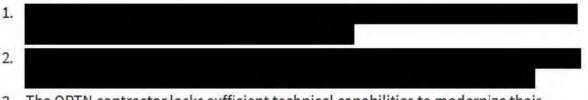
There were representatives from both HRSA and USDS on all of the vendor demonstration calls. There was some variation in process, but all calls were scheduled for two hours, and most calls began with the first 60-90 minutes used by the vendor for their presentations and the remaining time used by USDS to ask questions about particular parts of their demo or to dive a little deeper into specifics around their development processes and overall technical

capabilities. USDS had several debriefing sessions with HRSA stakeholders as the demos progressed to hear their impressions and to share our thoughts about what we were seeing. On some vendors, there was easy agreement about capabilities, and with others the two groups were widely divergent.

At the conclusion of the demo and debrief sessions, USDS produced two deliverables. The first was a bulleted assessment of each vendor presentation, and the second was a summarized report that addressed the technical issues we observed with the current OPTN contractor and a recommendation for proceeding with OPTN modernization efforts. Both of those were delivered to HRSA, and the latter was also shared with the HHS Secretary's office.

## PROBLEMS WE FOUND

As we explored the organ donation landscape, we identified four key problem areas:

1. ████████████████████████████████████████████████
2. ████████████████████████████████████████████████
3. The OPTN contractor lacks sufficient technical capabilities to modernize their systems.
4. The contract for the OPTN has issues that leave the government in an extremely tough position when it comes to any modernization or transition efforts.

### Statutory issues ████████████████████████

████████████████████████████████████████████████

████████████████████████████████████████████████

[REDACTED] The government has tried several times to encourage competition in the OPTN contract, but has never found success.

The most recent attempt to encourage competition was the RFI issued on November 14, 2019 for the MNRAS, which sought information for the possible procurement of a modern IT system that could perform the functions of a national resource allocation system, including matching algorithms, patient waiting list and donor management, and a membership database, and which utilizes an API-based architecture and makes all functionality available online. [REDACTED]

## Statutory interpretation [REDACTED]

Before proceeding with further procurement actions and issuing an RFP for an MNRAS, [REDACTED]

The HHS OGC interpretation [REDACTED]

Whether the procurement approach here resulted in the commercial-off-the-shelf solution available from one of the identified capable vendors, or the custom development approach from the others, it is questionable that a solution tailored to the current operations of the

---

[4] OPTN Final Rule: https://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5

OPTN could be achieved in a one-time purchase without incurring incredible risk that the system(s) will not meet the needs of the OPTN user. In order to ensure that the system is able to accommodate the changing needs of the OPTN into the future, the software development and deployment approach will need to occur over time with active participation from both the system contractor and the various users and policy makers in the OPTN.

It should also be noted that ███████████████████████████████████████████
████████████████████████ In fall 2012, HRSA funded a project led by an entrepreneur-in-residence from the U.S. Department of Health and Human Services Entrepreneur Program. That project resulted in the design, development, field testing, and launch of TransNet, a barcode scanning technology at the point of organ recovery to help label, package, and track organs being shipped for transplantation.[5] In June 2016, the OPTN board announced its intention to require all OPOs to use TransNet,[6] and at that point took over the tool. It is still in operation today, and under the ownership and servicemark of UNOS, despite internal agency belief that it should be government owned.

## Lack of expertise in technology leads to blind spots

████████████████████████████████████████████ HRSA has tried many things over the years to encourage more transparency and accountability from UNOS through the OPTN contract. All of these attempts have been met with hostility from the contractor -- UNOS has at times even threatened to walk away and continue operating the OPTN without a contract, despite the fact that it would be illegal for them to operate such a network independent of a government contract. ████████████████████████████████████
████████████████████████████████████████████████████████

While there have been some improvements (e.g., the time for implementation of new allocation policy in the matching algorithms has gone from several years to just one year), the contractor has been able to wiggle through and around most new contract requirements for the OPTN technology by hand-waving at change with technical jargon, while making no substantive progress.

████████████████████████████████████████████████████████
████████████████████████████████████████████████████████
████████████████████████████████████████████████████████
████████████████████████████████████████████████████████
████████████████████████████████████████████████████████

████████████████████████████████████████████████████████
████████████████████████████████████████████████████████

---

[5] OPTN News on TransNet: https://optn.transplant.hrsa.gov/news/innovative-electronic-labeling-and-packaging-solution-spreads-across-opos/

[6] UNOS Board Actions from June 2016: https://unos.org/news/optn-unos-board-actions-june-2016/

[black redaction bar]

[black redaction bar] In fact, until the December 10, 2020 UNOS market research session, no one in the government had ever seen a demonstration of the current system functionality. The government's only understanding of the OPTN systems was through the status reports required by contractual deliverables and what information they have picked up through their own attendance at OPTN committee meetings. [black redaction bar]

[black redaction bar]

## UNOS lacks the capabilities necessary to modernize their systems

We found the modernization capabilities of the current contractor, UNOS, to be severely lacking. Despite positioning their modernization efforts as having been in progress over several years, none have come to fruition. There were several efforts that were described as having been started and abandoned over the last 5-10 years because they proved too costly or too difficult in UNOS' estimation.

### The core systems are fragile

UNOS has also indicated that as long-time staff left the organization, they were unable to retain basic institutional knowledge about how the code was originally designed or built. While this pattern can be seen in large institutions everywhere -- both private and government -- with legacy code that is central to business functions, UNOS has never put together a cogent strategy or plan to address the issue.

We found indications that the allocation algorithms, the critical core functionality that determine how organs are distributed, are fragile. HRSA has heard from UNOS that it takes a significant amount of time for them to test and ensure that changes in one algorithm do not unknowingly change other organ allocation algorithms. While it is the case that UNOS would need to ensure that there weren't unintended changes through testing, the length of time

indicates that the codebase is at an unmanageable level of complexity. When asked directly about how they measure the cyclomatic complexity of their codebase, UNOS responded that they do not measure it because they do not believe there is "significant value" in this analysis. The fact that they have not done even this cursory analysis indicates they have likely never seriously considered moving from their current tech stack, nor do they have any plan to rewrite their code in the future.

It is also true that UNOS cannot version control the matching algorithms themselves. The algorithms are too enmeshed with each other and the rest of the system logic, so they can only meaningfully version the codebase as a whole. This lack of modularity and its attendant fragility and complexity lead us to believe that they will not take any of the risks to tackle meaningful change for fear of breaking core functionality.

HRSA is aware that UNOS attempted to modernize their core functionality around 2010, but after several years of indicating they were making good progress, they abandoned the effort when external consultants took a look and told them they had to start over again because it was a failure. We have seen no indications that UNOS is actively engaged in rebuilding this core functionality. Instead, they have placed on their product roadmap things like artificial intelligence, mobile delivery of functionality and advanced predictive modeling. Where UNOS should be focused on getting the basics right for the core functionality before they layer in additional complexity (some of which is questionable in terms of appropriateness and user need), they instead seem intent on adding shiny technology and distracting program stakeholders from the fact that at the core the matching algorithms are fragile.

## Technology limits policy development

We also saw indications that the current technology may be impacting transplant operations and limiting allocation policy development. Because of the entanglement of the OPTN and UNOS boards -- they share the same board of directors -- it is difficult to discern the level of influence that the state of UNOS' IT operations has on issues that the OPTN board and working committees are focused on advancing through policy.

Recently we learned that the OPTN is moving toward a continuous distribution model for its matching algorithms to develop a more equitable system of allocating deceased donor organs.[7] They approved the adoption of this continuous distribution model as a framework for development of future organ allocation policy in December 2018. The roadmap that UNOS shared with HRSA and USDS shows that the work to design an architecture to accommodate this new allocation method is not slated to begin until at least Q2 of 2022. It should be noted that this is not the implementation of new algorithms, which are not on the current roadmap

---

[7] OPTN Continuous Distribution Policy Initiative: https://optn.transplant.hrsa.gov/governance/policy-initiatives/continuous-distribution/

projections that run through Q2 of 2023, but rather the design phase for an architecture to accommodate the new algorithmic model that new algorithms could be based on.

Two other red flags in this area are that the current systems are not capable of sizing organs with the best available tools and it appears that the systems will not be able to accommodate Human Leukocyte Antigen (HLA) crossmatching in a meaningful and usable way. Both of those approaches are medically accepted as providing better patient outcomes, but they require the scalability of the cloud to fully realize, which the current vendor is not positioned to utilize, and in fact, seems to be actively resisting.

## Resistance to cloud modernization

From the demo presentation and follow-up questions with UNOS, we learned that the bulk of the critical functionality for the OPTN tech is deployed and maintained in an on-premise data center. This means that UNOS is solely responsible for the maintenance of all physical data center infrastructure, the physical and information security of the systems, monitoring of systems and network health, and the deployment of not just the system software, but also the deployment and application of any upgrades or patches to their existing technology stack. This approach does not allow UNOS to take advantage of any of the economies of scale that a modern cloud environment creates, particularly around flexible computing power and security.

The core functionality that supports the operations of the OPTN is not currently built in a modular way or utilizing a microservices architecture, and none of the core functionality is in the cloud. Only auxiliary services from other vendors, such as the generation of email messages for notifications, are cloud-based, but until directly questioned, the contractor tried to use the consumption of those third-party APIs as evidence of API development and modernization. UNOS also took the position that cloud is not safe for this system, trying to persuade HRSA stakeholders with examples of recent AWS outages. This positioning is simply not true.

Transition to the cloud would provide more extensive security capability than is currently available in their on-premise data center, because of the tools and features in modern cloud environments that aid with auditing, standard roles and group permissions, as well as the ability for cloud services providers to respond to the latest threat intelligence with monitoring and the application of the latest patches to infrastructure more efficiently and quickly than can typically be managed in a private, on-prem environment. A primary benefit in using the services of a commercial cloud provider comes in the learning at scale by the cloud provider itself. As problems are discovered and remediated for one client, those same remedies can be applied for all customers in their cloud environments.

## Insufficient uptime for life–saving system

Additionally, the current OPTN contractor could not give a clear picture of how they define system uptime, and described an approach to estimating uptime that does not align with industry best practice. When asked about system availability, UNOS said, "99.8 or 99.9 with some numbers after that." In answering written follow-up questions, UNOS clarified that they have experienced 99.79% uptime since 1999. This equates to approximately 17 days of total system downtime over the time period for which they reported.

This is an unacceptable answer for the life-saving nature of a system like this. The 24/7 critical nature of this system means that zero downtime for user and business operations should be the goal.

## Poor API adoption

While the current OPTN systems contain some APIs, the contractor could not provide usage data when requested. None of the APIs that have been developed had implementation of 100% of their associated data elements, which means that manual entry would still be required from users even if their facilities have integrated with the APIs. In their written follow up responses, UNOS provided a fuller accounting of their API efforts. While they have listed 13 APIs in production, most are being used by less than 8% of their intended user base, with only four breaking past the 20% adoption mark, and none at full adoption.

Although the current OPTN contractor has made APIs available, it is obvious that they won't be able to implement an API-first, or API-driven, approach to their systems. What is less obvious is what incentives facilities like transplant centers would have to spend the time and money to integrate with incomplete APIs. When asked about how they intended to drive API adoption, UNOS said they had no plans, and it was just left up to others to use what they had built.

## No real time integration

At every step in the UNOS suite of transplant tools that support the OPTN (UNet, TransNet, etc.), surgeons and individuals at organ procurement organizations (OPOs) must manually update information about the donor organ or patient and then manually start a new match run. The longer a surgeon has to spend in evaluating an organ for acceptance, the more time is lost on the viability of that organ. For example, the heart and lungs expire in 4-6 hours and if the system relies on human intervention to update a test result or value, the organs could become inoperable. All of this can lead to worse outcomes for patients and may suggest that these highly manual and time-consuming processes are contributing to the current organ waste issues in the transplant ecosystem.

DRAFT || DELIBERATIVE || PRE-DECISIONAL

A more ideal solution would be to develop data integrations directly with the EHRs at the points of care so that there is zero delay between new lab test results, organ viability indicators, or a patient's health degrading and calculating a more immediate match. It is unlikely that, as described to us during their demo presentation, the current development activities and plans of UNOS will ever achieve this level of real-time system integration and functionality for users.

### Disjointed user experience

Finally, the visual design and user experience of the current system creates an image of unnecessary complexity. UNOS claimed to use a design component library, but they had at least five entirely different user interfaces with very different user experiences. There was no evidence of consistent design across the applications, which is what we would expect to see from an organization who tells us they are using a design component library. Some aspects of the system appear to be more recently developed, but their current development on Waitlist functionality has a look and feel that is extremely outdated and is, once again, not consistent with other recently developed features and applications.

Based on all of these things, USDS has serious concerns about the current contractor's technical capabilities, in particular when it comes to the much-needed modernization of the systems that support OPTN operations.

## Contract issues reducing government leverage

Because of the size and nature of the single contract structure for the OPTN, and the vendor lock-in that it has created, all of the power lies with the vendor, while all of the risk is shifted to the government. ████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████████

This has set up a situation where the government does not have enough regular insight into the activities of UNOS and their obligations to fully support the needs of the OPTN. UNOS has also become very adept at protesting and causing delays to any moves by the government to gain more insight through issuing new RFIs to explore options, new RFPs when it's time to recompete the contract, or during contract negotiations.

### No mechanisms for modernization in the current contract

Despite both HRSA and UNOS talking about modernization efforts for the OPTN, there are no requirements, or mechanisms to create requirements, in the current contract to move the technology toward more modern development practices, or a modern cloud-native, API-first architecture to better support the needs of policy makers and OPTN users. UNOS knows this,

and it is why when asked directly about their timeline for modernization, they point at HRSA and just say, "We'll do it when they tell us to."
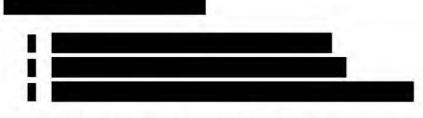
## The OPTN owns the data

The current OPTN contract gives ownership of all data rights to the OPTN. In this scenario, UNOS receives and manages the data submitted or created by OPTN members for the OPTN. The government only has insights at the level and frequency dictated by the reporting requirements of the statute and contract.

This means that the government isn't even in a position to do its own analysis about the health or efficiency of the services provided by the OPTN to the transplant community, and does not give the government any ability to utilize the data to find space for potential innovation. They are completely at the mercy of UNOS to identify where efficiencies can be created or innovations might be possible.

## Transition costs inhibiting future procurements

Additionally, there are issues around the cost of transition to any new vendor that have been built into the current contract that must be considered if a new procurement of any kind is to move forward. ███████████████████████████████████████████
████████████████████████

- ███████████████████████████████
- ███████████████████████████████
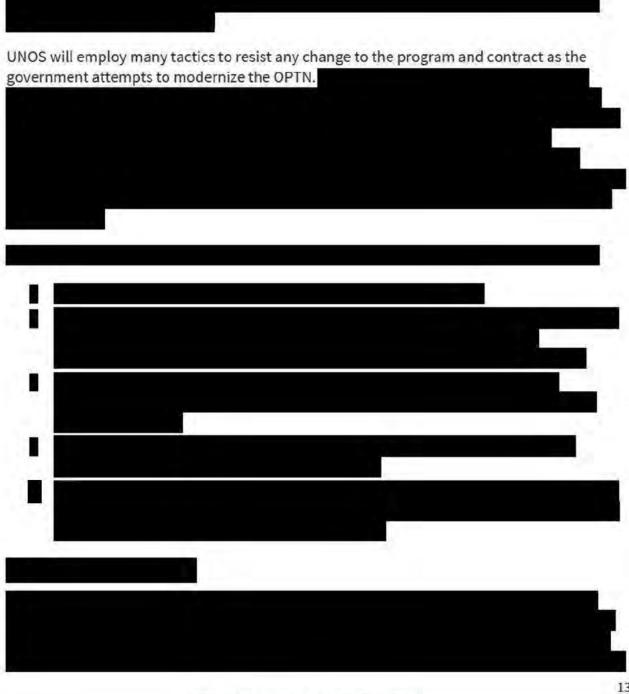- ███████████████████████████████████

The government should never have to be in a position to make the purchase of the existing systems in order to ensure the creation of modern systems that serve the needs of the OPTN and its users.

## OUR RECOMMENDATIONS

Based on the critical need to modernize the core functionality of the OPTN IT Systems and the ████████████████ we recommend the following three actions:

- ████████████████████████████████████████████████
████████████████████
- ████████████████████████████████████████████████
████████████

UNOS will employ many tactics to resist any change to the program and contract as the government attempts to modernize the OPTN.

14

[REDACTED]

[REDACTED]

[REDACTED]

## CONCLUSION

There are many opportunities to improve the realities of the organ transplant system in our country. [REDACTED]

[REDACTED] This is not just a tech modernization for the sake of modernization, but rather modernization of the whole because lives are at stake. In order to create better outcomes for people waiting for life-saving transplants, the entire organ transplant system must be addressed, beginning with the statute that is at the root of the problems.