HEALTH RESOURCES AND SERVICES

Organ Procurement and Transplantation Network (OPTN) RFI

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<u>C. Statement of Intent:</u> While Accenture is strongly inclined to supply a proposal to any future solicitation related to this requirement, we will make that final determination based on the scope, structure, and requirements / eligibility of each solicitation as it is released.

B. Responses to Questions. Accenture Federal Services (AFS), hereafter referred to as Accenture, is pleased to provide our response to the Health Resources and Services Administration's (HRSA) request for information. Accenture has the right team, right approach, and proven record of accomplishment to strengthen and improve the Organ Procurement and Transplantation Network (OPTN). With more than 6,000 professionals in our health care consulting practice, including more than 200 staff with clinical experience in care delivery processes, we serve over 850 clients in implementing core health information technology solutions. Our delivery teams consist of people with extensive experience in health IT, especially in clinical quality measures, standards development, and prior working relationships with HRSA. Additionally, Accenture is a global leader and pioneer in Human Centered Design (HCD). With 30 design studios world-wide, we have more than 1,200 talented professionals with specialized expertise in experience design, user research, and innovation and a comprehensive toolkit of well-tested HCD methods, tools, and templates. Our Accenture Federal Studio has conducted nearly 40 HCD projects over the last three years for agencies across government, including CMS, and is actively engaged in strengthening the OPTN. Please find Accenture's responses to selected questions below. Accenture has elected not to respond to questions which do not appear in this document.

A. OPTN Technology - IT System

A.1

Describe how you would/a vendor would implement and utilize modern IT architecture to: A.1.a.

Manage, track, and operationalize the OPTN organ donation, procurement, allocation, and transplant system, such as by adopting a "cloud-native," agile, and modular approach to IT development and maintenance.

It is our understanding that the OPTN system is already modern because the current OPTN contractor has been on a journey for several years to optimize and transform the systems necessary to operate the OPTN. For example, multiple systems have either been developed or rebuilt on an API-based backend (Donor Management Mobile and Security Administration are two examples). In addition, we understand a significant amount of effort has been undertaken to create organ-specific microservices. Accenture had the opportunity to work on the system for one of these cloud initiatives.

one of these cloud initiatives.	(b) (4)	·

Considering all the different workflows supported by the OPTN system, we recommend taking a flexible, hybrid approach to agile Continuous Integration (CI)/Continuous Delivery (CD) DevSecOps processes. For example, any regulatory changes related organ allocations and changes to the organ allocation algorithms require extensive reviews across the entire OPTN ecosystem. Similarly, any changes to APIs etc. that affect external systems and stakeholders like hospital systems would need to follow more of a Release Train approach to give an opportunity for the external systems to support the changes. (b) (4) approach and experience focus on speed and agility across the environment and delivers high levels of reliability – transforming and modernizing the system incrementally while maintaining the expected uptime and stability -i.e. "building the plane as we are flying it". We work to analyze all changes holistically to identify dependencies throughout the CI/CD pipeline. Our goal is the minimization or elimination of manual tasks to reduce effort and errors. Our processes focus on learning from every challenge to improve performance and quality. The implementation phase includes a detailed project plan along with the risk and mitigation strategies. (b) (4) We continue to strengthen our strategy, delivery, and methods by integrating the latest innovations and experience with successfully demonstrated practices and lessons learned through our Federal and commercial implementations. We have utilized most industry-standard tools such as Jenkins, GitLab, Terraform, and cloud-based services—such as Azure DevOps, BitBucket, and AWS CodePipeline—in the domain of CI/CD as depicted in Figure 1. Our focus is on building standard processes through automation to increase quality and efficiency. We provide CI/CD services along with the available technology stack in direct support of the governments business transformation goals. An increased focus on automation allows us to adopt new technologies and practices more easily.

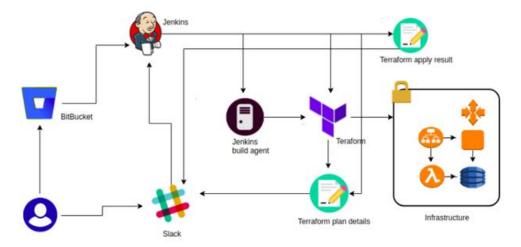
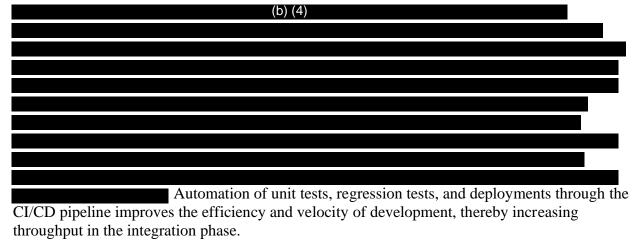


Figure 1. CI/CD Pipeline Workflow



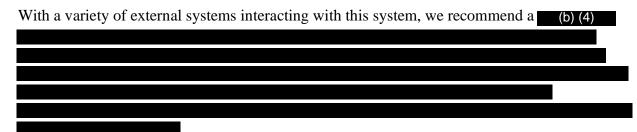
With growth in deployment frequency, we shift compliance to the left of the CI/CD process by performing more frequent audit trails including tracking necessary approvals and versions of applications that are getting deployed into production, using more guards and guardrails to inspect any unwanted release and avoid unauthorized rollouts, and seeking higher collaboration between the DevOps and compliance and audit teams.

A.1.b.

Prioritize the use of publicly accessible application programming interfaces (APIs) to enhance data sharing and integration with the electronic health records (EHRs) and other tools used by OPTN members and patients.

We understand that HRSA seeks to improve the adoption of Application Programming Interfaces (APIs) across the OPTN community so that vital information is populated across the ecosystem in as close to real time as possible for transactions that are time sensitive. In non-time sensitive situations, (e.g. submission of post-transplant forms) APIs help reduce manual data burden and transfer data from system to system securely. Most modern systems, including the OPTN system, make APIs available to improve efficiency through better integration and enhance data sharing.

APIs also enable improved user experiences that establish trust through improved transparency in a complex, multi-part, life-changing system like OPTN.

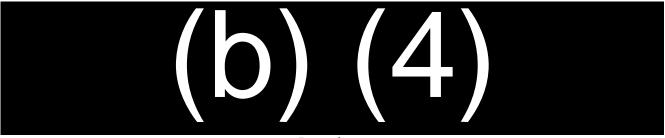


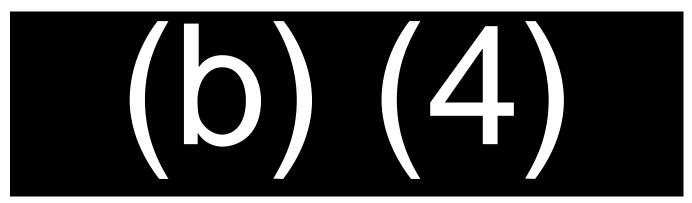
API management allows monitoring the API usage, queries served per hour, latency in responding to requests, end to end integration, transaction logs, historical data logs, overall hits, completed transactions, data objects returned, the volume of data transferred, amount of compute time, other internal resources consumed, and other metrics that better inform the status as well as the success of the APIs available. We use the above-mentioned data and metrics to take informed decisions. This includes real-time monitoring of the API serving a 24/7 donor-facing applications with alerts being raised directly or via a higher-level network management system, for instance, if the load on an API has become too great, as well as functionality to analyze historical data, such as transaction logs, to detect usage trends.

However, the challenge with APIs is that they must be consumed in order to be valuable. Some may believe the "if you build it, they will come" principle. In our experience, this is often not the case. The existing OPTN system has available APIs, but adoption challenges exist with ecosystem members, such as independent providers and EHRs, because they would need to make significant IT investments changes to their platform to consume current/future OPTN APIs.



We agree with HRSA's intent to make more information available to patients, yet unfortunately the patient experience is often constrained by third party products of the OPTN community. If community members lack federal or commercial incentives and are not intimately involved in prioritization of APIs and other improvements, it is unlikely that the patient experience will be significantly improved unless the OPTN approves or endorses use of patient centric tools. It is for this exact reason that the OPTN community and members need to be engaged in better understanding what APIs would be most valuable to the patients they serve.

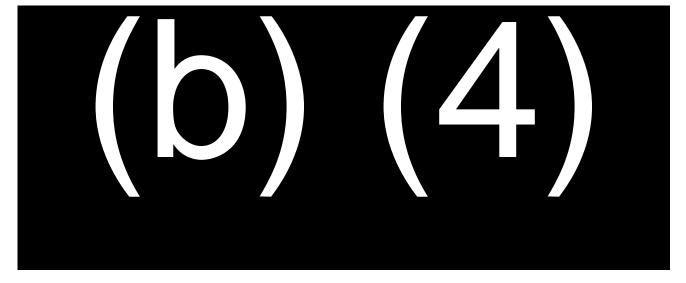


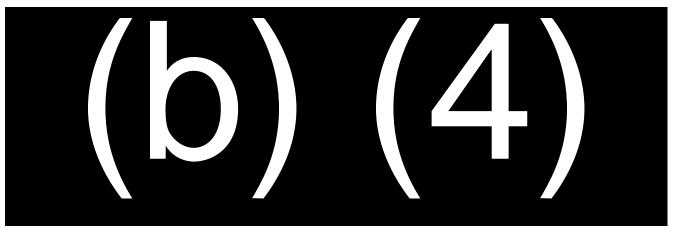


A.1.c.

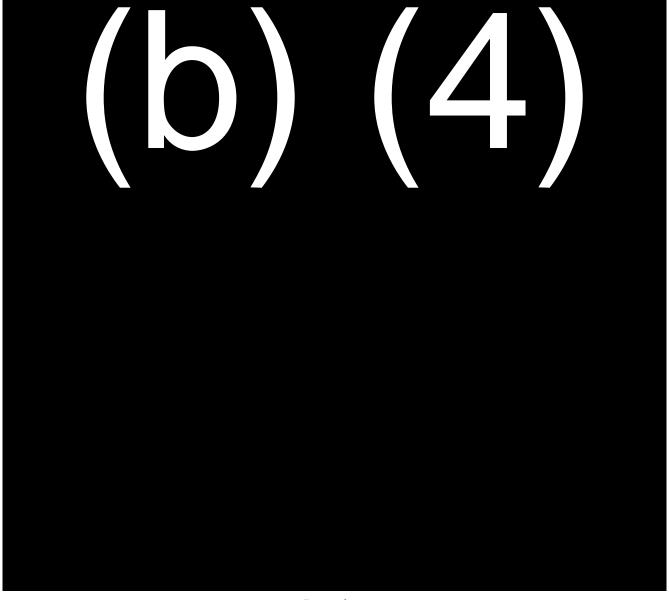
Enhance user interfaces to improve the ability of the OPTN IT system to conduct enhanced real-time tracking of donated organs, allocate organs more efficiently and support increased transplant center engagement with patients in organ acceptance decisions.

Accenture believes in an agile, human-centered approach to design and innovation. We reimagine people's relationships with the digital and physical world. Using proven methods, our Washington, D.C.-based Accenture Federal Studio uses the power of design to create engaging, memorable, and valuable experiences. We believe for a system to deliver it's promised outcomes it has to be user friendly, simple, intuitive, and efficient. Creating these experiences requires a variety of specialized skills and talent, a thorough understanding of human nature and change models and systems of every type, and skills in facilitating collaboration and co-creation. Accenture is a global leader and pioneer in Human Centered Design (HCD). With 30 design studios world-wide, we have more than 1,200 talented professionals with specialized expertise in experience design, user research and innovation and a comprehensive toolkit of more than 85 well tested HCD methods, tools and templates. With our end-to-end design knowledge and skills, we collaborate with our clients from discovery to service development and deployment, adapting our methods to fit the unique needs of each client and our Accenture Federal Studio has conducted nearly 40 HCD projects over the last three years for agencies across government.





We look forward to the opportunity, if presented, to enhance the UX/UI of other parts of the OPTN system to drive improved user experiences and ultimately, improved patient outcomes.



(b) (4)
In our 2018 engagement with CMS, Accenture identified numerous concepts for solutions which including increasing patient engagement in response to specific barriers identified. See section F. for further detail. If HRSA decides to follow the recommendations in the NASEM report around patient engagement, then we (b) (4) A.1.d.
Produce public performance dashboards and actionable data to identify opportunities for program improvement, reduce inequities, and benchmark OPTN member performance.
Accenture brings extensive experience designing, building, and maintaining custom dashboard solutions, for public-facing and enterprise-wide use. Accenture is a leading end-to-end analytics services provider, currently providing analytics services to 28+ federal agencies and commercial entities from diverse sectors: public safety, defense, health, telecommunications, banking, insurance, credit, and retail. Our staff have the skills and experience needed to understand and overcome advanced analytics challenges, including developing KPIs, implementing data collection to improve performance measurement, identifying predictive analytics opportunities, and building predictive models. Accenture's data and analytics practitioners leverage Human Centered Design (HCD) methods to create data solutions that will work within existing operational context – this significantly mitigates any risks around transition. We identify opportunities, experiment, test, and learn to refine solutions and add mathematical rigor for decision intelligence. For example,
Additionally, we have been involved in designing end-to-end data solutions including big data processing, extract-transform-load (ETL) process design and building dashboards while working with business owners and other key stakeholders.
To provide value, a dashboard must measure something meaningful. This requires clearly understanding the goals of the dashboard user and an understanding of the appropriate metrics to select for informing those user goals. (b) (4)

The current OPTN website provides 2 dashboards:

- o OPTN metrics dashboard which includes details on Donors/Transplants/Waitlist, trends over time and region
- Equity in Access dashboard which includes Variability in Access-to-Transplant Scores (ATS) with drill downs by factors for each organ.



(b) (4)

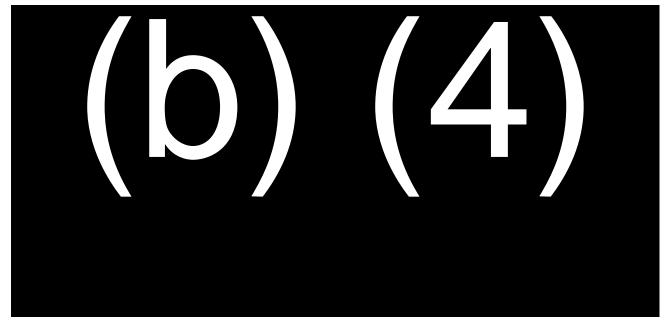
Accenture recognizes that there is already a considerable amount of data available—existing OPTN data, SRTR data, and OPTN advanced reports portal—and that it is feasible to coordinate data throughout the ecosystem. The challenge, however, is to create a portal that can service such a diverse set of stakeholders such as the research community, general public, Capitol Hill, patients and their families, transplant centers, OPOs—and to ensure that this is done in a way which support patient engagement policy. Each audience has different needs and want to look at the system from their unique perspective. For example, while we applaud the special project funding recently granted to the SRTR to explore a patient specific experience, we recognize a much bolder vision and corresponding investments would be required in both OPTN and SRTR to transform patients' ability to engage in true shared decision-making models. We can help.

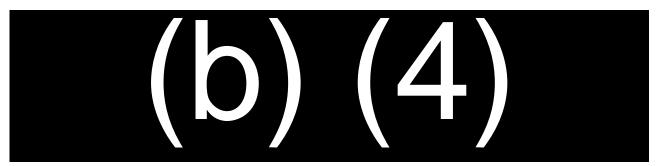
(b) (4)

A.1.e.

Maximize these and other tools to save critical time in the organ allocation process, minimize errors, and improve patient outcomes.

Accenture has been driving efforts within the health care sector, including within the OPTN, to make workflows more efficient, to optimize task completions within applications and reduce errors in an effort to improve patient outcomes and, additionally in the case of OPTN, to expedite the organ allocation process.



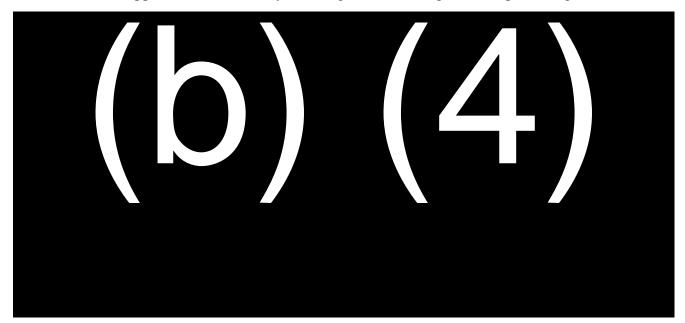


This initiative has been in pilot since early January across multiple centers and is planned to be expanded nationally across the transplant center community.

A.2.

The current contract requires system availability uptime of 99.5%. HRSA is planning to target a 99.999% uptime for this lifesaving OPTN IT system. Is 99.999% uptime reasonable and achievable? If not, what is an appropriate uptime standard for an IT system of this importance?

The OPTN system is a critical life-saving system, and we agree with the goal of determining the appropriate standard and uptime SLAs for the OPTN IT system. Accenture has experience implementing mission critical federal systems as well as commercial health systems with extremely high uptime requirements but based on our understanding, while the organ transplant work performed through the OPTN ecosystem is critical, the individual processes through this workflow that impact critical life-saving decisions do not necessarily happen through the IT system on a seconds or minutes basis. Some examples of such processes include adding individuals to the transplant waitlist, updating individual data with the latest clinical and other data which happen over a timespan of multiple days. Even the processes where life-saving decisions happen near real-time, like organ allocations which happen within one hour of organ availability notification there are numerous steps in the workflow that happen outside the IT system (e.g. OPOs calling the transplant surgeons).

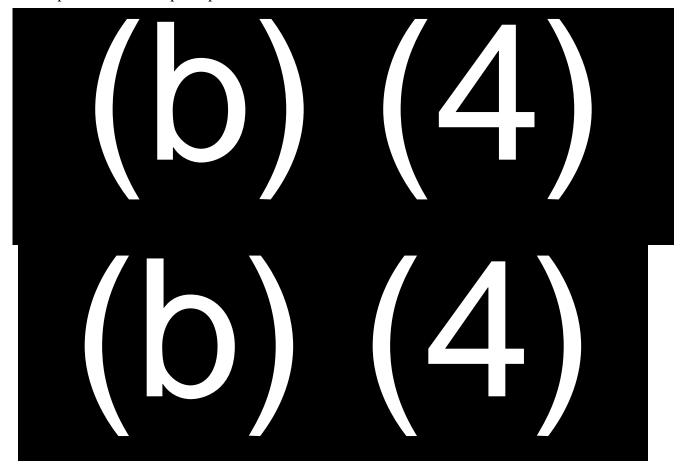


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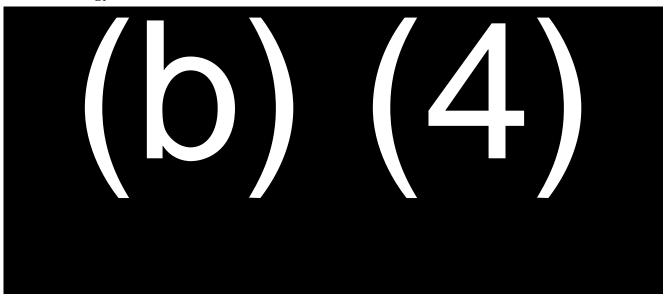
A.3.

How can the OPTN ensure data collection is relevant, accurate, timely and streamlined in order to improve organ allocation processes?

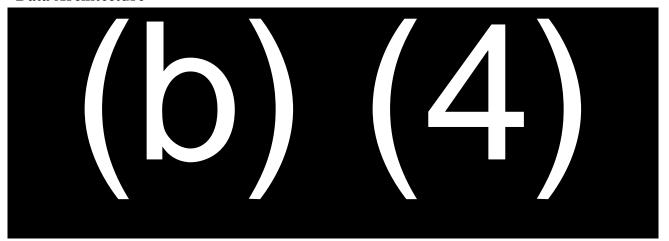
It is unclear if this question refers to the collection of data from users within their use of the application and/or APIs or if this is instead referring to collecting system data from the use of the system to identify patterns and trends of OPTN members that identify bottlenecks, inefficiencies, and other opportunities to drive a more effective and efficient organ allocation process. It is also not clear on what data collection gaps that HRSA perceives exists today between the OPTN and SRTR contracts that would need to be enhanced. Our CMS work looked at data collection opportunities and we would be happy to engage in live discussions to share our thinking around opportunities to create/collect more data throughout the transplantation process to drive improvements in the organ allocation and other parts of the transplant process.



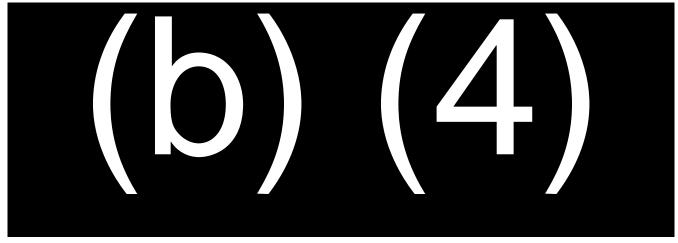
Data Strategy



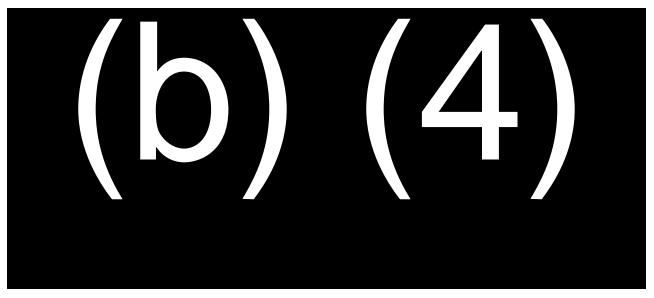
Data Architecture



Data Quality & Cleansing



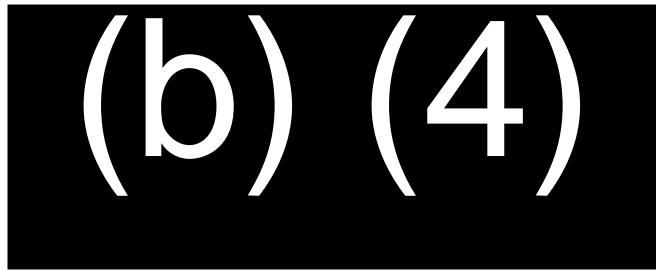
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A.4.

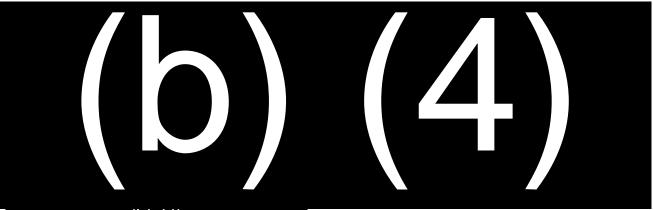
How would you/a vendor ensure ongoing security enhancements to protect against emerging and evolving IT security threats?

Accenture ensures ongoing security enhancements to protect against emerging and evolving IT security threats using a proven DevSecOps framework. DevSecOps brings together traditional development, security, and operations activity into a unified workstream—making security a pervasive feature of the systems lifecycle translates into higher security with reduced risk and cost of ownership. Accenture uses infrastructure- and configuration-as-code (IAC/CAC) to standardize security and operations configurations wherever possible, achieving consistent deployment across environments and enforcing policy compliance.

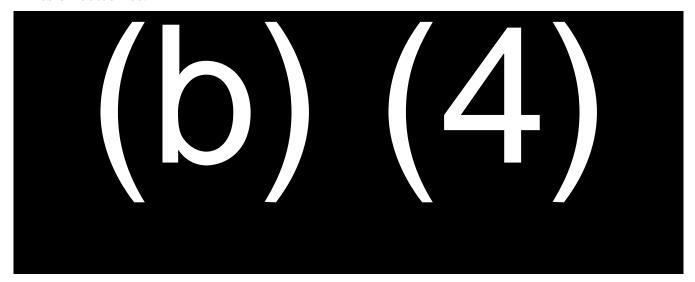


A.5.

How would you/a vendor ensure adherence to the latest industry best practices for IT security infrastructure, practices, and standards?



Additionally, Accenture brings unmatched relationships with leading technology companies such as Microsoft, Splunk, ServiceNow, Cisco, Google, and Palo Alto. We bring unique insights from an ecosystem of 150+ large technology partners and 5,000 startups. These insights include an advanced understanding of the technology capabilities, early access to product roadmaps, new features, licensing costs, and negotiation power, all of which benefit our clients' ability to adopt new tools that improve mission outcomes.

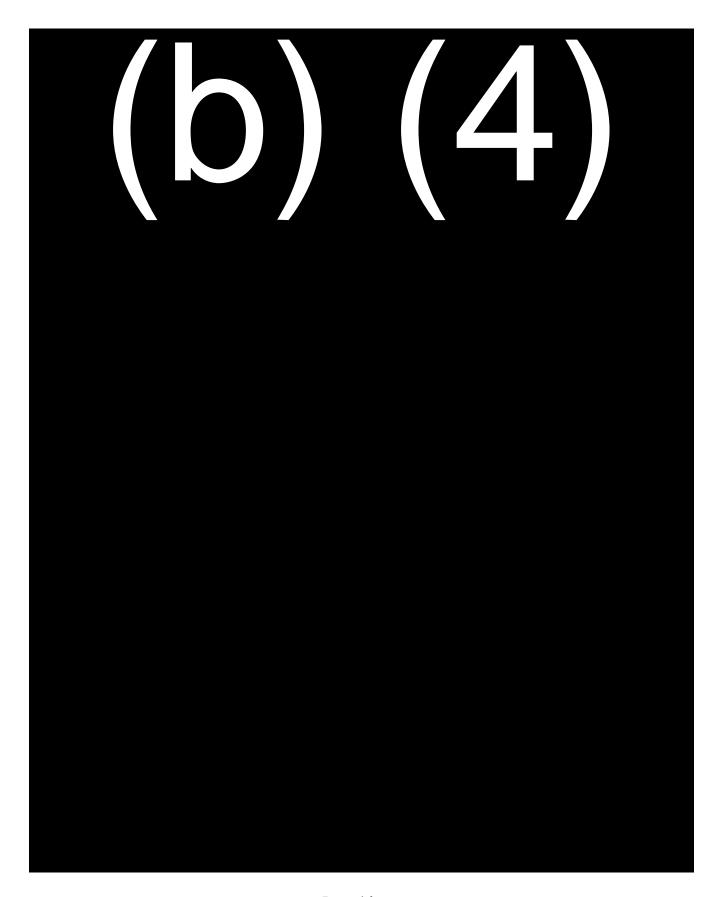


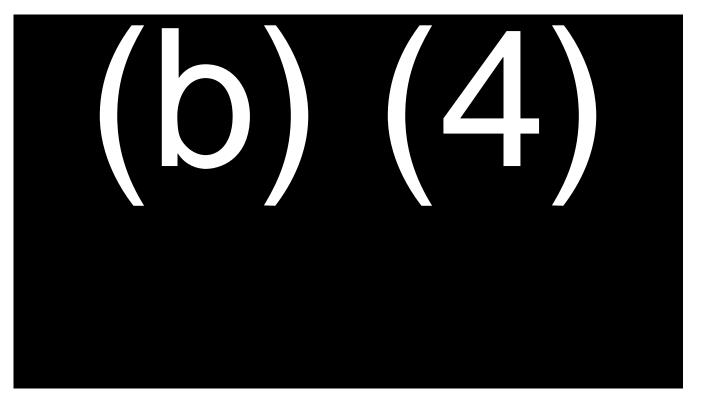
B. Data Collection Activities

B.1.

Describe how you would/how vendors could develop performance metrics and benchmarks for the organ donation, procurement, allocation and transplant system, including through expert consultation, subcontracting, and engagement with transplant candidates, transplant recipients, organ donors and their families about the metrics they value.

In order to effectively developing performance metrics and benchmarks for the organ donation, procurement, allocation, and transplant system we must first understand what participants within that system – and the general public - value and identify gaps between those desired benchmarks and the current benchmarks currently available within OPTN and SRTR programs/systems.





Understanding these kinds of tensions and balancing these competing values is vital to the success of the system. A patient would want them to pursue every organ possible and want every organ possible to be recovered, but we know that there's natural tension in the system which prevents this from bring true. Figuring out the unintended consequences of competing metrics is important and keeping people at the center of that effort is a proven way of uncovering and navigating that tension and mitigating any possible negative consequences.

B.2.

Describe how you would/how vendors could structure data collection and reporting mechanisms for the system:

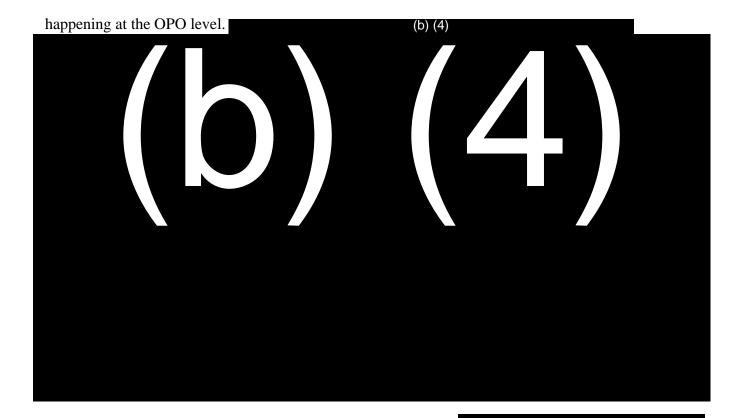
B.2.a.

To report OPTN performance metrics including process, outcome, and patient engagement measures.

(b) (4)

In this system, desired outcomes include the number of transplants, the number of discards, the survival rate of those recipients and among others, metrics identifying how many people are successfully waitlisted and how many organs are donated and recovered annually. We understand that the process that an organization executes, including engaging with patients, is typically a driver of those outcomes. In order to understand what's successfully contributing to those outcomes when you have good outcomes, or what is potentially blocking those outcomes when you fail to have such outcomes, you also need to measure the process and, specifically in this case, patient engagement, as these will serve as leading indicators to outcomes.

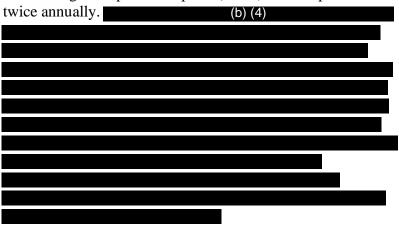
The current OPTN system is centered around transplant centers and OPOs today – and not around the transplant candidates and recipients. Engagement with recipients is typically happening at the transaction center level. Engagement with donors and their families is



B.2.b.

To establish OPTN member performance benchmarks.

It's our understanding that the current OPTN contractor collaborates closely with and feeds data into the SRTR contract that develops benchmarks for both OPOs and transplant centers on their public-facing website and in the SRTR Program-Specific Reports (PSRs) that are published



B.2.c.

To capture patient and donor demographics, including race, ethnicity, language, and socioeconomic factors.

(b) (4)

It is our understanding that some OPTN systems currently collect patient and donor
demographics which are directly relevant to ensuring a compatible organ match and include ethnicity and race. (b) (4)
(b) (4)
During our prior CMS work, Accenture identified over 50 concepts addressing the root cause of kidney discard and as having the highest potential for impact for patients and clinicians.
(b) (4)
B.2.d.
To create public OPTN national, regional and local performance dashboards.
One of the vital functions of performance dashboards is to highlight the natural, expected variance in the system. OPTN performance dashboards at the national, regional, and local levels would visualize where there is geographic variance occurring. (b) (4)
is identified and understood, it can then be addressed by
developing innovative healthcare quality improvement solutions to overcome the barriers in certain geographies and replicate the successes in others.
B.2.e.

To track long-term patient outcomes and health and non-health-related factors that contribute to outcomes.

For too long, the transplant system has focused on short-term outcomes. While doing so is important, it needs to be paired with an equal focus on the longer-term outcomes. One of the challenges in doing so is the ability and ease of collecting data on long-term outcomes. For example, data on 5-year survival rates is harder to collect than at the shorter-term 3-month, 6-month, and 1-year marks. Better understanding data on the survival of patients and grafts many years after transplant would provide valuable insight into trends and identify the key factors contributing to positive and negative long-term outcomes.



C. OPTN Finances

C.1.

Describe how you would/vendors could ensure that any fees, beyond OPTN registration fees, charged to transplant centers or others:

Our understanding is that the additional fees charged by the current OPTN contractor:

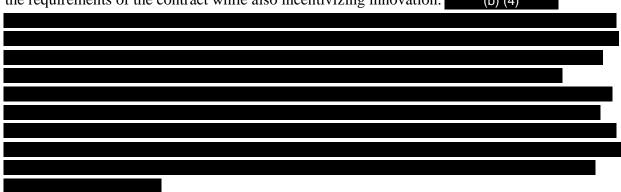
- Are not required in order to participate in OPTN
- Do not duplicate Medicare payment or result in unnecessary additional Medicare reimbursement
- Do not cover anything that OPTN contract supports
- Do not impact status in or allocations through the OPTN

If our understanding is incorrect, we welcome the opportunity to share our experience to help design a governance structure that balances the need to drive cost effectiveness for OPTN members, accountability and transparency in OPTN financial structures, while encouraging and enabling innovation in the OPTN system through piloting novel capabilities for OPTN members.

C.2.

What requirements and oversight mechanisms could be utilized to ensure appropriate federal review of the OPTN registration fee, any additional contractor fees, and the development of the overall OPTN budget?

We recognize that there has been scrutiny about additional contract fees being generated through the development of products and services above and beyond the requirements of the contract. We understand the need for clarity, but we assume HRSA wants to bring innovation and continuous improvement to modernize the system. It is our understanding that the current OPTN contract is a cost-share between the government and the contractor with the government contribution capped by law at \$7M. Our experience working with large scale government programs and systems is that it is important to structure the contract / commercial relationship between the government and the prime contractor in a way that holds the contractor accountable to delivering the requirements of the contract while also incentivizing innovation.



Such commercial agreements require trust, communication, and transparency to be effective for all stakeholders and Accenture has used such arrangements extensively with other federal agencies to drive significant innovation and public outcomes.

D. OPTN Governance

D.1.

It is our understanding that this is possible today and that there are distinct, discrete steps that need to occur for this to happen. First, the OPTN needs to be incorporated as a distinct entity. Then, the correct formal relationships between HRSA and the incorporated OPTN need to be established, as well as the relationship between the OPTN contractor and the distinct incorporated entity of OPTN. All of these relationships need to be formally established. This is possible, but it will require effort. It is our understanding and perception that there's been no pushback or resistance to this concept by the current OPTN contractor and that decisions need to be made and actions need to be taken by the government to directly facilitate this or to approve it and facilitate it to happen.

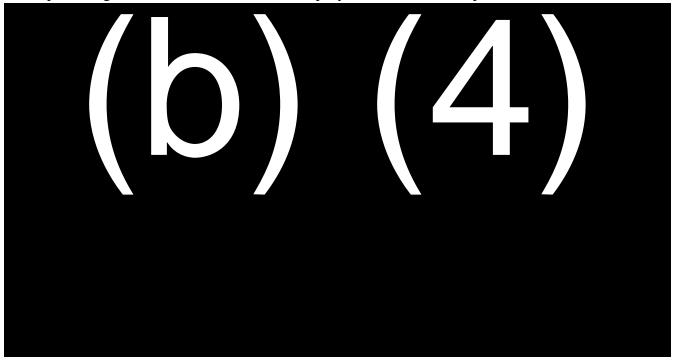
D.2 - D.4.

To address governance concerns by the government or stakeholders, we recommend leveraging an independent auditor to assess these relationships and to provide recommendations defining the governance structure, as well as a roadmap for implementing the recommendations.

E. Increasing Organ Donation and Improving Procurement E.2.

How could the OPTN facilitate OPO engagement in research protocols to improve procurement?

To improve procurement through research, the OPTN can employ a combination of quantitative research and qualitative human-centered design (HCD) methodologies. The OPTN contract could and should be expanded to include an HCD scope of work that uses more extensive research and facilitation techniques to engage with the OPOs to identify opportunities to improve procurement, conduct co-creative workshops to align on concepts, test and validate those concepts through user interviews, contextual inquiry, and test-and-learn pilots.

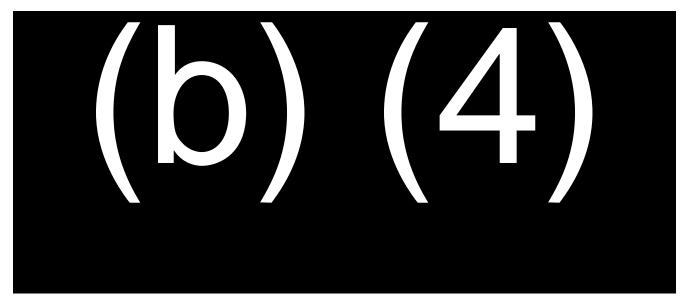


E.3.

What additional research could contribute to improving organ procurement?

solutions in total across the transplantation system. For example,

Human-Centered Design research methods are designed to understand and engage the human acting in or influenced by a system. (b) (4)	18
We recommend that HRSA engage Accenture in market research discussions where we can	
share in detail the findings from our work and communicate all of the potential ideas that car	ne
out of our past research that would improve organ procurement – part of more than 50 propo	sed



F. Organ Usage

CMS sought Accenture's expertise to evaluate drivers of the increasing high donor kidney discard rate, from 5% in 1988 to nearly 21% today. Employing human-centered design, we explored the factors driving both patients' and surgeons' behaviors as they move throughout the transplant ecosystem, identifying opportunities that can potentially decrease the discard rate and increase the number of kidneys transplanted.

Accenture's in-depth research composed a holistic view of the organ transplant ecosystem, allowing us to identify the root causes of discard. Our research was synthesized into two major findings:

(b) (4)

(b) (4)

After two days of collaboration, more than two dozen ideas emerged as having the highest potential for reducing discard while balancing the demands of implementation within a complex system. The Accenture team refined these ideas, evolved them into detailed solutions, and displayed them as the kidney care ecosystem of the future (Figure 6), a world in which these concepts had been fully realized.

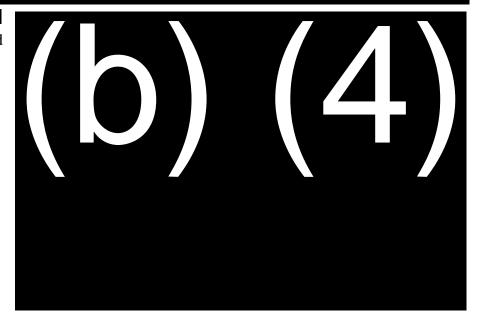
(b) (4)

(b) (4)

(b) (4)

CMS engaged Accenture a second time to apply the same HCD research and co-creation methods to understand the opportunities to decrease the discard rate by influencing the actions of transplant centers and surgeons.

(b) (4)





Once we uncovered the key pain points and opportunity areas

Figure 7: Optimization Blueprint

within each system, we conducted a root cause analysis to understand the pressures driving organ refusal decisions. (b) (4)

(b) (4)

(b) (4)

By understanding the key factors contributing to the success of high performers, we were able to propose solutions to replicate those best practices across the ecosystem. We synthesized the root problems and best practices into an optimization blueprint (Figure 7) to provide a single, holistic view of the opportunity areas across the ecosystem.

We then set out to define solutions to eliminate the pressures the 4 systems are putting on people at the 3 decision moments in order to minimize or eliminate inappropriate "no's."

Our understanding of the transplant ecosystem and the ESRD patient journey allowed us to create 50+ high impact concepts aimed at decreasing the kidney discard rate and increasing patient access to transplant. Our research findings and concept ideas continue to reverberate across the transplant community and have inspired new efforts within federal agencies and non-profits to improve organ allocation technology, transplant policy, ESRD patient education, and

transplant ecosystem collaboration – including being represented throughout the recent NASEM report. Accenture would be honored to participate in extensive market research discussions to walk HRSA through the full scope of proposed solutions we came up with in both the patient-and surgeon/transplant center-focused research engagements with CMS.

G. OPTN Operations and Policy Development Improvements G.2.

Describe how you would/vendors could engage with experts in quality improvement and stakeholder collaboration in executing OPTN deliverables.

The OPTN is a large, complex, and far-reaching system – it's truly a system of systems – and, as previously stated in Section B.1., there are significant and tangible tensions in the system. We recognize that to be successful in driving the nation's desired outcomes around maximizing the number of people who receive transplants, significant collaboration with experts in quality improvement and other various stakeholders is required. In our experience, simply establishing a mindset of collaboration, transparency, and connectedness is a critical first step and key to success when trying to transform a system.

G.3.

Describe what you would/vendors could include in their code of business ethics and conduct for the entity that holds this contract to ensure the highest standards of conduct and integrity are observed.

The entity that holds this contract should ensure the highest standards of conduct and integrity are observed and included in their code of business ethics and conduct.

Accenture's Code of Business Ethics (found here) builds on our core values by providing greater detail about expected behaviors and drives our culture of compliance, ethical conduct, and accountability. At Accenture, we care deeply about doing the right thing. We share a commitment to operating with the highest ethical standards and making a positive difference in everything we do. It's part of our culture. It's who we are. Our Code of Business Ethics is more than just a policy—it defines what we believe, how we live and how we lead. It helps each one of us make ethical behavior a natural part of what we do every day. It's also essential to our business. Our shared values and business ethics are how we earn the trust of our clients, our partners, our communities, and each other every day. Only with that trust, can we act as true partners to deliver the value Accenture is known for. Our 6 enduring core values—Client Value Creation, One Global Network, Respect for the Individual, Best People, Integrity, and Stewardship—shape the culture and define the character of Accenture. They serve as a foundation in how we act and make decisions.

G.4.

What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contact?

Fundamentally, based on Accenture's recent participation in a similar policy governance structure on another HRSA contract - the SRTR Review Committee (SRC) - we have come to understand how critical it is to make sure that the OPTN contractor is engaged, that they are bringing the right data and insights to facilitate data-driven and fact-based decision-making, and

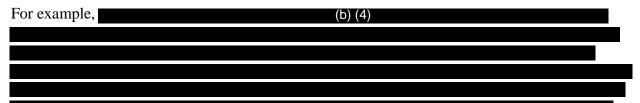
that they are making sure that all stakeholders are explicitly agreeing on principles of decision-making. When engaged, the contractor is not just facilitating and acquiescing to what OPTN members initially demand, rather they are explicitly laying out the situation (challenge and/or opportunity), the possible courses of action, and the pros and cons – including the unintended consequences - of each policy. They're pointing out where there are inconsistencies in their decisions over time because it's their job as the contractor to facilitate an effective and efficient decision-making and policy development process. It is important to do so in a timely manner so that the OPTN members have confidence in the decisions they're making.

Additionally, it is critical to communicate and articulate the policy decisions out to the broader stakeholder community. These are complex topics issues. Having enough resources, such as clear content authors and communicators, to really promote the decision and the rationale clearly is vital to the success of policy development.

H. Stakeholder Engagement

While there are many potential ways OPTN members can improve the way they engage with stakeholders, such as nephrologists, dialysis workers, clinicians, patients themselves, etc., the system today is limited in its ability to facilitate new or better approaches to engaging stakeholders due to the currently defined set of user audiences. This is especially true for patients and their families, who are not currently users of the OPTN system. Evolving the system to include patients as users would open up a whole new world of possibilities to engage patients and facilitate shared decisions in ways that aren't possible or feasible today given the highly siloed, inconsistent, and disconnected/manual processes executed by transplant centers today.

It is important to consider both the technology and policy updates required to support this kind of change. The technology currently in place is flexible and can be expanded to adopt these changes as long as the policy supports it. Building capacity and mechanisms into the OPTN contract to fund such technology expansion and innovation would incentivize exploration into the art of the possible and truly deliver the opportunity for patient engagement that drives health outcomes.



This was one of the highest prioritized recommendations from our work due to its potential to have the biggest impact on the offer acceptance decision – and therefore higher kidney utilization and decreased kidney discards. Accenture has already planned out how this concept could be tested as an experiment to demonstrate the value it would have on the discard rate and offer acceptance. We look forward to the opportunity to discuss this – and many others - concept with HRSA that would drive increased stakeholder engagement and increased patient outcomes.



Enterprise Transplant Management Platform

May 23, 2022

Attention: Naomi Inazawa

Re: Organ Procurement and Transplantation Network - RFI HHS/HRSA/OAMP 541611

Dear Ms. Inazawa:

Thank you for providing (b) (4) with the opportunity to showcase its Afflo platform for the Health Resources and Services Administration (HRSA) planning and market research for the Organ Procurement and Transplantation Network. (b) (4)

Afflo (www.afflo.io) is the industry's only commercially available organ allocation and end-to-end transplant management platform that is ready for US national-scale deployment.

(b) (4)

Afflo was designed in conjunction with leading clinical transplant experts in North America, and is aligned with the US transplant operational model. Afflo represents a significant leap forward, driving both technological and process advancements across the entire organ transplant ecosystem with an aim to eliminate data and process silos. Our product addresses sector shortcoming by integrating OPOs, waitlisted recipients and Transplant Centers, resulting in less waste and greater optimization of organ matching and usage, and vastly improves stakeholder accountability, patient access, equity and outcomes.

Afflo's cloud-native architecture and modular implementation is production hardened and ready to be configured to meet the needs of HRSA/OPTN, OPOs, transplant hospitals, labs, and reporting entities. Our platform improves speed and accuracy in organ procurement, matching and allocation processes through better decision support, which directly addresses HRSA's priority of saving more lives and reducing organ discards. This includes a rapid, low-code policy builder for matching and offers, using allele-level HLA data, donor and recipient management, and automated workflows.

Afflo exchanges healthcare and operational data across the transplant ecosystem using our built in integration platform allowing us to connect with any custom legacy, internal, or third-party system. System stakeholders can monitor, maintain and manage the interfaces, own and control their data, and integrate to the transplant world with less risk, and without the need for complex IT expertise.

Should you have any questions regarding the Afflo product, please do not hesitate to contact me by phone or email.

Sincerely,

Joseph Siahou

Josph Jalon

CEO



Enterprise Transplant Management Platform

Notice ID: RFI HHS/HRSA/OAMP 541611

Initiative: Organ Procurement and Transplantation Network

(b) (4)

(OPTN)

Deadline: 1 p.m. EST, May 23, 2022

Toronto ON, Canada

Contact: Joseph Siahou

Title: CEO

Vendor:

Phone: (b) (4)

E-mail: jsiahou@afflo.io

Overview

Incremental and piecemeal changes to the US transplant system only serve to prolong the challenges facing OPTN and the current IT system may not be adequately supporting the goals of the organ transplantation system. Afflo represents a significant leap forward, driving both technological and process advancements across the entire organ transplant ecosystem by integrating OPOs, waitlisted recipients and transplant centers, minimizing waste and adverse effects, optimizing organ matching and usage, and vastly improving stakeholder accountability, patient access, equity, utility and outcomes.

Afflo (www.afflo.io) is the market's only commercially available organ allocation and end-to-end transplant management platform that is ready for US national-scale deployment. Designed in conjunction with some of North America's leading clinical transplant experts, Afflo is a cloud-native system with a flexible Matching and Offer Engine and Afflo Interoperability Framework (AIF) to connect stakeholders, accelerate the transplant process, and improve patient and system outcomes. (b) (4)

The platform is a complete transplant solution that includes donor management, waitlist management, matching/allocation and offer, local exclusion rule builder, as well as easy to manage tools to track and measure end-to-end performance. Our system empowers clinical business users—not just IT experts—to maintain, test, and update matching algorithms, as well as manage granular business rules like hospital and patient-level acceptance criteria.

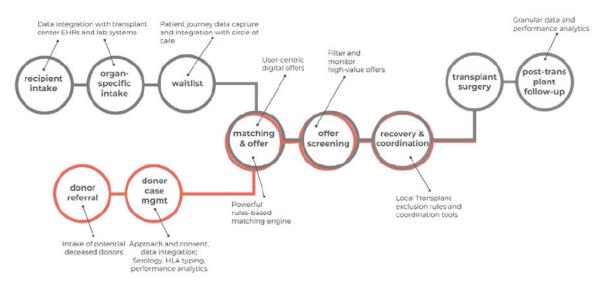


Figure 1 - Functional View of Afflo

Afflo Insights Workbench allows for reruns of matches to simulate how existing and new rules affected historical allocations results, allowing researchers, policy-makers and clinicians to understand from past practice how to best update the policies of tomorrow. This is a key



accelerator to achieve goals of greater equity and transparency with minimal operational disruption by understanding the policy and clinical decisions which have led to inequities in the transplant lifecycle.

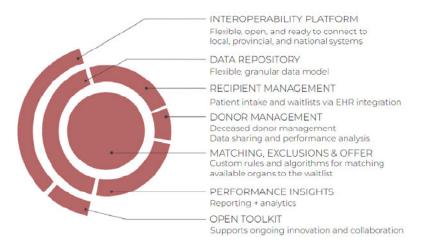
Importantly, Afflo represents a significant advancement in and support of ongoing transplant management innovation. The platform solves fundamental OPTN system challenges by dramatically reducing the long cycles to update, test, and measure matching algorithm changes, as well as creating timely and secure data access across transplant system players. This increases operational transparency, standardizes processes, and drives better decision-making and improved outcomes.

The Afflo solution was designed with to achieve the following key transplant system objectives:

Low-Risk Implementation: While transitioning a sensitive and complex enterprise system has inherent risks, Afflo is a robust and production-ready COTS (Custom-Off-the-Shelf) system for HRSA/OPTN, US OPOs, transplant hospitals, labs, and reporting entities. Initial implementation and on-going improvement would largely be configuration-based, slashing the time to go-live and dramatically reducing risks normally associated with a custom IT development effort. Afflo's innovative and modern architecture supports continuous operations post go-live and is designed to ensure seamless transition without functional downtime. (b) (4)

Efficient, Accurate and Easily Managed Matching/Allocation: Afflo improves speed-to-right-offer, and accuracy in organ procurement and allocation through a sophisticated matching and offer process and flexible workflow tools. This includes a rapid, low/no-code algorithm builder, Insights Workbench, to facilitate change of policy, our Matching and Offer Engine with virtual

crossmatch using
high-resolution allele-level
HLA data, and waitlist
management with
automated workflows.
Matching rules can be
modified quickly to
address changing policies
and science. In addition,
the Afflo Insights
Workbench manages the
local exclusion rules of the
transplant center, which
means exclusions are



automated and organs find the right recipient quickly, reducing the analysis times and phone calls during the offer process. Patient acceptance criteria are also captured in a standardized way. Afflo Insights Workbench masks sensitive data to simulate and test algorithms nationally as well



as local exclusions. This accelerates analysis of the factors that contribute to matches and improves organ/recipient allocation processes.

Continuous Distribution and Discrete Categorization Ranking Algorithms: Afflo supports discrete categorization and continuous distribution/scoring algorithms for ranking of matched recipients. By enabling mixing and matching of both types of ranking algorithms, Afflo facilitates incremental adoption of OPTN's new continuous distribution points-based approach to deceased donor organ allocation and ranking of recipients. As OPTN continuous distribution policies are ratified on an organ-by-organ basis, Afflo's Insights Workbench enables rapid creation of ranking rules to encode the new policies, while allowing other organs to still use the older discrete category rankings. For example, lung continuous distribution policies are expected to be ratified summer of 2022, and could be implemented in Afflo immediately, while other organs such as heart, kidney, etc. would continue to use the legacy discrete category ranking approach until their policies were ratified. Afflo's support of both types of ranking algorithms simplifies the allocation and ranking of clustered organs (eg. Heart/Lung recipients) during the planned multi-year transition to the new continuous distribution policies.

Secure Integration: Afflo Interoperability Framework allows users across the transplant ecosystem to securely access and exchange healthcare and operational data in real time. AIF means Afflo can integrate with any custom legacy, internal, or third-party system. Ordinary business users, not IT, can monitor, maintain and manage their data through secure integrations. AIF goes beyond APIs and enables the management of many interdependent connections through isolation and loose coupling of the integration points.

Transparency and Equity: Improving transparency across the transplant continuum, from patients to programs, increasing access, and driving equity are not an afterthought in Afflo but already built into our system. Afflo captures end-to-end, standardized transplant data at a highly granular level across the transplant ecosystem, allowing for unparalleled access, sharing, analysis, and reporting both for privileged users and the public. Stakeholders can use self-service reporting and advanced analytics including real-time insights. Afflo's Matching and Offer Engine simplifies rules configuration. visually represents the rules used and what data informed those rules, and allows for traceability between decisions and outcomes, thereby improving transparency, reporting, and measurement of equity and access implementations against objectives. Afflo Impact Workbench is an accelerator that allows users to see how past and updated rules—both at the level of national policies and individual transplant centers—affect allocations. Detailed demographic information can be captured and integrated in a frictionless way using Afflo Data Capture without administrative and operational burden.

Increased Accountability: Accountability starts with a clear view of not only who is prioritized in the matching and offer process, but also who is waiting the longest, what organs are discarded and why, and why organs are rejected when offered. More data is possible with less burden through integration. Afflo exposes this data and traces these decisions to streamline analysis of the right data, not just the easily available data. By improving efficiency and standardizing processes while also accounting for local rules and differences, Afflo frees up transplant OPOs and transplant centers to implement benchmarking, quality, accountability, and reporting initiatives.



A.OPTN TECHNOLOGY - IT SYSTEM

A.1 Modern IT Architecture

(a) Managing, Tracking and Operationalizing the Organ Lifecycle + IT development and maintenance approach

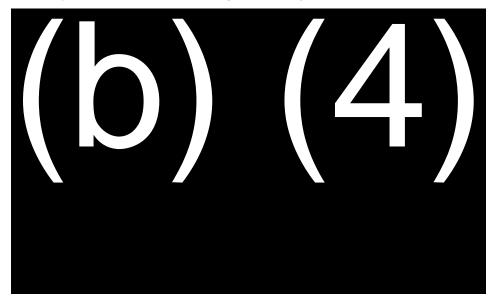
Describe how you would/a vendor would implement and utilize modern IT architecture to manage, track, and operationalize the OPTN organ donation, procurement, allocation and transplant system, such as by adopting a "cloud-native," agile, and modular approach to IT development and maintenance.

Afflo is a complete transplant solution that manages, tracks and operationalizes the entire organ transplant lifecycle. Components include donor and waitlist management, our Matching and Offer Engine using algorithms to generate allocation recommendations, local exclusion rule builder, and easy-to-manage tools to track and measure end-to-end performance. Afflo represents a significant advancement in support of ongoing transplant management innovation, resolving many of the fundamental OPTN system challenges by dramatically reducing the long cycles to update, test, and measure matching algorithm changes, and giving transplant system players timely and secure access to data.

Our cloud-native, scalable architecture is designed to far exceed the US's transaction volume. Afflo platform modules include an HL7 FHIR compliant Integration Framework with full lifecycle API governance, as well as a data repository, Recipient and Donor Management modules, Matching and Offer Engine, and Performance Insights. Afflo's modular, microservices design means clients can adopt relevant modules. Cross-functional working groups and collaboratives can also adopt configurable relevant instances quickly and easily for pilots or special projects such as quality improvement and equity and access initiatives. These modules can be hosted separately from the core solution, providing additional scale and hosting flexibility.

How We Manage, Track and Operationalize the Organ Lifecycle

Afflo operationalizes organ donation, procurement, and allocation through an integrated operating model across the transplant ecosystem- from policy-driven matching organizations to OPOs to transplant centers, labs, and reporting entities—through a role-based system that is mapped to and mirrors the clinical process, mobilizing information that is entered and updated and shared in real-time. Recognizing that



inconsistent and incomplete data, alongside manual data entry, all create risk, Afflo uses a <u>flexible model</u> for integration. Existing information from legacy systems can be ingested through

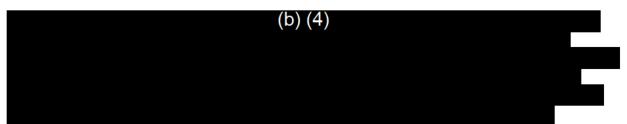


the Afflo Integration Framework and prebuilt HL7/FHIR message definitions to pull data from EMRs, lab information systems, legacy donor or transplant software, or any reporting entity. This centers the patient in addition to streamlining operations, as all relevant data from previous clinical encounters can be captured. With APIs, orchestration, messages, and events, Afflo moves beyond integration to true interoperability so transplant users not only share data but build best-in-kind data-driven workflows, policies, and decision-making across the transplant continuum. Integration makes it easier to manage the recipient waitlist by ingesting referral data, alerting care providers if lab values expire or patient information is out of date, and integrating directly with labs.

Afflo slashes cycle times to update algorithms, matching and offer processes through our low-code rules builder and matching and offer engine developed with leading North American transplant experts. With highly granular allele-level data, our virtual crossmatch eliminates unnecessary physical crossmatches and associated increased cold ischemia times, wait times, and graft survival. Within the Canadian system previously, allocation recommendations only considered virtual crossmatch at the antigen level, with allele-level cross-matching performed manually, resulting in a 25-90 minute manual workaround per recipient; Afflo's virtual crossmatch is able to complete this allele-level analysis in seconds.

How We Built It: IT Development and Maintenance

Afflo is cloud-native not just cloud-hosted, which means it was constructed in the cloud with elasticity, scaling, and operational optimization baked-in. Afflo operates as a collection of connected and secure services. Each secure service can operate virtually independently from all other services. Since no system service is dependent on any other, we can create unparalleled reliability to meet HRSA's high availability needs. Further, as dictated by needs, requirements, or network innovations, we can independently apply system updates to individual services while maintaining overall system functionality. Furthermore, services are also highly modular internally, using flexible techniques such as versioned functions, feature switches and data-driven configuration to reduce the time and cost of customization, testing, maintenance and/or enhancement.



is achieved through Afflo's embedded system level redundancy and streamlined disaster recovery processes. This means that individual services, beyond operating mostly independently, are designed with upgradability and flexible deployment across a heterogeneous hosting landscape. Services are containerized using industry standard technology and independent from vendor-specific lock-in. The platform can be deployed in private or public clouds, including standing multiple cloud providers for singular implementation. As updates are required, individual service containers can be shut down, refreshed, and reintegrated without disrupting operations. All data storage is granular and real-time without schema constraints or limitations.





(b) APIs and Enhanced Data Sharing

Describe how you would/a vendor would implement and utilize modern IT architecture to prioritize the use of publicly accessible application programming interfaces (APIs) to enhance data sharing and integration with the electronic health records (EHRs) and other tools used by OPTN members and patients.

Industry-standard APIs are essential for critical, system-wide innovation. Afflo's open and accessible APIs deliver interoperability and enhanced data sharing that is built into the fabric of the solution. The platform fully integrates with EHRs/EMRs and lab systems, exposing and ingesting APIs through Afflo's Integration Framework (AIF). AIF's API management layer enables decoupling APIs from internal implementation and allows for backwards compatibility of all message formats.

Afflo is designed to ingest data from multiple data formats including APIs, UI-driven file and form data capture, direct database exports, HL7 v2 and FHIR standards-based formats, web services, flat files, legacy forms and imaging, PDFs, and even printed materials through Afflo Data Capture. This is enabled by our transplant-specific data model that interacts with, identifies and validates critical data from external sources and loads it into Afflo's core system. Afflo is able to manage, interpret and correct for inconsistent data sources and formats, which typically require significant investment from clinical and operational staff. Afflo's ingestion capabilities reduce manual data entry and data duplication, thereby increasing data integrity and reducing data error, while also identifying opportunities for capture of additional data points that may be valuable but too laborious for manual capture. Afflo is also capable of delivering outgoing data via multiple methods by accommodating various portals, technical APIs and reporting interfaces to enable custom analytics.

The API Management layer connects to back-end services built and running on any technology stack and eliminates the need for the API redevelopment from scratch. These capabilities are essential for large, complex, heterogeneous integration scenarios like those of HRSA/OPTN, with disparate entities and stakeholders, especially as the integration landscape evolves and new organizations, technologies and services emerge while legacy on-premises systems still exist. With our model, customers are not locked into any proprietary APIs, and can instead manage them independently if desired.

(c) Enhanced User Interfaces

Describe how you would/a vendor would implement and utilize modern IT architecture to enhance user interfaces to improve the ability of the OPTN IT system to conduct enhanced real-time tracking of donated organs, allocate organs more efficiently and support increased transplant center engagement with patients in organ acceptance decisions.

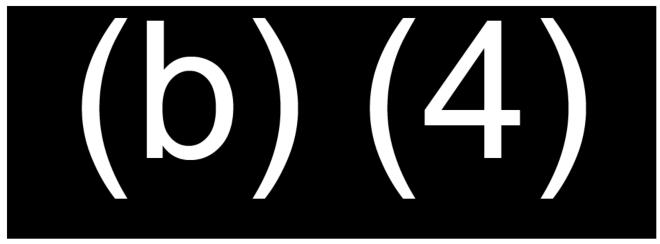
Afflo's contains flexible user interfaces and real-time dashboard to monitor available donor organs, organ matching and allocation, and patient engagement in organ acceptance decisions at the transplant center level. User interfaces can be configured to align with the needs of multiple

stakeholders permissions, including clinicians, OPOs, Transplant Centers and patients. Afflo's user interface pages present chronological, filterable and sortable views of significant events to better manage all aspects of the transplant lifecycle.

(d) Dashboards and Actionable Data

Describe how you would/a vendor would implement and utilize modern IT architecture to produce public performance dashboards and actionable data to identify opportunities for program improvement, reduce inequities, and benchmark OPTN member performance.

Afflo provides customizable, anonymized dashboards that let stakeholders (OPTN, OPOs and Transplant Centers) as well as research and special interest groups track the specific metrics that they care about the most, delivering actionable data to identify opportunities for system-wide and program improvements, benchmarking for key performance indicators, and identifying areas for intervention to reduce inequities in accessibility and outcomes.



Open Data: Publishing and extracting data in an open format is built into Afflo's architecture, facilitating a significant upgrade in HRSA's capacity to deliver on administration priorities of equity and open data. Afflo can be configured to include a cloud-based data warehouse specific to supporting open data queries. The AIF interoperability platform makes it easy to define new APIs that expose data using appropriate data standards. This also ensures that the data shared conforms to legal confidentiality requirements in order to protect personally identifiable and personal health information, as well as other legally or commercially sensitive data.

They use masked data and removal of PHI-related data fields, support common data standards such as HL7 (v2, v3, FIHR,) using JSON, XML, or custom formats.

(e) Saving Time, Minimizing Errors and Improving Patient Outcomes

Describe how you would/a vendor would implement and utilize modern IT architecture to maximize these and other tools to save critical time in the organ allocation process, minimize errors, and improve patient outcomes.

Afflo represents a significant advancement in the support and ongoing innovation of transplant management by solving for the long cycles to update, test, and measure the impact of matching algorithms and enabling system-wide interoperability to ensure that transplant decision makers and patients have accurate, real-time data to inform decisions. Because users across the

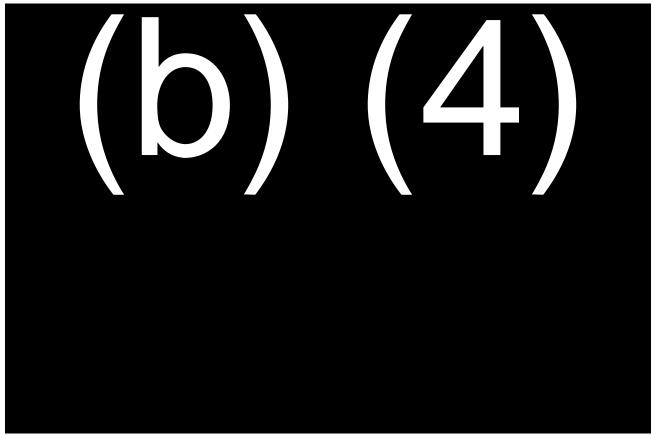


transplant ecosystem are provided with updated policies, and the right data at the right time, better matches, offers, and decisions are made to reduce unnecessary discards and improve transplant outcomes. One additional way Afflo improves speed-to-right-offer through better matches is by including local transplant center exclusion information so decisions around organ offer acceptance (whether an organ is accepted or declined by a Transplant Center) occur as expeditiously as possible, facilitating exponentially faster organ acceptance, reducing organ discards. To this end, Afflo has incorporated one third of the US's local transplant exclusion policies.

Afflo's rapid, low-code algorithm builder enables easy change of policy, with a matching and offer engine that uses allele-level HLA data, and waitlist management with automated workflows. Matching rules can be modified through a low-code workbench to quickly meet the speed of policy and science. Further, our workbench tool masks data and is used to simulate and test algorithm changes using program-specific conditions and exclusions to understand the factors that contribute to matches and continuously improve organ/recipient allocation processes.

A.2 Uptime

The current contract requires system availability uptime of 99.5%. HRSA is planning to target a 99.999% uptime for this life-saving OPTN IT system. Is 99.999% uptime reasonable and achievable? If not, what is an appropriate uptime standard for an IT system of this importance?



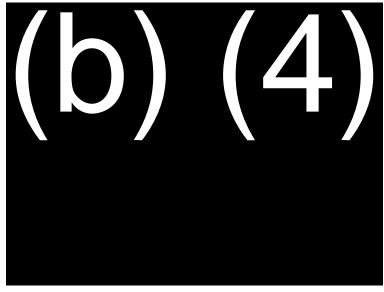
A.3 Data Collection

How can the OPTN ensure data collection is relevant, accurate, timely and streamlined in order to improve organ allocation processes?



Afflo is designed to be the system of record for all things transplant. It captures, mobilizes and retains data from all the phases of the organ transplant lifecycle through integration, ingestion, and intuitive workflows, from donors and OPOs, to referred patients, waitlisted patients and their preoperative health states, as well as transplant centers and their exclusion rules and post-operative outcomes.

Data integrity and accuracy are built into the data layer of the Afflo system as well as field-level validation in the screens and functionality. Streamlined processes are achieved by integration as well as by the systems' sophisticated authorization and user permissioning (hospital patient coordinators and physicians, HLA and serology laboratories, organ procurement organizations and reporting entities). To ensure the integrity and accuracy of entered data, validation and data integrity constraints are enforced at multiple levels within the architecture and the User Interface (UI). Afflo



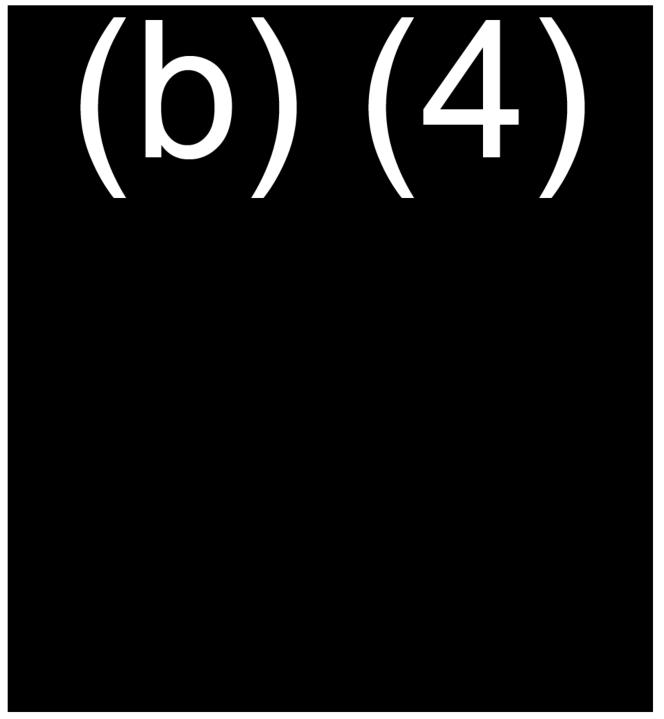
architecture applies a further level of data integrity confirmation to guarantee business-level data consistency. Afflo uses a common validation framework across the UI and API/Microservices tiers to ensure consistency. Finally, stringent data integrity guarantees are provided by the underlying database engine.

For those customers who elect not to use Afflo's Donor and/or Recipient Waitlist modules and wish to maintain their data in third-party applications, Afflo's Integration Framework (AIF) provides a powerful integration solution based on industry healthcare standards and has out-of-the-box parsers for both HL7 as well as FHIR. This enables our solution to standardize data collection and dissemination for all transplant partners and point-of-care organizations who use third party Donor or Waitlist Management systems.

Regardless of the volume of data provided, frequency of submission, and technical capability, this standardization is critical to robust data governance by minimizing data redundancy as well as optimizing accuracy and timeliness. The challenge of different variations in the same message standard, and differences in the message standard entirely (e.g. HL7 v2.x vs FHIR), is overcome by having an integration engine that can transform messages from one standard to another in a centralized location where minimal work at most is required on the endpoint systems. Complex logic can be created, modified, transformed, and workflows can be handled in the integration platform to minimize any potential negative impacts on the pre-existing systems. Additionally, HRSA and OPTN will only need to maintain one system for any changes that need to be made, instead of involving multiple systems, environments, and organizations that request the upstream or downstream system when change is required.

A.4 Protection Against Emerging IT Security Threats

How would you/a vendor ensure ongoing security enhancements to protect against emerging and evolving eats?

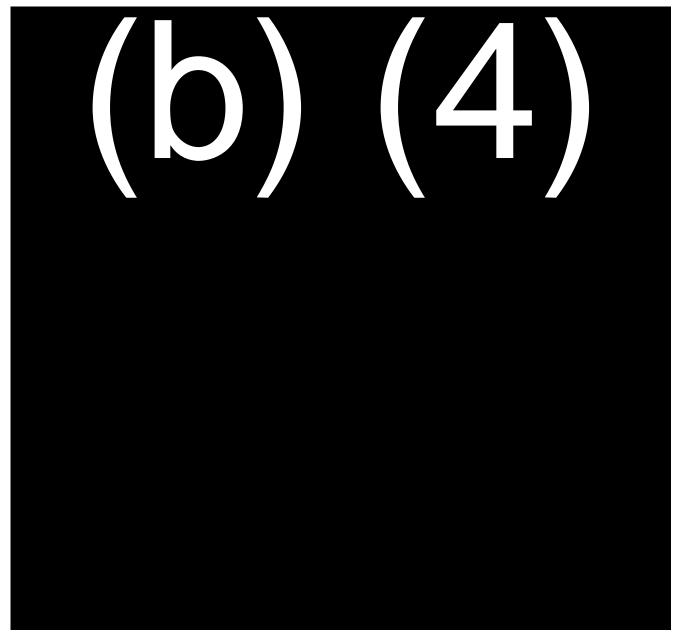


A.5 Industry Best Practices for IT Security

How would you/a vendor ensure adherence to the latest industry best practices for IT security infrastructure, practices, and standards?

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B. DATA COLLECTION ACTIVITIES

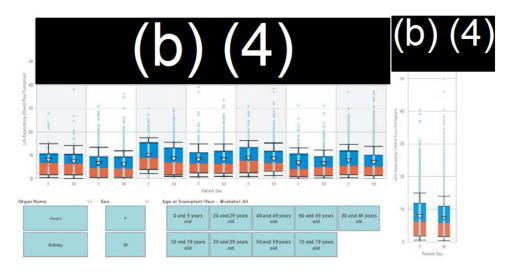
B.1 Performance Metrics and Benchmarks

Describe how you would/how vendors could develop performance metrics and benchmarks for the organ donation, procurement, allocation and transplant system, including through expert consultation, subcontracting, and engagement with transplant candidates, transplant recipients, organ donors and their families about the metrics they value.

Performance metrics and benchmarking are often policy-driven and can be divorced from operational realities, creating a disconnect between clinicians and regulatory entities. As noted in the NASEM report, performance metrics are often output rather than outcome based, which can disincentivize meaningful improvement. Operational impacts are often misunderstood and clinical judgment in edge-cases undervalued. A short-term approach (e.g., 1-year graft survival vs long-term survival) is often preferred.



With these challenges in mind, Afflo was designed to incorporate success factors for better quality indicators. These success factors include a wide variety of granular, loosely coupled data sources, data standards and vocabulary management, easy of use and automated collection, the largest possible data set and



high adoption, as well as AI/Machine Learning modeling.

With a granular data model that captures the end-to-end transplant process, cloud-based data warehouse, integration, and quality data, as well as predictive analytics, Afflo can be mobilized to develop in-depth performance metrics and benchmarks for the entire organ donation, procurement, allocation and transplant system. Researchers, oversight committees, and funders are empowered to move beyond standard quality metrics to measure more meaningful data for patients, including long-term survival, unplanned return to operating room, patient survival, efficient referral, evaluation, and listing processes, readmission within 30 days of discharge, and more.

Because Afflo presents a low administrative burden and high usability it allows researchers and stakeholders to access the valuable metrics they need to drive impactful decisions that increase organ usage and improve patient outcomes. Afflo reduces the burden of data collection through automated data capture methods and a data model that captures the complete transplant life cycle, Afflo Data Capture for additional demographic insights. Afflo Performance Insights allow for real-time queries of large transplant data sets, with a data repository that is driven by a bespoke, schema-driven data model. It enables data quality and effective management, field-level validation, PHI support and data dictionary management. It allows for performance insights through user-defined views and queries to run analytics system performance, and real-time data exploration of outcome factors, and high value insights via AI/machine learning.

Afflo's integration with EMRs/EHRs, transplant modules, laboratory systems, national registries and OPOs results in the largest possible data set with undue burden on clinicians and administrators, which provides opportunities for in-depth and targeted analysis. Afflo's automated data collection, integration, and reporting capabilities also reduce the burden on governing entities like HRSA and OPTN and enable focus on data governance and standardization.

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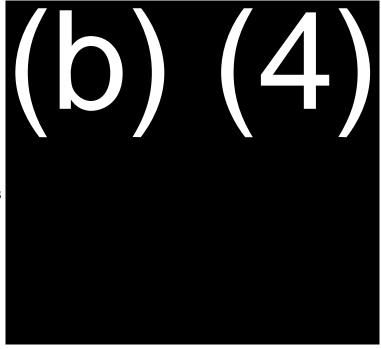


(b) (4)

Afflo is uniquely structured around significant events or changes in conditions of donor organs and recipients. Significant events are defined by changes to key data elements, case management status, and process steps. Significant events can be used to trigger notifications through various delivery mechanisms if desired (eg. email, SMS, pager, REST/HTTPS, dashboard notification, etc.) when key information or status changes. Afflo keeps a history of how data has changed over time, enabling historical review, understanding of decisions at any point in time, and the opportunity to improve system quality in the future. The Afflo solution also uses significant events as key data points internally to manage process flow and provide user interface pages that

present a chronological, filterable, sortable view of significant events to better manage the transplant lifecycle.

Currently, the organ match and offer system is dictated by broad, national-level policies. OPOs are typically more attuned to waitlist and regional knowledge around patient demographics and equity, along with transplant hospitals, who bring their own specific operational considerations and constraints. At the patient matching level, they may have specific exclusion criteria and varying risk thresholds (e.g., a patient may be more or less willing to accept a non-standard organ). Afflo facilitates improved performance metrics and benchmarks in all the above mentioned areas



because all the various rules, preferences and processes can be captured and configured in our matching and offer algorithms and analytics. This results in more empowered transplant clinicians and surgeons, and more appropriate and comprehensive system oversight. Barriers to or risks of accepting an organ, including among specific demographics, can be documented and become actionable data. New algorithms can be co-created and tested faster and more frequently.

Afflo enables appropriate oversight and an equity lens that also continues to be operationally aware and metric centric. Data integration and interoperability mean fewer data silos, decreased burdens in reporting and data collection, and more capacity for impactful oversight of regional variances and equity issues, analysis, and new policy and algorithm development. Accurate, complete and system-wide metrics will further support the development of strong data governance standards.



B.2 Data Collection and Reporting Mechanisms

(a) Reporting OPTN Performance Metrics

Describe how you would/how vendors could structure data collection and reporting mechanisms for the system to report OPTN performance metrics including process, outcome, and patient engagement measures.

Our platform starts with this end in mind. We have created data collection and reporting mechanisms that are enabled through the Afflo Performance Insights module by default. Performance Insights includes self-service reporting, advanced analytics, and data warehousing to assess and improve organ procurement, allocation, and transplant processes and outcomes, as well as patient engagement measures— all out of the box. From patient intake and donor organ referrals to transplant system performance and post-transplant patient surveys, Afflo supports programmatically ingesting clinical and non-clinical data for analytics. Importantly, the platform can easily make this data available to third-party applications to enable broader and more transparent reporting, all while keeping the data secure through the "secure by default" principle that supports the entire solution.

Highly granular data points support extensive and customizable reporting, auditing, and traceability coverage to make compliance easier and system oversight more manageable. In addition to Afflo Performance Insights, Afflo data warehouses come with out-of-the-box integrations to common BI/Analytics tools such as PowerBI, Tableau and others. Afflo is delivered with an extensive inventory of both operational and informatics queries, views and reports to support typical donor/recipient/transplant requirements.

(b) Establishing OPTN Member Performance Benchmarks

Describe how you would/how vendors could structure data collection and reporting mechanisms for the system to establish OPTN member performance benchmarks.

Afflo facilitates performance benchmarking for OPTN members by lowering the burden on data submitters. It does this by automating data collection through interfaces that ingest and push data, as well as ensuring standardization, and supporting dissemination to all data partners, regardless of the volume of data provided, frequency of submission and technical capability.

Data can be accessing out-of-the-box reporting capabilities that query across the varying operational layers within the OPTN, from initial EMR data and patient referral, to patient consultation, preoperative patient health state, donors and OPO activities, all the way to postoperative follow up care. Because Afflo offers a complete, system-wide view in a single solution, all performance factors within the OPTN can be exposed and considered in the process of developing appropriate, low-burden, high-quality performance benchmarks and quality indicators. Finally, data can be securely packaged and delivered to enable outside research and analytics (eg. SRTR) that can further leverage advanced analytics techniques like machine learning.

Data that is captured in legacy systems or other data sources can be ingested through Afflo Data Capture, standard transfer protocols, messaging interfaces for managing data transfer, and stream-based services clients. Recognizing that the use of data standards alone does not guarantee standardization, Afflo's Integration Framework can transform messages from one standard to another with no work required on the endpoint systems.



Within participating and authorized institutions, Afflo offers extensive self-service reporting as well as customizable operational reporting for diverse end-users, including advanced analytics for data analysts and research teams. Afflo's innovative, metadata-based approach to the operational database and data warehouses simplifies and accelerates custom business intelligence and analytics. This access to actionable data is particularly important in addressing the significant variations in performance among donor hospitals, OPOs and transplant centers that are noted in the NASEM report. These real-time insights can assist in developing policy interventions to incentivize desired performance improvement. Further, the data can be used to create real-time national, regional and local performance dashboards (see (d) below) to monitor system performance and drive policy decisions.

(c) Capturing Patient and Donor Demographics

Describe how you would/how vendors could structure data collection and reporting mechanisms for the system to capture patient and donor demographics, including race, ethnicity, language, and socioeconomic factors.

Afflo is already purpose-built to capture and manage data related to transplant, including donor and patient race and ethnicity. Afflo's Data Capture module enables our clients to construct no-code, customized data capture applications for any additional demographic data that directly integrate into Afflo's core product. Any captured data can also be integrated into any other third party data source and use customized workflow and business rules to process captured data in the way that is appropriate for customer needs, including more granular demographic parameters for donors and recipients. Customizable dashboards would then let user groups like diversity, equity and inclusion working groups specify the metrics and reporting relevant to crafting policies and incentives that encourage diversity and equity.

Afflo Data Capture provides two capture methods: web-based form capture or machine-learning based image processing. Web-based forms are created using our machine learning-based automated conversion feature that translates PDF forms, Microsoft Office files, or images. Alternatively, customers can use our form designer for easy-to-use drag-and-drop form creation. In both cases, the resulting forms benefit from our business rules engine and workflow. Embedded business rules in PDF or Office documents are automatically converted and applied; they can be adjusted in our business rules toolbox. For image-based forms, our algorithm interprets typical field-level settings (such as dates, phone numbers, and addresses) and applies the appropriate field types.

Our alternate data capture capability uses machine learning to process scanned paper documents or PDF files. Our algorithm automatically recognizes data within the document and extracts it, based on tags defined by the customer. These tags act like fields in our web-based forms, enabling business rules and workflow to be applied to extracted data.

In all cases, captured data can be connected to any other system using our data integration engine. Our engine allows customers to define data sources and mapping. These data sources allow for bi-directional data exchange with Afflo's Data Capture module. Using Afflo Data Capture and by connecting to multiple data sources, HRSA could easily capture required transplant data, while also gathering key population data. This additional population data could be directed, in whole or part, to Afflo or other appropriate systems for later analysis.



(d) Creating Public OPTN National, Regional and Local Performance Dashboards

Describe how you would/how vendors could structure data collection and reporting mechanisms for the system to create public OPTN national, regional and local performance dashboards.

Afflo provides out-of-the-box dashboards that are entirely customizable to track specific metrics at the national, regional and local levels, delivering specific, actionable data to identify opportunities for system-wide and local program improvements. Using geo-coded sources, Afflo integrates data from across the transplant lifecycle to provide users and system stakeholders with powerful, interactive visualizations and insights showing differences among regional programs and their outcomes, including rates of organ allocation and transplant, and patient outcomes.

Self-service query tools mean that business stakeholders can define and perform these analytics. Transparency is further supported through publishing and extracting data to support open data queries.

(e) Tracking Long-Term Patient Outcomes

Describe how you would/how vendors could structure data collection and reporting mechanisms for the system to track long-term patient outcomes and health and non-health-related factors that contribute to outcomes.

Afflo collects and retains data from all phases of the organ transplant lifecycle, including patient intake data that can incorporate key demographic details, pre-operative health state while waitlisted and post-operative outcomes. This patient data input from the entirety of their organ transplant journey can be incorporated into longer-term patient follow-up reporting to analyze and understand the myriad factors that contribute to both positive and negative outcomes. The large data sets generated by Afflo's integration with EMRs, laboratory systems, waitlist registries and additional demographic data ingestion capabilities driven by Afflo Data Capture provides insights into factors that drive successful and unsuccessful transplants. Afflo Data Capture can also assist in capturing data from systems that are not directly integrated. This could mean automatically processing PDF reports from transplant hospitals, integrating third-party health data from consumer services (e.g. FitBit, Apple), or clinical telemetry devices. All this additional data can be immediately incorporated and made available through Afflo's Analytics module. As a result, Afflo dramatically reduces data acquisition, capture, and ingestion burdens, providing health trend and pattern discovery far beyond what's currently possible and, importantly, connecting inputs to outcomes without the attendant administrative burdens.

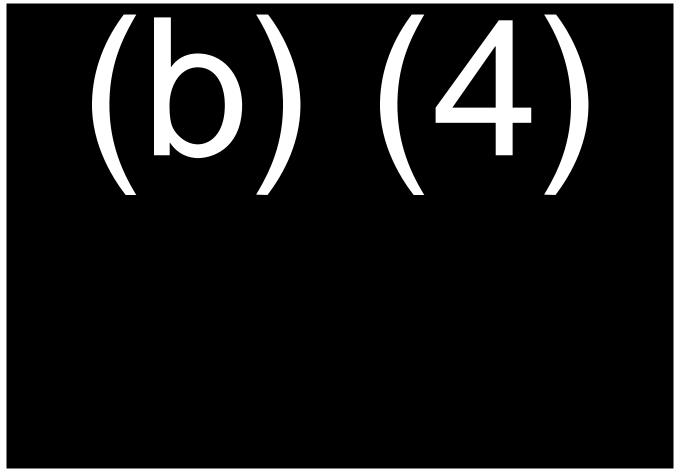
C. OPTN FINANCES

C.1 Fees

Describe how you would/vendors could ensure that any fees, beyond OPTN registration fees, charged to transplant centers or others:

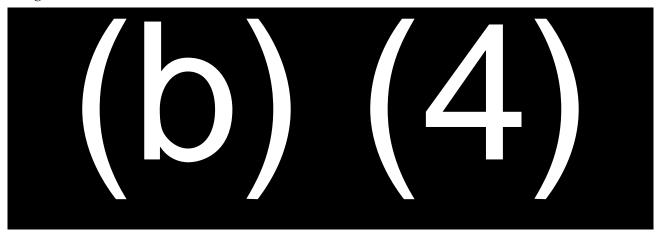
- a. Do not duplicate Medicare payment or result in unnecessary additional Medicare reimbursement.
- b. Do not charge for functions that are OPTN contract-supported functions.
- c. Are not perceived as mandatory for participation in the OPTN or for receiving core OPTN services.
- d. Do not impact, or create a perception of impact, status in or allocations through the *OPTN*.





C.2 Requirements and Oversight Mechanisms

What requirements and oversight mechanisms could be utilized to ensure appropriate federal review of the OPTN registration fee, any additional contractor fees, and the development of the overall OPTN budget?



D. OPTN GOVERNANCE

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E. INCREASING ORGAN DONATION AND IMPROVING PROCUREMENT

E.1 Policy Requirements for OPOs

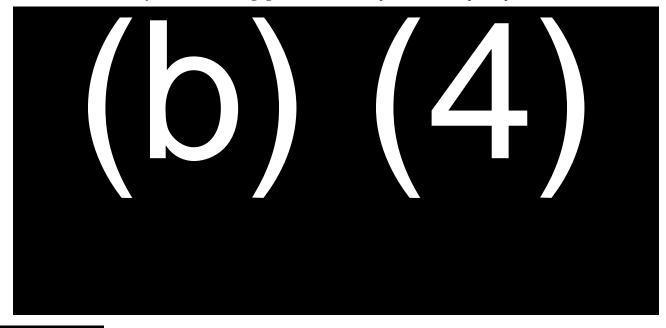
Describe how you would/how vendors could support the OPTN in revising OPTN policy requirements for OPOs to reduce variations in practices and procedures, facilitate increased organ donation and improved procurement, and otherwise improve OPO performance.

OPOs are foundational to the organ transplant lifecycle. They perform critical and essential functions including, but not limited to identifying and recovering donor organs, supporting donor families, and liaising with transplant centers to connect with waitlisted recipients. As a result, they need the right facilities that help identify the right operational insights to measure current performance and identify future improvements. Afflo was built to help transparently report current performance and uncover potential inconsistencies and opportunities.

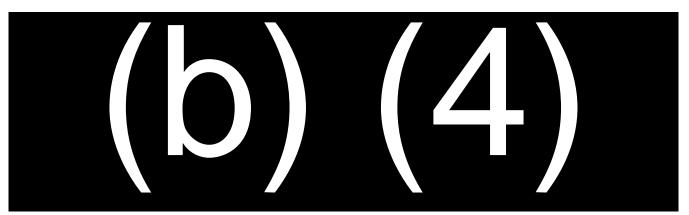
Whether it is OPO organ procurement rates, transplant center deceased donor organ acceptance, or something else, Afflo provides an intelligent data model and unified functional components that drive and inform policy decisions, facilitating improved OPO performance. Rather than functioning as a simple data entry tool like many solutions. Afflo's unique insights, garnered through transparent data outputs, granular auditability and accessible analysis, empower OPOs to actively and effectively measure their performance and work towards improvements - informed by practical, real-time data. Its integrated data-gathering and data-reporting capacity provides invaluable and specific information OPOs need to make informed and targeted interventions in the organ procurement process to improve clinical outcomes. Critically, performance data capture is simply an operational consequence and does not burden OPO or Transplant Center staff.

E.2 OPO Engagement

How could the OPTN facilitate OPO engagement in research protocols to improve procurement?

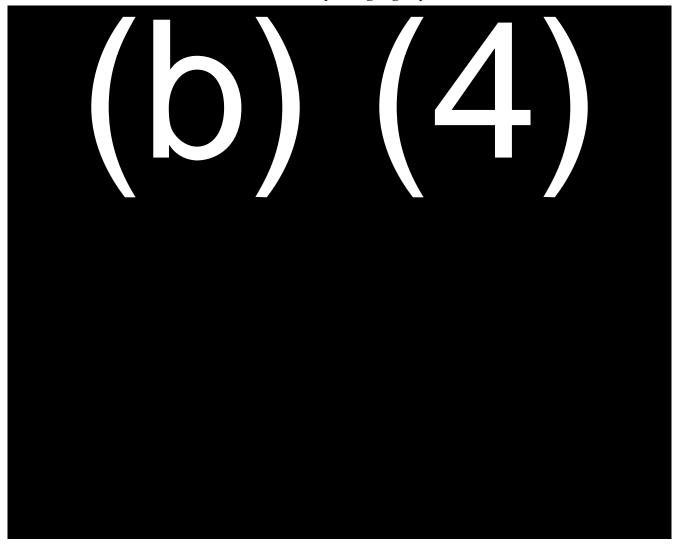






E.3 Research and Improved Organ Procurement

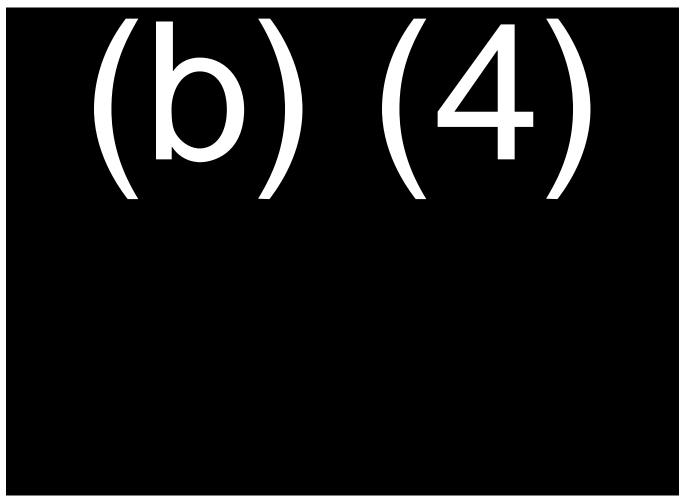
What additional research could contribute to improving organ procurement?



E.4 Increasing Equitable Access

How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?





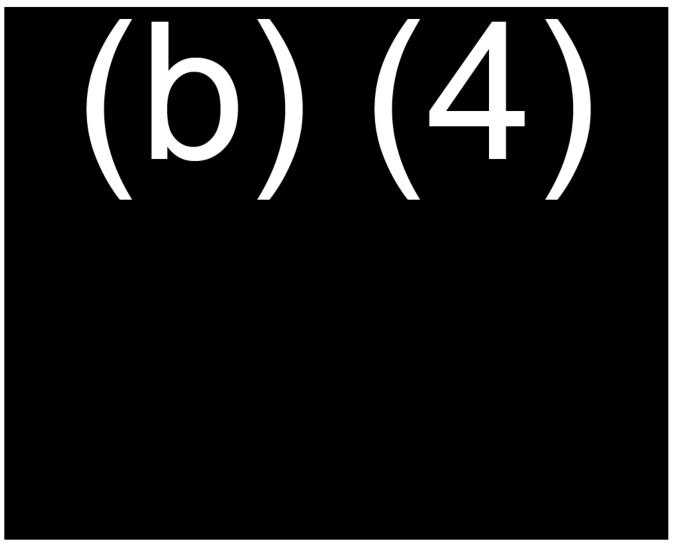
F. ORGAN USAGE

F.1 OPO Performance Improvement

Describe how you would/a vendor could support the OPO performance improvement activities to decrease discarded organs and further increase the use of organs.

Afflo is designed to deliver clear, transparent and data-driven insight into all actions, which can drive OPO performance improvement activities to decrease discarded organs and increase organ use. Afflo provides increased transparency through granular, point-in-time auditability, and promotes innovation and adaptability through modular, configurable API-based processes. Rather than relying on OPOs to self-report on performance metrics, Afflo allows for the extraction of objective, system-generated data that is transparent, accessible and reliable. OPTN can use the accessible data store to effectively measure performance in order to construct, measure, adjust, test, and implement incremental improvements over time without interrupting the life saving work OPOs perform. Starting with Afflo's rules engine, it provides a no/low code facility to create allocation rules targeted to specific organizations. Afflo's flexibility allows for the ability to adjust and calibrate rulesets that reinforce each OPOs strengths and diminish operating inefficiencies given their unique operating contexts. In other words, each of the current 57 OPOs has to adjust their operating model to fit their DSA reality and the OPTN can fine tune rules to match.

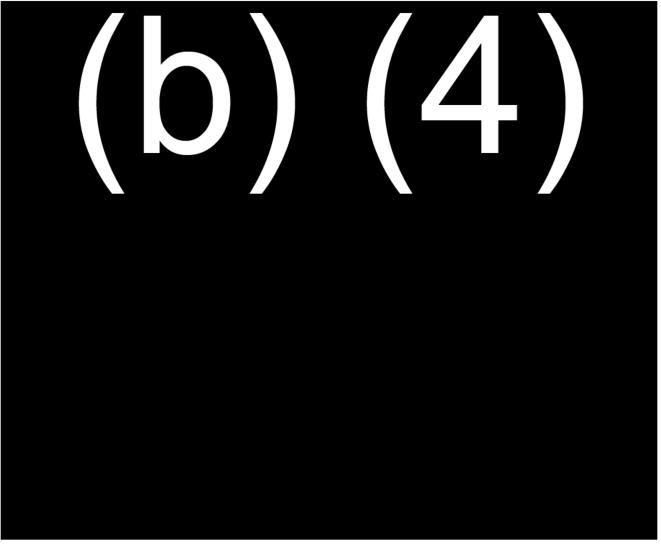




F.2 Decreasing Non-Usage of Procured Organs

How can OPTN organ matching activities be modified to decrease non-usage (discards) of procured organs?





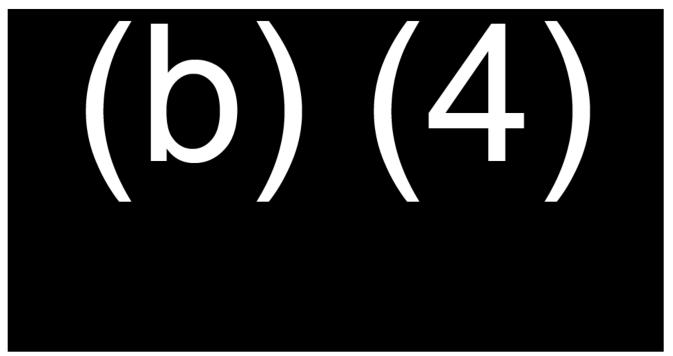
F.3 Improving Transparency

Describe the steps you would/vendors could take to improve transparency around the organ matching and acceptance process for transplant candidates, transplant recipients, other affected patients, organ donors and family members served by the OPTN.

As the NASEM Report outlines, transparency in the organ matching and acceptance process for transplant candidates, recipients, organ donors and family members is a key component to combating current inequities in the organ transplant system. The Afflo solution directly addresses important healthcare concerns like equity and transparency through multiple solution factors. At its core, the platform provides extensive auditing and logging, providing clear line-of-site to all system functions; all transactions are recorded and preserved, and the platform's rules engine allows both easy-to-use rules configuration and clear outcome visibility, eliminating the obscure and vague connection between donors and recipients.

(b) (4)





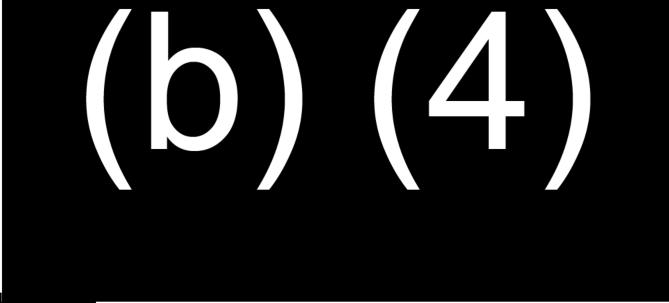
G. OPTN OPERATIONS AND POLICY **DEVELOPMENT IMPROVEMENTS**

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H. STAKEHOLDER ENGAGEMENT

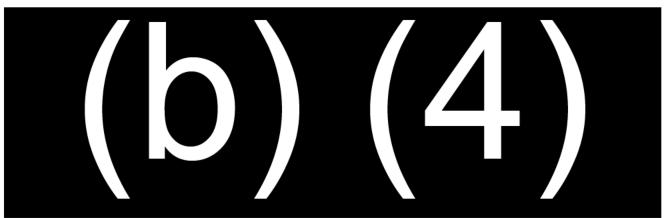
H.1 Improving Stakeholder Engagement

Describe how you would/vendors could support the OPTN incorporating the NASEM report's recommendations on improving their stakeholder engagement efforts and activities, including whether and how to improve patient awareness of all organs they have been offered and by monitoring their changing health and attitudes impacting organ acceptance decisions.



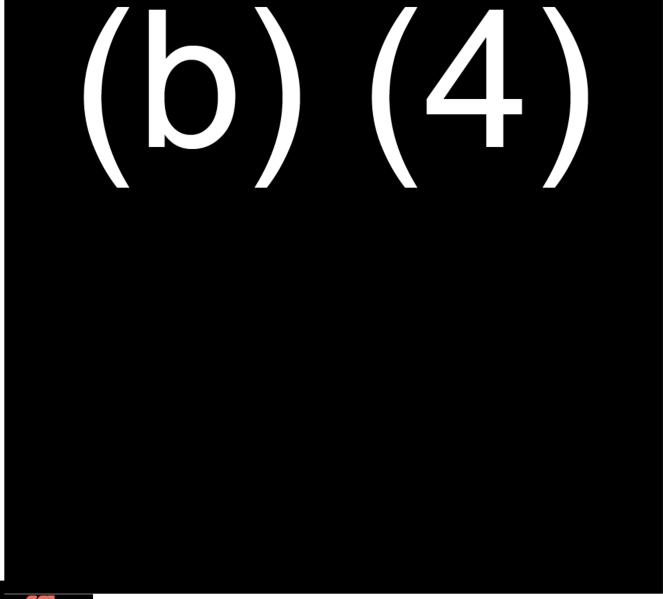
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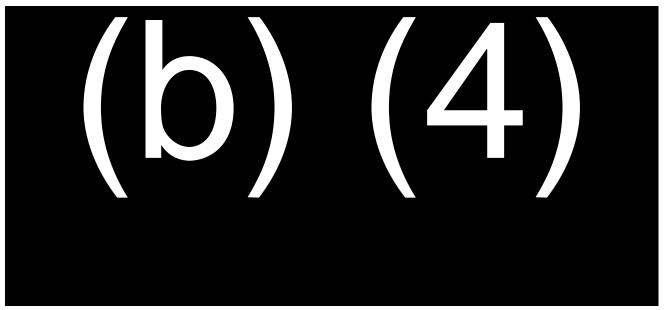




H.2 Improved Stakeholder Engagement Strategies

Describe how you would/vendors could support the OPTN in requiring OPTN members to adopt improved stakeholder engagement strategies that advance equity, access, and transparency.





H.3 Approaches for Including Stakeholders

How can and/or should the contract incorporate new or better approaches for including stakeholders in a shared decision model for organ acceptance?



STATEMENT OF INTENT TO SUPPLY PROPOSAL FOR FUTURE SOLICITATION

Statement of intent to supply a proposal on any future solicitation related to this requirement.

(b) (4) intends to respond to any future solicitation related to the current RFI with Afflo, its Enterprise Transplant Management Solution, (b) (4)





May 23, 2022

Battelle Proposal No. OPP221495

HHS/HRSA/OAMP 5600 Fishers Lane Rockville, MD 20852 E: NInazawa@hrsa.gov

Response to Request for Information (RFI) Titled "Organ Procurement and Transplant Network (OPTN) issued April 8, 2022

Dear HHS/HRSA/OAMP:

Battelle Memorial Institute, through its Corporate Operations (Battelle), is pleased to submit this response to the RFI identified above.

Battelle Memorial Institute 505 King Ave Columbus, Oh 43201-2696

DUNS# 00 790 1598 CAGE Code 79986 Unique Entity ID F125YU6SWK5

Battelle is registered in the System for Award Management (SAM). Further, signature on this Letter shall serve as confirmation that the documents they provided from SAM are true and correct and Battelle is not debarred, suspended, or proposed for debarment by the Federal Government.

Battelle is pleased to provide information on our knowledge and expertise of the market research sections listed in the RFI. Please see the list of responded questions below:

A. OPTN Technology – IT System: A.1.a. – A.1.e.; A.2.; A.3; A.4.; A.5.

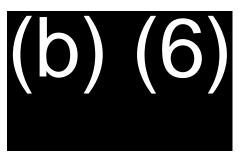
Battelle warrants, to the best of its knowledge and belief, that it does not have any conflicts of interests pertaining to the subject contract as defined in FAR 9.5.

Battelle will be pleased to follow up with a formal proposal and cost estimate in addition to negotiating mutually agreeable contract terms and conditions upon your request for this and any future solicitation related to this requirement.



Please direct questions of a business or contractual nature to the undersigned at or (b) (6) @battelle.org. Technical questions should be directed to (b) (6) at (b) (6) (6) or (b) (6) @battelle.org.

Sincerely,



This Request for Information (RFI) contains proprietary and confidential information of Battelle. This RFI includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed—in whole or in part—for any purpose other than to evaluate this RFI. If, however, a contract is awarded to this offeror as a result of—or in connection with—the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in the sheets marked "Use or disclosure of data contained on this sheet is subject to the restriction on the signature page of this RFI".



Organ Procurement and Transplantation Network (OPTN) Request for Information (RFI)

RFI: Organ Procurement and Transplantation Network (OPTN) (Battelle OPP221495)

May 23, 2022

Submitted to:

Office of Acquisition Management and Policy Health Resources and Services Administration Health and Human Services

Prepared by: Battelle Memorial Institute 505 King Avenue Columbus, Ohio 43201

	Business Point of Contact	Technical Point of Contact
Name:		(b) (C)
Title:		
Phone:		
Email:	(b) (6) <u>@battelle.org</u>	(b) (6) @battelle.org

Organization Information:

Size: Large Business (non-profit)

DUNS: 00-790-1598

Registered in System For Award Management (SAM), Unique Entity ID: F125YU6SWK59

Relevant Federal Supply Schedules and Government-Wide Acquisition Contracts:

OASIS Pool 1: GS00Q14OADU102* OASIS Pool 4: GS00Q14OADU402* Multiple Award Schedule: GS-00F-084CA

* Battelle holds contracts in all unrestricted OASIS pools. However, we believe these two pools are

most relevant to this RFI.

This document is provided for discussion purposes only and should not be considered a formal offer at this time. Should you want to pursue the outlined plan further, a formal proposal will be submitted for your consideration.

This document includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed - in whole or in part - for any purpose other than to evaluate this document. This restriction does not limit the Government's right to use information contained in these data if it is obtained from another source without

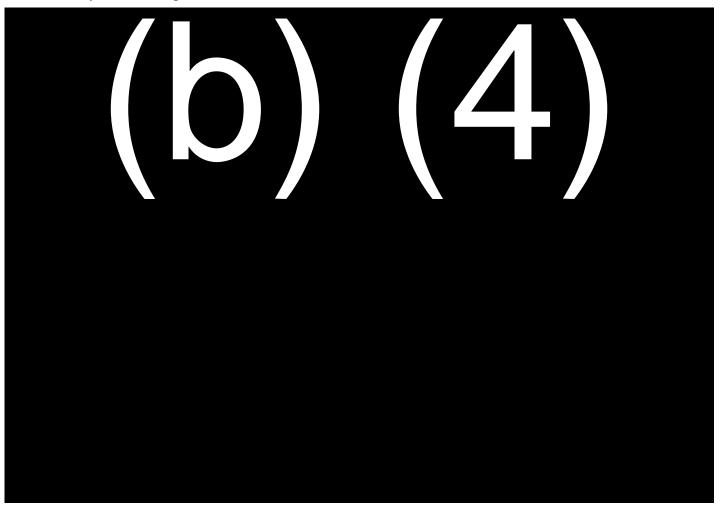


Summary

Recognizing the urgent need for modernizing Information Technology (IT) to achieve the mission of Health Resources and Services Administration (HRSA) serving the nation's organ transplant needs via the Organ Procurement and Transplantation Network (OPTN), Battelle is excited to share our major capabilities ready to address HRSA's need.

As recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM) committee, there are two major approaches to manage the risks associated with procuring the IT functionality necessary to perform the basic and sophisticated operations of the OPTN IT system:

- (i) Operate the current United Network for Organ Sharing (UNOS) IT infrastructure in parallel with a new IT infrastructure over a prescribed period of time. This approach ensures that a fallback capability remains available as the new IT infrastructure comes online.
- (ii) Build an agile system where key basic IT functions are made operational in a new system; once the first several functions are operational, then additional functions are systematically developed and added over time. This approach ensures that the eventual complete system is functional from the first day of its full operational status and not subject to catastrophic system development failure.





A. OPTN Technology - IT System

A.1. Describe how you would/a vendor would implement and utilize modern IT architecture to:

A.1.a. Manage, track, and operationalize the OPTN organ donation, procurement, allocation and transplant system, such as by adopting a "cloud-native," agile, and modular approach to IT development and maintenance.

To allow smarter regulation, increased transparency, better accountability, and improved efficiency, a system should be developed to incorporate a modern IT architecture that can perform the primary functions of a national resource allocation system.

(b) (4)

A.1.b. Prioritize the use of publicly accessible application programming interfaces (APIs) to enhance data sharing and integration with the electronic health records (EHRs) and other tools used by OPTN members and patients.

Application Programming Interfaces

To provide direct transmission of clinical and other data among authorized providers as well as to reduce burden on OPOs, transplant programs, and histocompatibility labs, the IT System should incorporate modern health information exchange approaches.

(b) (4)

Electronic clinical quality measures are

(b) (4)



(b) (4)

A.1.c. Enhance user interfaces to improve the ability of the OPTN IT system to conduct enhanced real-time tracking of donated organs, allocate organs more efficiently and support increased transplant center engagement with patients in organ acceptance decisions.

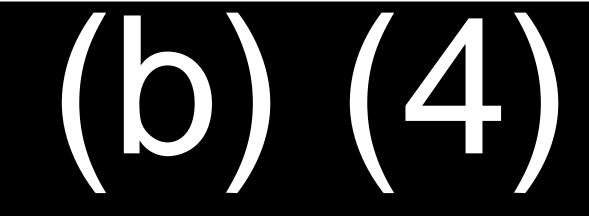
Online Functionality

To facilitate a rapid and accurate organ transplant process, implementation of online functionality that provides information transparently on the entire process of organ matching, including timing of offers and rejections, will be of paramount importance. Specifically, this online functionality includes: ability to enter and transmit clinical and other information on donors, transplant candidates, and transplant recipients; capability to transmit notifications of offers, acceptances of offers, patient safety concerns, decision-making tools, data transfer, and to facilitate logistics.

(b) (4)

(b) (4)

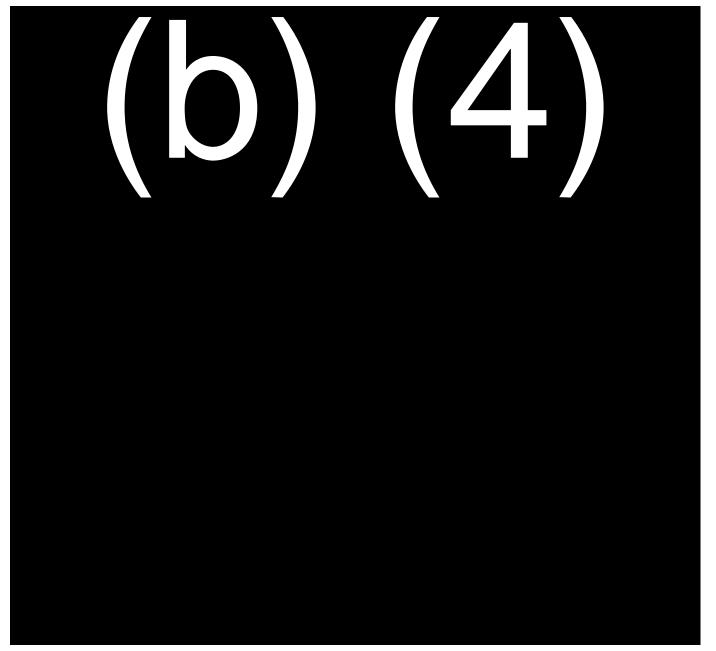


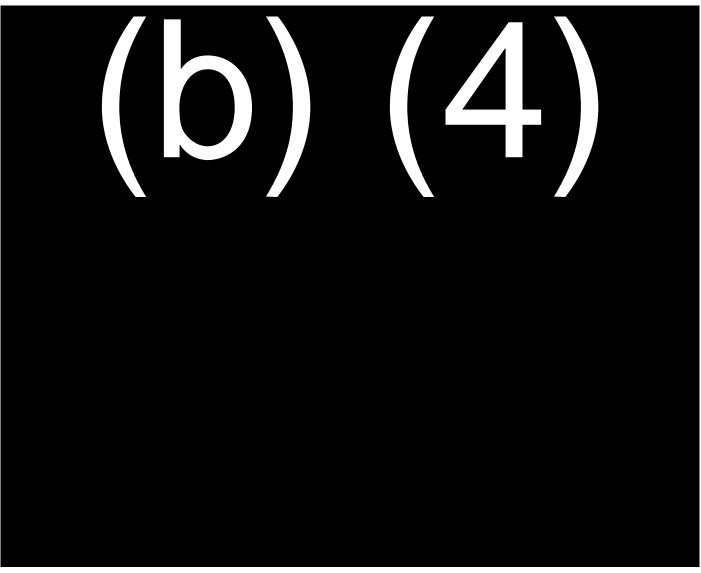




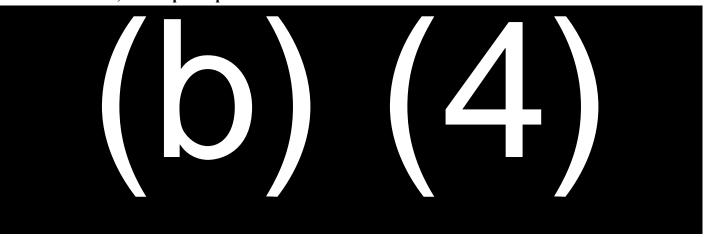
(b) (4)

A.1.d. Produce public performance dashboards and actionable data to identify opportunities for program improvement, reduce inequities, and benchmark OPTN member performance.



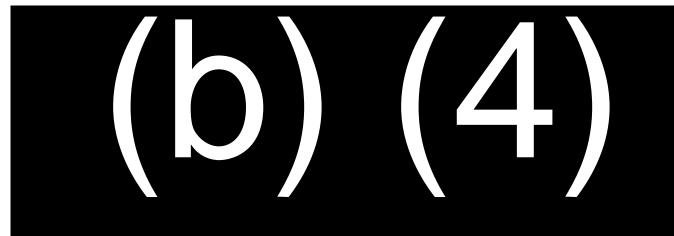


A.1.e. Maximize these and other tools to save critical time in the organ allocation process, minimize errors, and improve patient outcomes.

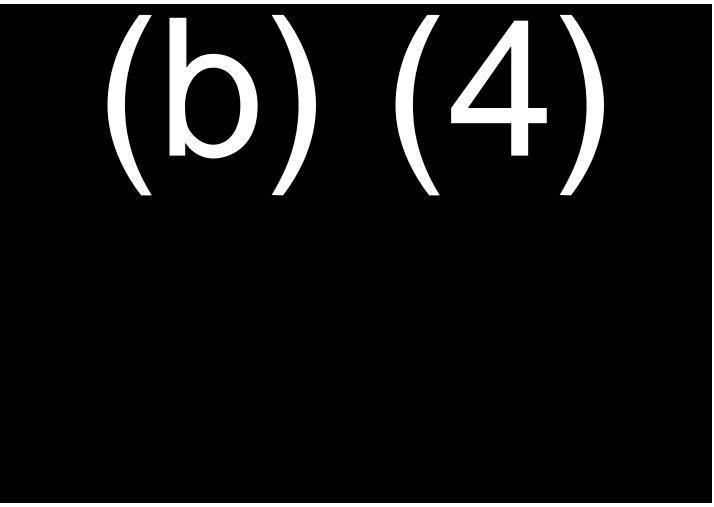


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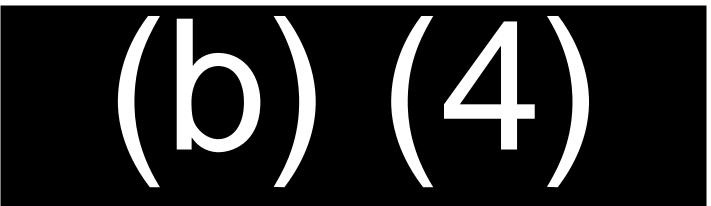








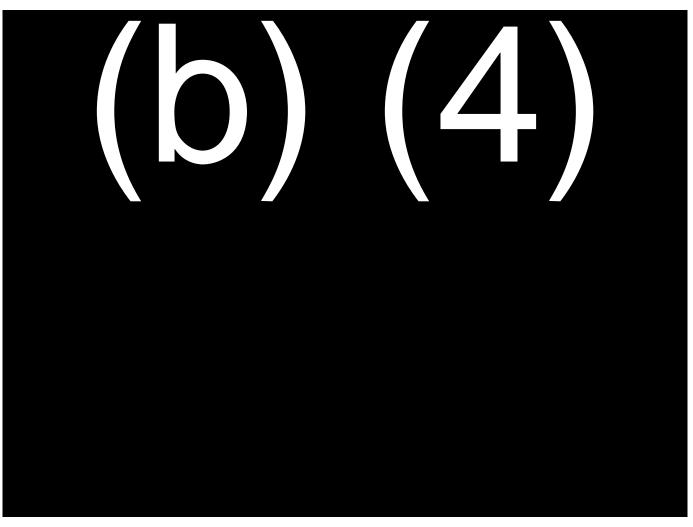
A.2. The current contract requires system availability uptime of 99.5%. HRSA is planning to target a 99.999% uptime for this life-saving OPTN IT system. Is 99.999% uptime reasonable and achievable? If not, what is an appropriate uptime standard for an IT system of this importance?



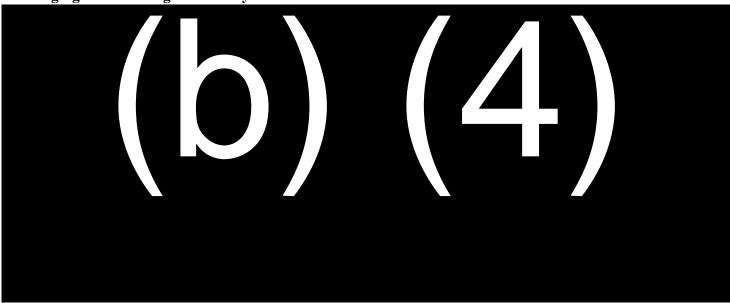
A.3. How can the OPTN ensure data collection is relevant, accurate, timely and streamlined in order to improve organ allocation processes?

(b) (4)

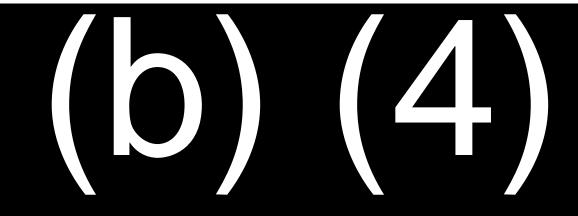




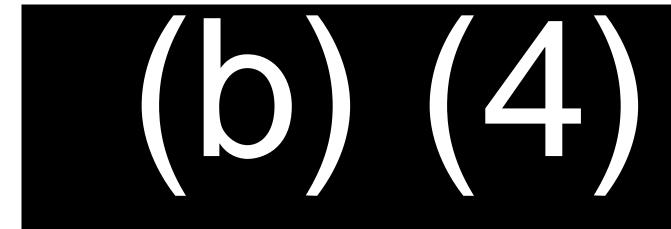
A.4. How would you/a vendor ensure ongoing security enhancements to protect against emerging and evolving IT security threats?





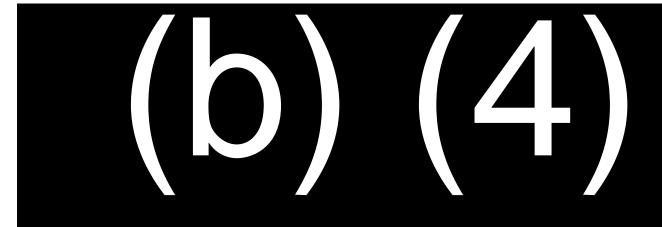


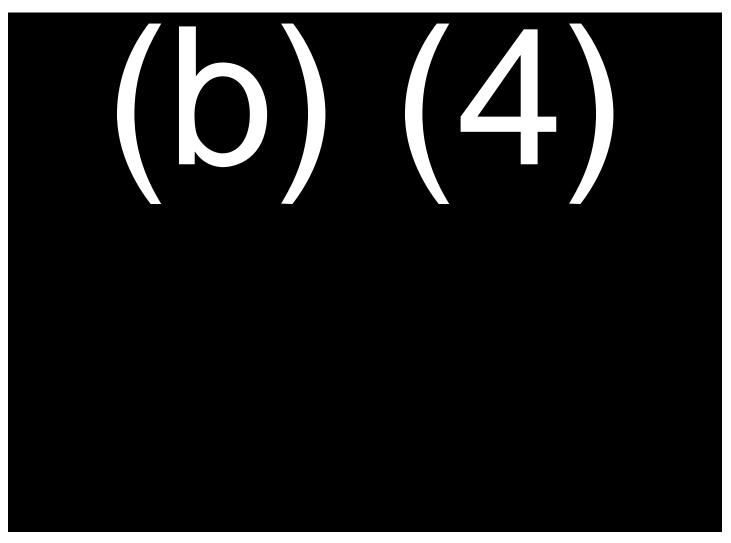




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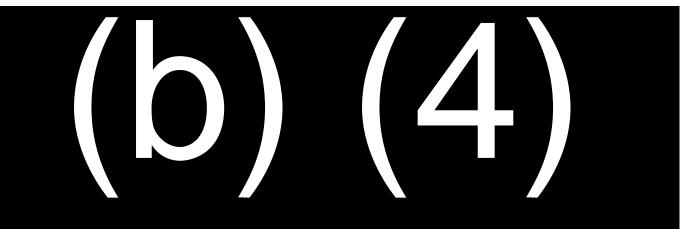




A.5. How would you/a vendor ensure adherence to the latest industry best practices for IT security infrastructure, practices, and standards?







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(b) (4)



Health Resources and Services Administration (HRSA) Organ Procurement and Transplantation Network (OPTN) Notice ID: HSB115C1031 Response to RFI

Prepared by:

Customer Value Partners, LLC

3701 Pender Drive, Suite 200 Fairfax, VA 22030 DUNS: 113045715

UEI/SAM: L6R3M86AFBB5

TIN: 01-0570597

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Date of Issuance: 8 April 2022

Date of Submission: 23 May 2022, 1:00PM

On 5 August 2021, Customer Value Partners, Inc. converted to Customer Value Partners, LLC as its successor in interest. There was no change in the assets or capabilities of the company or its DUNS number and TIN. Note: at the time of this submission, a name change package is in process to reflect Customer Value Partners, LLC and the System for Award Management will be updated when that submission is approved.

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed—in whole or in part—for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this Offeror as a result of—or in connection with—the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in all sheets of this proposal.



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BUSINESS INFORMATION (A)

COMPANY INFORMATION

CVP is pleased to respond to this RFI issued by the Health Resources and Services Administration (HRSA) for Organ Procurement and Transplantation (OPTN). Please find below information requested in Section A of the RFI solicitation:

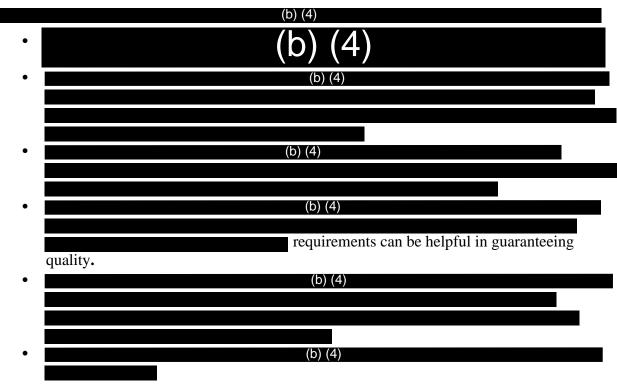
- 1. **Notice Number, Title, & Date of Issuance:** HSB115C1031 | Organ Procurement and Transplantation Network (OPTN) | 8 April 2022
- 2. Name of Company: Customer Value Partners, LLC
- 3. Address: 3701 Pender Drive, Suite 200 | Fairfax, VA 22030
- 4. **Point of Contact:** Cheree Hodges | Vice President, Contracts | T: 703.345.9138 | E: contracts@cvpcorp.com

CVP is an award-winning healthcare and next-gen technology and consulting services firm that helps organizations achieve lasting transformation and build a healthy, safe, and equitable world. The combined challenges faced by HRSA in improving the societal impact of the OPTN, combined with the need for modernization of the technology involved is core to CVP's mission.

SOLICITATION FEEDBACK

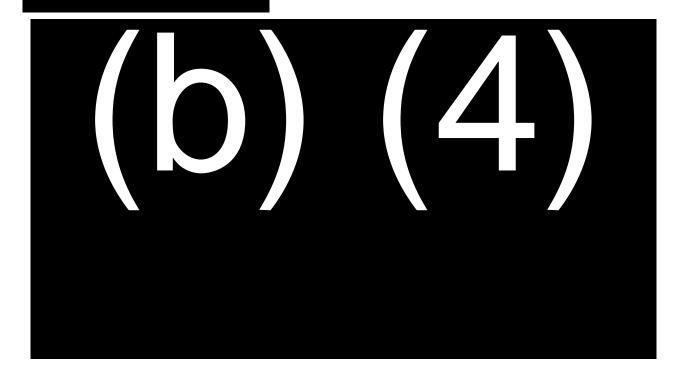
In terms of lives saved, the Organ Procurement and Transplantation Network (OPTN) is one of
the most impactful programs run by the United States Federal government. (b) (4)
The program's operability and effectiveness are matters of life and death. In accordance with the National Organ Transplant Act of 1984 (NOTA), the OPTN must be operated under Federal contract by a private, non-profit entity having expertise in organ procurement and transplantation. This is a very specific requirement, which not many organizations can meet. The current OPTN IT system has been run by the same non-profit organization for quite some time.
HRSA has outlined many objectives with this RFI which include increasing accountability in OPTN operations, governance, data transparency, policy, enhancing the usability and performance of the system, and strengthening equity and access in the organ donation process.
The mission criticality of this program creates unnecessary risk in switching contractors, yet the user community will greatly benefit from a modernization. (b) (4)
collaborating and enhancing OPTN. CVP proposes the idea (b) (4) We
believe HRSA should consider the (b) (4)
This vendor is held responsible for certain (b) (4)
RECOMMENDATION 1
(b) (4)





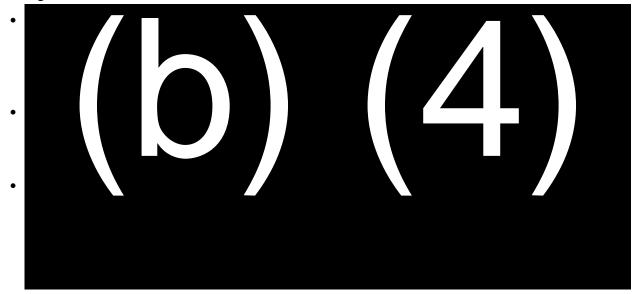
With our proposed recommendation, the core OPTN systems contract would remain intact, and the focus would continue to be development and maintenance to meet their statutory requirements.

(b) (4)





This type of contract is quite common in the Federal government where agencies have limited personnel available to supervise very large, complex IT projects. We have performed this type of role at agencies like:



In our response below, please see detailed case studies on the projects referenced above.

Ensure the development contractor

- (b) (4)

and that

- HRSA has a way to rapidly assess the system's functions. Give HRSA HSB an agent
- Reduce government burden in complex technical tasks

PROPOSED SOLUTION TO MEET NASEM RECOMMENDATIONS

As part of the proposed new |

(b) (4)

We bring depth of experience helping our Federal clients produce strategic plans, and work hand-in-hand to help clients achieve their strategic goals and objectives.

RECOMMENDATION 2



RESPONSE TO QUESTIONS (B)

This RFI is soliciting answers to many important questions, but as experts in this area, we find that many of these are difficult to answer in a truly useful manner without additional context. To meet all the needs called out in the RFI,

(b) (4)

RECOMMENDATION 3

(b) (4)

(b) (4)

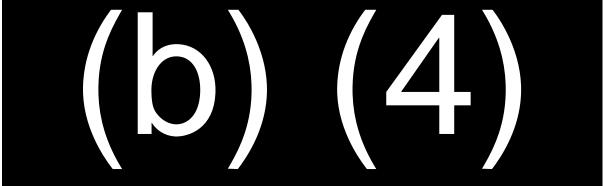
Based on what we have learned from the RFI and other documents,

(b) (4)

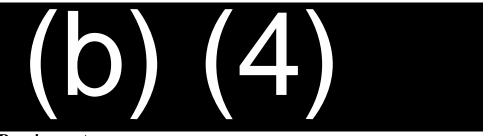
OPTN TECHNOLOGY – IT SYSTEM (RESPONSE TO QUESTION A.1 & A.2)

To recommend actionable, practical, and cost-effective improvements to modernize a system, we start with a detailed assessment of the current state of the system. This current state assessment would cover topics like:

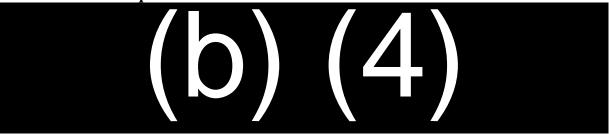
• Business Use or Functional Requirements:



• Integration:



• Non-functional Requirements:





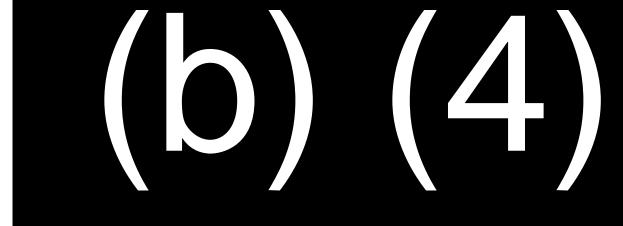
(b) (4)

We have worked with customers where 99.99% availability was required, but only during core business hours in the continental United States, meaning they can halve their cost for a backup data center without affecting their operational processes.

The answers to the above questions let us thoughtfully design a cost-effective solution that meets OPTN's needs without over-engineering a complex system that may be extremely expensive to

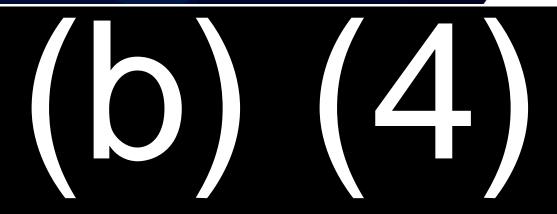
operate. For a customer at another (b) (4)

SUPPLEMENTAL & RELEVANT CASE STUDIES



Health Resources and Services (HRSA) Organ Procurement and Transplantation Solicitation No: HSB115C1031





Health Resources and Services (HRSA) Organ Procurement and Transplantation Solicitation No: HSB115C1031









STATEMENT OF INTENT (C)

It is critical that the Government be able to use resources at its disposal to eff money is spent on systems and how effective those systems and programs a	, .	
In the case of OPTN, we believe that HRSA can meet their goals to modern system with the use of the (b) (4). This contract array	ize and enhance their	
lditional (b) (4)		
innovation to meet the needs of OPTN today and tomorr opportunity to discuss in more detail.	row. We welcome the	
Of note, CVP is not a private non-profit; we would not be able to respond that is released with the requirement of award to a private non-profit.		

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ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK RFI

NOTICE ID: HSB115C1031

Department of Health and Human Services Heath Resources and Services Administration Office of Acquisition Management & Policy

May 23, 2022

SUBMITTED TO:

Naomi Inazawa Contract Specialist HRSA ninazawa@hrsa.gov

SUBMITTED BY:

Amanda Bonser Huron 678-468-0221 abonser@hcg.com

Large Business

Unique Identifier: VCE5JFBRME47 (fka DUNS 11367897)

CAGE: 3KVQ9



Special Item Numbers (SINs): 333318TDTM, 54151S, 541611, 611430 Multiple Award Schedule

IT and Professional Services Categories

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Huron Response to HRSA

Organ Procurement and Transplantation Network

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Executive Summary

The Health Resources and Services Administration (HRSA) can increase accountability, enhance performance, and strengthen equity, access, and transparency in OPTN operations by working with Huron. As you continue market research activities, Huron is poised to advise on leading practices from across the industry and inform the upcoming OPTN contract. Collaborating with Huron, HRSA receives optimization expertise with an unmatched combination of experience across governance, finance, technology, data collection, and policy to create an efficient and equitable system.

Our feedback in the following sections is founded on experience, industry leading practices, and lessons learned across over performance improvement engagements. HRSA benefits from Huron's feedback for the following reasons:

Competitors	Huron
Focus solely on digital, finance, or operational activities	Has a robust understanding of healthcare delivery to inform our recommendations. (b) (4) Our team includes over 1,000 healthcare professionals including physicians, providers, and nurses that deliver a rare blend of technical, operational, and clinical expertise to help solve complex business problems.
Lack healthcare-specific, data-driven platforms to develop impactful strategies	Acquired Perception Health in January 2022. Perception Health has built APIs, applications, and ETL processes to connect data and intelligence from our platform directly into the CRM, PRM, Business Intelligence, Cloud Storage, and population health software that clients like HRSA rely on to execute their strategy. Partnerships with Microsoft, AWS, Innovaccer, and Salesforce deliver the intelligence into systems already in use.
Some technology-focused firms are just entering the performance improvement space	Over the past 20+ years Huron has invented, tested, and refined our (b) (4) HRSA benefits from a methodology deployed at thousands of clients across industries to tackle broad, strategic initiatives of this size.
Have partnerships with relevant technology tools and platforms	We provide more than just a contracting conduit. With a team of more than 1,600 dedicated technology professionals with experience delivering more than 600 engagements across a variety of software and services, HRSA gains a vendoragnostic partner with the expertise to make technical recommendations that drive innovation, integration, and a better user experience.

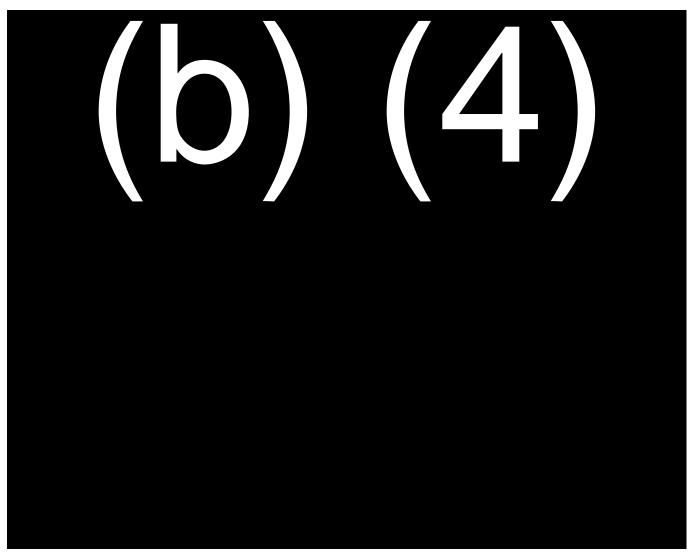


STATEMENT OF INTENT

Huron is interested in responding to an upcoming Request for Proposal (RFP) or any future solicitation relating to the market research requirements outlined in this Request for Information (RFI). With a teaming network of (b) (4), we stand ready to leverage our bench of expertise to support HRSA's primary objectives for improvements in the contract arrangement. We would welcome the opportunity to brief HRSA on our point of view regarding this RFI via a reverse industry day presentation.

LETTER OF RECOMMENDATION







Organ Procurement and Transplantation Network HSB115C1031

(b) (4)



Market Research Questions

A. OPTN TECHNOLOGY - IT SYSTEM

A.1 Approach to implement and utilize modern IT architecture

A.1.a Manage, track, and operationalize the OPTN organ donation, procurement, allocation and transplant system, such as by adopting a "cloud-native," agile, and modular approach to IT development and maintenance.

The technology that powers OPTN sets the pace for strategic goal achievement. We appreciate your underlying need to leverage technology and data to enhance the usability and performance of the OPTN IT systems. Huron aligns technology with strategy to enhance your agility and modernize the OPTN systems to manage each step of the organ donation process with actionable data insights. Our technology professionals evaluate your core and emerging technology platforms and tools to understand your complex ecosystem of digital assets and make specific recommendations for cloud adoption that yields a modern, scalable, and sustainable OPTN IT system. For optimal results, we gain a thorough understanding of your existing analytics footprint and capabilities to support your cloud data integration.

A.1.b. Prioritize the use of publicly accessible application programming interfaces (APIs) to enhance data sharing and integration with the electronic health records (EHRs) and other tools used by OPTN members and patients.

(b) (4)

Huron experts

can assess, analyze, and prioritize technologies that allow easy implementations of integration tools/processes across the system while increasing data integrity and reducing data burden.

A.1.c. Enhance user interfaces to improve the ability of the OPTN IT system to conduct enhanced real-time tracking of donated organs, allocate organs more efficiently and support increased transplant center engagement with patients in organ acceptance decisions.

Huron technical experts can assess and create processes for high quality data aggregation while creating reporting with actionable insights to allow for tracking, easy organ allocation, and patient engagement. Huron experts can design dashboards to push real-time¹ data for end users to enhance workflows in the organ donation, allocation, and transplant processes. Performance metrics/analytics are created from integrated data to monitor and assess transplant and OPO performance. We complete a comprehensive assessment of current user interfaces and technologies to optimize current technologies.

¹ Definition of real time: Relating to a system in which data is processed within milliseconds so that it is available virtually immediately as feedback (e.g., in a missile guidance or airline booking system); and any time.



4

Organ Procurement and Transplantation Network

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A.1.d. Produce public performance dash	v
	t, reduce inequities, and benchmark OPTN
member performance.	
Our digital experts develop	(b) (4)
	Constructing a user-
	Public performance dashboards should include, at
minimum,	(b) (4)
	_
Huron's digital professionals use	(b) (4)
	experienced user interface developers carry the design
	ality to ensure dashboards are highly reliable and lay
the groundwork for an optimal and equitab	ole digital experience.
A.1.e. Maximize these and other tools to	save critical time in the organ allocation process,
minimize errors, and improve patient or	
Huron experts review and assess current te	
A.2. The current contract requires syste	m availability uptime of 99.5%. HRSA is planning
	aving OPTN IT system. Is 99.999% uptime
	is an appropriate uptime standard for an IT
system of this importance?	is an appropriate aprime standard for an in
Huron believes that an uptime target of 99.	.999% is reasonable and achievable, (b) (4)
(b) (4) HRSA m	ust note that additional objectives should be
established with your system and environm	nent regarding reliability and performance as uptime is
just one of many measures.	(b) (4)
just one of many measures.	(~) ()
	·
A.3. How can the OPTN ensure data col	laction is relevant accurate timely and
streamlined in order to improve organ a	
	management, aggregation of data at a certain tier,
	ent technology, and leveraging new technology to
allow easy management of data for actiona	able insights. (b) (4)



Organ Procurement and Transplantation Network

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A.4. How would you/a vendor ensure ongoing security enhancements to protect against emerging and evolving IT security threats?

OPTN must work with your hosting services provider to ensure they are providing appropriate security measures. Huron can help OPTN review your existing policies and build out a proactive and robust cyber security program that includes various healthcare and industry independent standards for cyber security frameworks. Standards could include NIST, HITRUST, Critical Security Controls, ISO, and/or COBIT to provide the necessary policies and procedures to secure the integrity, confidentiality, and availability of OPTN's data.

A.5. How would you/a vendor ensure adherence to the latest industry best practices for IT security infrastructure, practices, and standards?

Huron recognizes that HIPAA security requirements are not methods of achieving compliance but rather define the compliance requirements using one of the frameworks mentioned in question A.4, or a similar framework.

(b) (4)

While developing the right framework is important, HRSA must prepare risk mitigation processes including downtime and recovery testing. Given the very high incident rate of personnel introducing malware into the environments themselves, establishing strong training/education programs of personnel is critical.

B. DATA COLLECTION ACTIVITIES

B.1. Describe how you would/how vendors could develop performance metrics and benchmarks for the organ donation, procurement, allocation and transplant system, including through expert consultation, subcontracting, and engagement with transplant candidates, transplant recipients, organ donors and their families about the metrics they value.

Huron takes a holistic and collaborative approach to metric and benchmark development that is informed by our experience in data analytics, governance, and change management. Huron can partner with OPTN to

(b) (4)

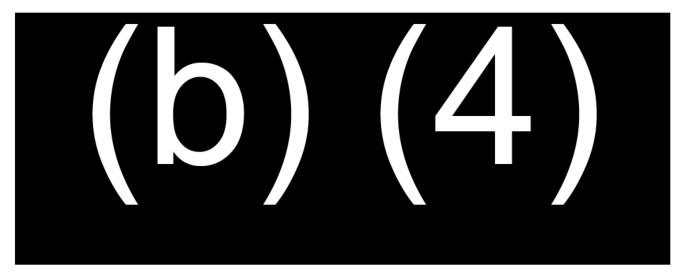
These forums can be used to source feedback directly from stakeholders the additional performance metrics beyond those outlined in OPTN's strategic plan, expectations of performance and outcomes to set benchmarks, and other desired goals for transparency, experience, and equity. Huron can assist with a review of possible data sources to drive each metric and provide recommendations on performance management, KPI goal setting, data governance, stakeholder engagement, and long-term change management.



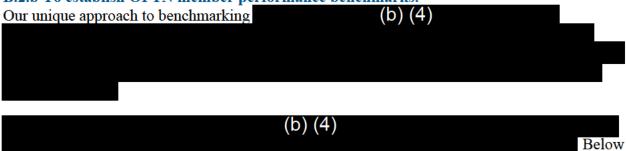
B.2. Approach to structuring data collection and reporting mechanisms for the system

B.2.a. To report OPTN performance metrics including process, outcome, and patient engagement measures.

Additionally, all metrics need definitions that are consistent and transparent to end users.

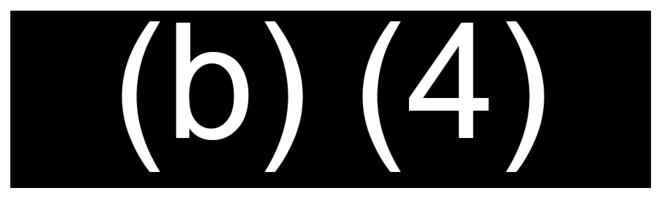


B.2.b To establish OPTN member performance benchmarks.



is a list of data sources Huron uses for benchmarking and analyses activities:



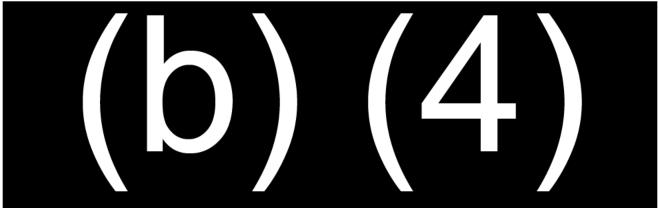


Huron can assist OPTN with creating predictive models around each of the major organ transplant categories, (b) (4)

Huron can also

assist OPTN with the assessment and integration of additional benchmark data sources, (b) (4)

B.2.c. To capture patient and donor demographics, including race, ethnicity, language and socioeconomic factors.



B.2.d To create public OPTN national, regional and local performance dashboards.

To advance strategic goals, OPTN must create public performance dashboards that deliver quantitative information and supporting detail that leads to action, increases the number of transplants, and improves transplant recipient outcomes. (b) (4)

Om

visual design process focuses on the aesthetics of the public dashboards and its related materials by strategically implementing images, colors, fonts, and other elements.



Organ Procurement and Transplantation Network

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The Huron team believes a successful visual design does not take away from the content on the page or function. Instead, it enhances visual design by engaging users and helping to build trust and interest in the public dashboards. Huron is a leader in driving analytics to the end-user through industry-leading data visualization tools (e.g., Tableau, PowerBI). (b) (4)

Huron's visualization team leverages industry-leading tools and thoughtful user interfaces to create dashboards that are user friendly, intuitive, and interactive.

B.2.e. To track long-term patient outcomes and health and non-health-related factors that contribute to outcomes.

Tracking complete, long-term patient outcomes requires combining the elements listed throughout question B.2 in a consolidated view.

(b) (4)

Such transparency and specificity for each patient not only

highlights factors driving patient health, but also allows for identification of inequitable outcomes across different patient populations.

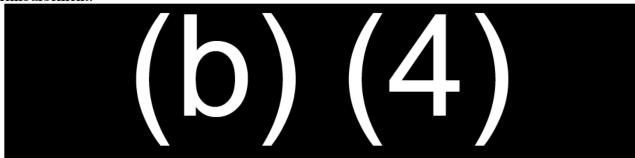
C. OPTN FINANCES

C.1. Approach to Fees

The current structure, policies, and procedures under which UNOS operates and receives payments for its services needs to be thoroughly reviewed and may require changes to its legacy operating procedures. Any recommended changes should be in the interest of the transplant community, ensuring equitable access to services and reducing costs to providers, which are primarily reimbursed by Medicare. Huron's experience working with organizations in all segments of healthcare creates a unique platform to identify opportunities to design and execute on new governance programs and implement appropriate oversight and accountability. Our team can design steps that align various stakeholders in achieving a new and efficient strategy. Below are some initial steps that we would recommend in the review of UNOS.

C.1.a. Do not duplicate Medicare payment or result in unnecessary additional Medicare reimbursement.

The OPTN contractor should take the following steps to prevent unnecessary Medicare reimbursement:



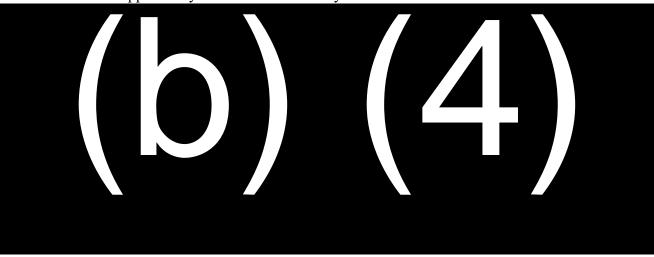


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(b) (4)

C.1.b. Do not charge for functions that are OPTN contract-supported functions.

Huron recommends that the OPTN follow the below steps so that fees are not charged for functions that are supported by the OPTN contract by:



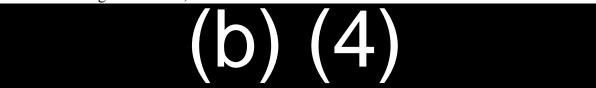
C.1.c. Are not perceived as mandatory for participation in the OPTN or for receiving core OPTN services.

Huron recommends that the OPTN follow the steps outlined below so that additional fees beyond the registration fee are not perceived as mandatory to receiving core OPTN services:



C.1.d. Do not impact, or create a perception of impact, status in or allocations through the OPTN.

To prevent any fees beyond the registration fee from creating a perception of impact in status in or allocation through the OPTN, Huron recommends that the OPTN:





C.2. What requirements and oversight mechanisms could be utilized to ensure appropriate federal review of the OPTN registration fee, any additional contractor fees, and the development of the overall OPTN budget?

Appropriate federal review of the OPTN registration fee, additional fees, and OPTN budget can be facilitated by simplifying the review process and providing transparency into the network's finances using the methods below.



D. OPTN GOVERNANCE

D.1. Describe how you would/how vendors could structure, finance and staff an OPTN board of directors independent of membership of the OPTN operational contractor's board of directors.

Huron believes that the first step to effectively structuring your board of directors (b) (4)

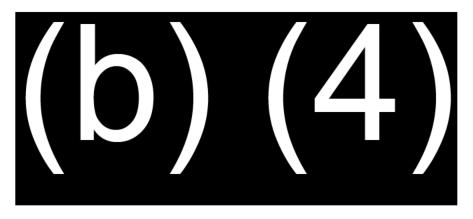
Huron

leverages our 16 years of experience working with the federal government and our two decades in the private sector to guide organizations like the OPTN through the process of structuring and restructuring their boards as well as assisting in facilitating board discussions, analysis, and staffing.

Below we have outlined our recommended steps to structuring and restructuring your board.







D.2. Describe the conflict-of-interest policies you would/vendors could implement to ensure independence of the OPTN board of directors.

OPTN board members and employees in general are expected to dedicate their best efforts to advancing the network's interests and to make decisions that affect the agency with objectivity and freedom from conflicting priorities.

(b) (4)



Through our experience, we've found that the best approach for the OPTN board of directors is to avoid potential conflicts whenever possible and disclose situations that might create a conflict, or even the appearance of a conflict. We believe that by following these recommendations for a conflict-of-interest policy, OPTN can create and maintain the independence of its board of directors.

D.3. Describe the reporting mechanisms you would/vendors could utilize to hold operational contractors' accountable for system performance and outcomes.

When establishing vendor accountability metrics Huron recommends that OPTN perform the following actions to inform and create reporting mechanisms that hold contractors accountable for system performance and outcomes:



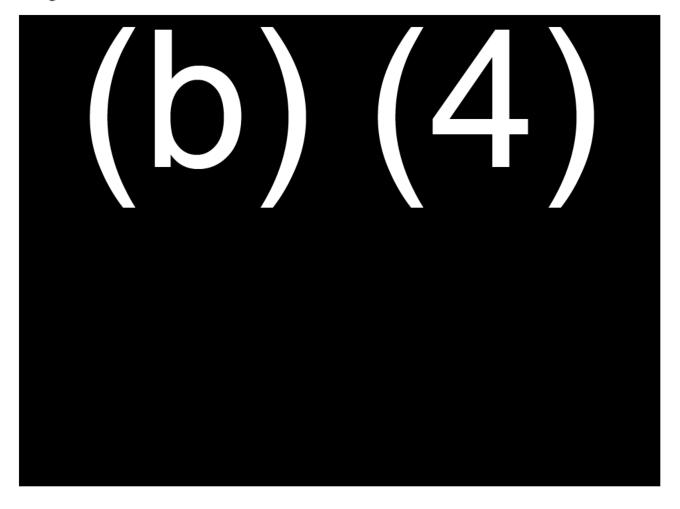


- Develop a vendor performance scorecard to effectively manage vendor performance, priorities, and return on investment
 - Performance scorecard should be customized to measure against key performance indicators that are relevant to the project and included in the contract

D.4. Describe the additional factors and process steps you would/vendors could take to ensure effective operations of such an independent board of directors.

There is no one-size-fits-all approach to effectively maintaining, monitoring, and evolving an agency's board of directors. (b) (4)

To sustain effective operations, leaders must constantly consider renewal and updates to the board. To determine whether it's time to renew a board, leadership teams must regularly think through:





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When transforming the network's leadership to spur innovation or navigate a modernization or transformation, boards of directors should not be immune to adaptation. By proactively disrupting the board of directors, OPTN can respond faster and more strategically to patient, family, taxpayer, employee, and management needs. To maintain a board that can support your agency at each stage of its evolution, it's critical that leaders:



E. INCREASING ORGAN DONATION AND IMPROVING PROCUREMENT

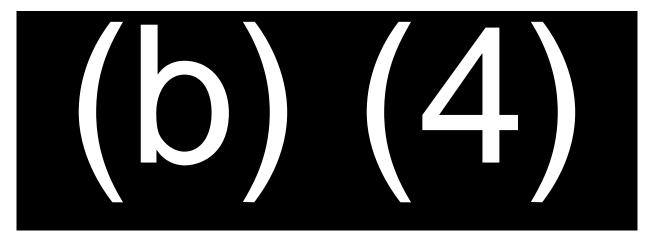
E.1. Describe how you would/how vendors could support the OPTN in revising OPTN policy requirements for OPOs to reduce variations in practices and procedures, facilitate increased organ donation and improved procurement, and otherwise improve OPO performance.

Veteran's Affairs **Experience:**

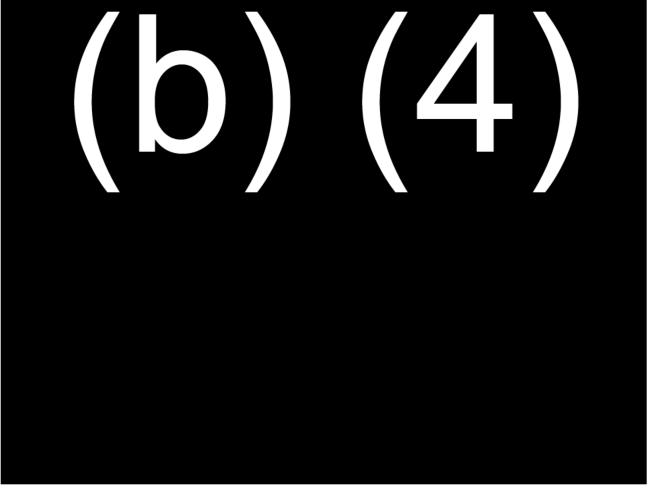
Huron worked with the VA to establish standardized policies that consolidated processes and procedures across 170 disparate VA Medical Centers in to seven regionally aligned business offices.

Federal agencies like HRSA can experience an overwhelming range of activities as you work to meet taxpayer expectations, regulatory responsibilities, mission goals, and objectives. Of the 57 Organ Procurement Organizations (OPO) within the OPTN, there may be 57 different processes followed for organ donation and procurement. HRSA should continue market research efforts with vendors that bring experience implementing performance improvement leading practices in other large government agencies and healthcare organizations.

Huron can support the OPTN in revising policy requirements to reduce variations in **practices** and procedures by:







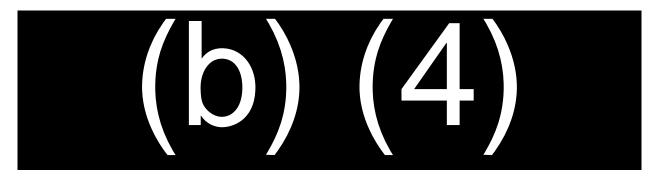
We implement these offerings using a proven methodology developed over our 20 years' experience providing process improvement consulting. By following this process, HRSA can efficiently implement process improvements throughout the network, allowing for increased unity and overall performance improvement.

E.2. How could the OPTN facilitate OPO engagement in research protocols to improve procurement?

Some organizations can consider research low on their priority list due to cost and time constraints. OPTN can facilitate OPO engagement in research protocols to improve procurement by engaging a consulting firm like Huron to provide research administration and support. (b) (4)

By engaging with a research administration partner, OPTN can receive operational and financial support services to free up valuable time and resources to engage in research opportunities more fully. The research solution should:



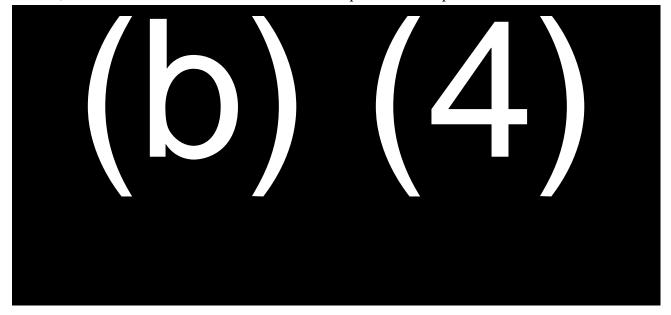


E.3. What additional research could contribute to improving organ procurement?



E.4. How can HRSA best incorporate the NASEM report's recommendations on increasing equitable access to transplants?

Increasing the supply of organs and improving organ procurement efficiencies can help alleviate downstream inequities in transplant access. However, increased organ supply does not address inequities caused by underlying organ transplant policies and processes. HRSA can incorporate the recommendations outlined in the NASEM report multiple ways, each with varying benefits, timelines, and costs. Our recommendations to address processes and policies include:





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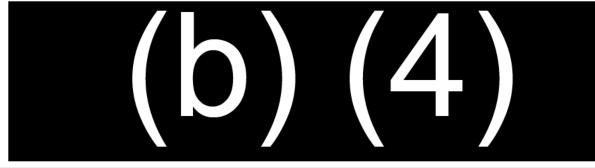
F. ORGAN USAGE

F.1. Describe how you would/a vendor could support the OPO performance improvement activities to decrease discarded organs and further increase the use of organs.

(b) (4)

HRSA can address

understaffing, communication and coordination, and accountability by assessing transplant workflow. We can increase OPO's availability and address anticipated staffing issues by:



(b) (4)

F.2. How can OPTN organ matching activities be modified to decrease non-usage (discards) of procured organs?

Organ matching activities require accurate input of a donor's clinical data and dedicated staff to work quickly in finding a transplant center and recipient. Time is valuable and staff require proper training and scheduling to maximize efforts. HRSA can benefit from Huron's experience increasing productivity through labor management tools, real-time leadership decision support, and automation.

F.3. Describe the steps you would/vendors could take to improve transparency around the organ matching and acceptance process for transplant candidates, transplant recipients, other affected patients, organ donors and family members served by the OPTN.

Transparency can be improved with better technology. As stated in question B.2.d, (b) (4)

Additionally, HRSA can limit discretionary activities among OPOs by clearly defining roles, responsibilities, and governance policies. Currently, OPOs have their own definitions of viability. Huron specializes in clearly defining policies and processes that improve performance.

(b) (4)



G. OPTN OPERATIONS AND POLICY DEVELOPMENT IMPROVEMENTS

G.1. Describe how you would/vendors could incorporate, to the full extent permitted under applicable law, the NASEM report's recommendations on increasing racial, ethnic, professional, and gender diversity on the boards and committees responsible for developing OPTN policies.

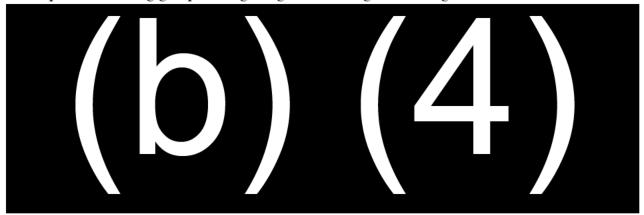
Our organization has been coaching and training healthcare leaders since 1999. Since our inception, our team has provided professional services that equip large-scale organizations with a proven approach to driving accountability. To incorporate the NASEM report's recommendations around diversity, equity, and inclusion (DEI), OPTN requires a vendor who has delivered this work in the federal landscape.

(b) (4)

We are currently deploying this approach at a VA Healthcare System. We are working with the health system's leaders — senior executives through frontline managers — to implement systematic changes within their culture to achieve DEI objectives.

G.2. Describe how you would/vendors could engage with experts in quality improvement and stakeholder collaboration in executing OPTN deliverables.

Through our work with 12 federal agencies, we have built an understanding of the complex challenges the federal workforce faces and have the in-house expertise to address quality improvement and stakeholder collaboration goals. Our team includes former executives with direct experience leading groups through large-scale changes including:



We regularly engage with external experts in quality improvement and stakeholder collaboration to execute on our clients' deliverables. For example, (b) (4)



HSB115C1031

G.3. Describe what you would/vendors could include in their code of business ethics and conduct for the entity that holds this contract to ensure the highest standards of conduct and integrity are observed.

A detailed and organized code of business ethics and conduct is essential to make certain that government contractors are providing their services as the highest possible standard. We take business ethics and codes of conduct seriously. An effective code should include:



Huron's Code of Business Conduct and Ethics (The Code) highlights our ethical way of doing business, which we believe is essential to our reputation as a leading consulting firm. The Code guides our performance through every client engagement. We believe our conduct should also demonstrate ethical leadership and promote a work environment that upholds our reputation for integrity, responsibility and trust. We reinforce our expectations through regular compliance training, including mandatory courses on preventing sexual harassment in the workplace, data security and privacy as well as a comprehensive review exercise covering all of our primary compliance policies and procedures. Additional training is provided to employees who may be engaged in more high-risk areas, such as the protection of protected health information (PHI) subject to the Health Insurance Portability and Accountability Act (HIPPA) or securing client data and technology subject to U.S. export control laws. Our Code is administered by our chief compliance officer (CCO), who reports directly to the company's general counsel and indirectly to the Audit Committee of the board of directors. The CCO provides a quarterly report to the Audit Committee detailing investigations concerning violations of company policies or ethical concerns and any resulting disciplinary actions.

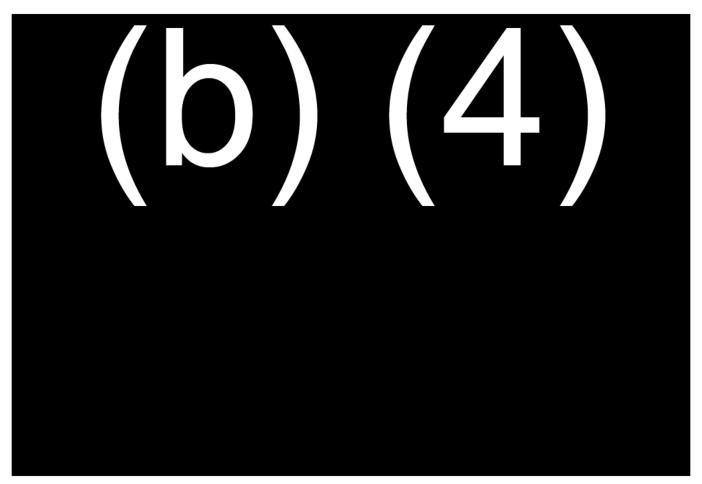


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G.4. What other improvements to OPTN operations and policy development processes can and/or should be incorporated into the OPTN contract?

Comprehensive Analysis

HRSA requires a comprehensive analysis of the current state of the OPTN contract to make improvements in the areas of accountability, usability, transparency, and performance. (b) (4)



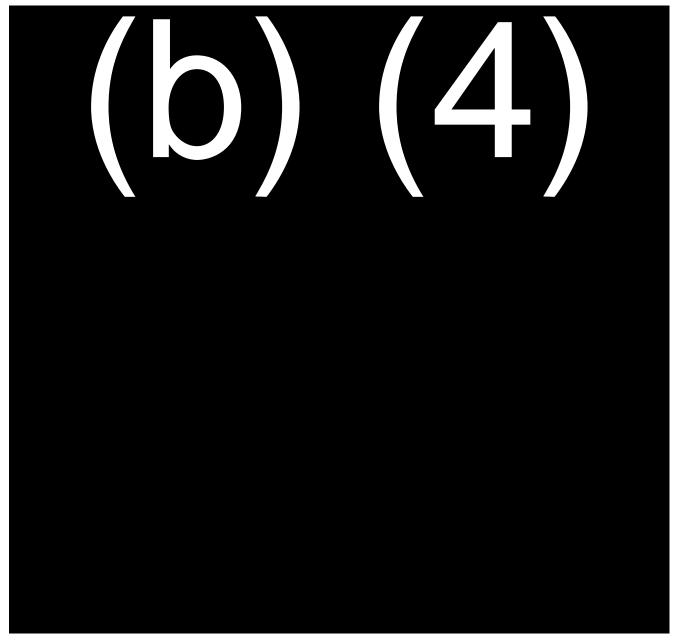
H. STAKEHOLDER ENGAGEMENT

H. 1. Describe how you would/vendors could support the OPTN incorporating the NASEM report's recommendations on improving their stakeholder engagement efforts and activities, including whether and how to improve patient awareness of all organs they have been offered and by monitoring their changing health and attitudes impacting organ acceptance decisions.

OPTN can improve stakeholder engagement efforts and activities by performing the following actions:



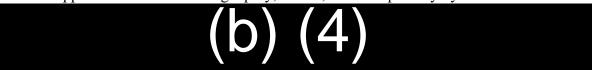




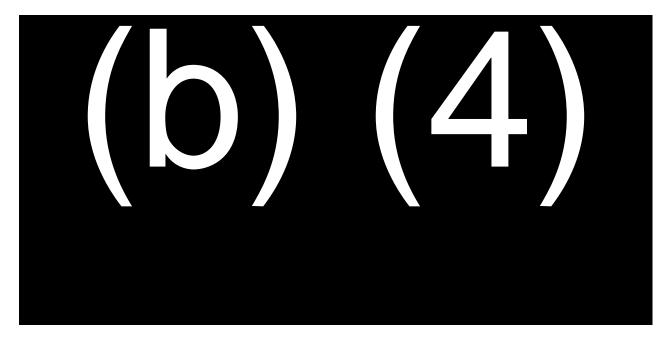
Huron has deployed this proven approach at dozens of organizations across the public and private sectors.

H.2. Describe how you would/vendors could support the OPTN in requiring OPTN members to adopt improved stakeholder engagement strategies that advance equity, access, and transparency.

Huron can support OPTN in advancing equity, access, and transparency by:

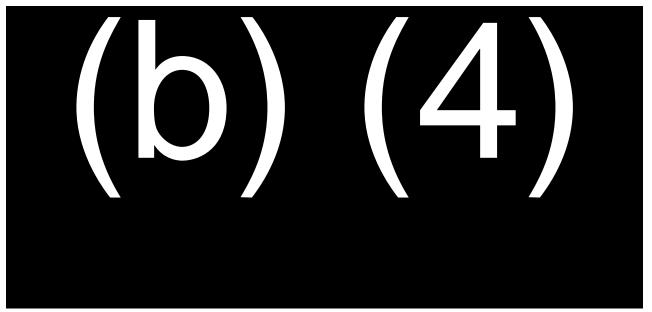






H.3. How can and/or should the contract incorporate new or better approaches for including stakeholders in a shared decision model for organ acceptance?

Huron recommends that the contract include the following approaches for including stakeholders in a shared decision model:



Focusing on new ways to communicate and offer care, providing education, and implementing a CRM not only makes for a better experience for those needing transplants, but it helps to create a better approach to include stakeholders in a shared decision model.



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Health Resources and Services Administration (HRSA)

Organ Procurement and Transplantation Network (OPTN)

Request for Information (RFI): SAM.gov ID# HSB115C1031

May 23, 2022/1:00 PM ET

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1 Request for Information

1.1 Introduction

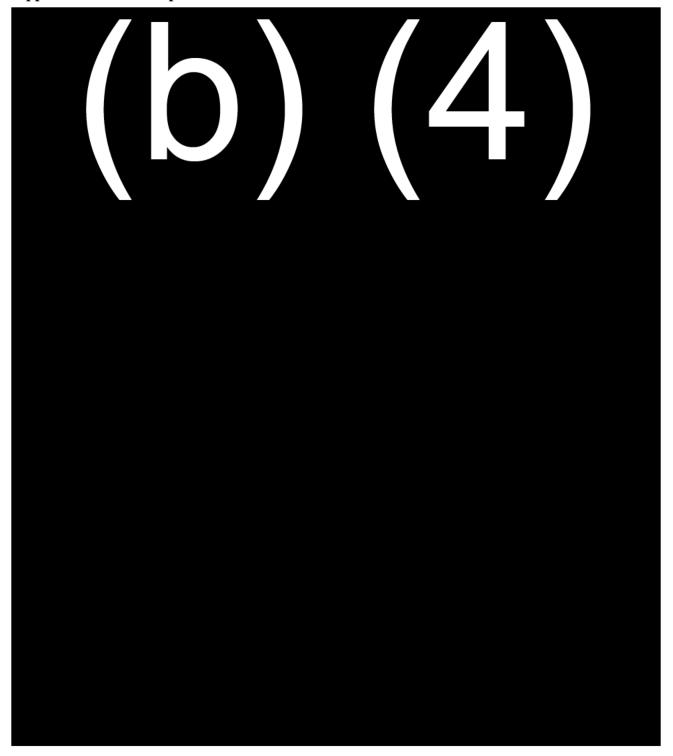
The Organ Procurement and Transplantation Network (OPTN) plays a vital role in bringing together a wide range of organizations and medical professionals to manage and orchestrate national organ donation and transplantation process to save lives. Today there are over 390 OPTN members consisting of transplant hospital programs, organ procurement organizations, transplant histocompatibility laboratories, voluntary health organizations, public members, and medical professional/scientific organizations. As outlined in the OTPN's 3-year (2021-24) strategic plan and supported by the objectives of this RFI, there are several areas of improvements in the OTPN systems and processes to increase the number of transplants, bring efficiency and equity in the matching process, reduce wastage of organs, and reduce the wait list. The strategic plan identifies several initiatives to achieve the identified goals to address the improvement areas. Given the complexity, size, and critical function provided by OTPN the execution of these strategic initiative will be challenging but key to continue improvement of OTPN and save more lives.



We have participated in the previous OPTN market research efforts and are responding partially to the below questions from this RFI.

A. OPTN Technology - IT System

- A.1 Describe how you would/a vendor would implement and utilize modern IT architecture to:
- A.1.a. Manage, track, and operationalize the OPTN organ donation, procurement, allocation, and transplant system, such as by adopting a "cloud-native," agile, and modular approach to IT development and maintenance.



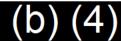


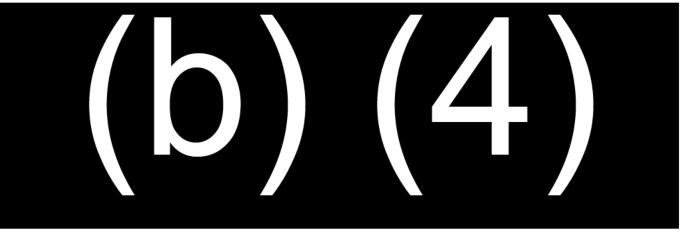
Figure 1 (b) (4)





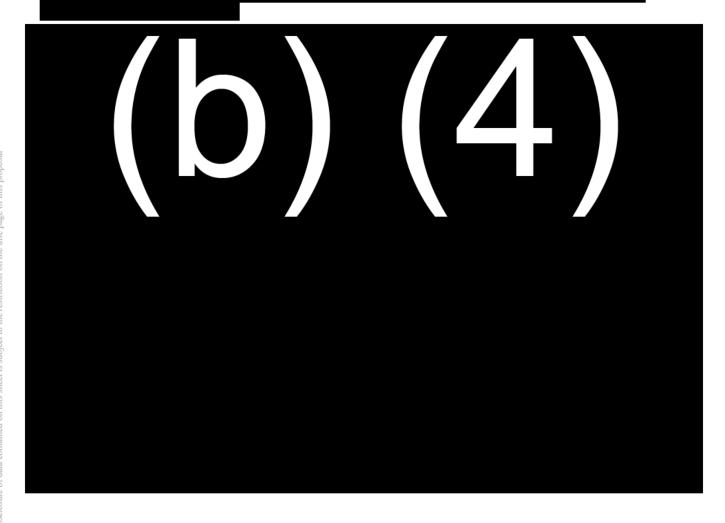


Figure 1: (b) (4)

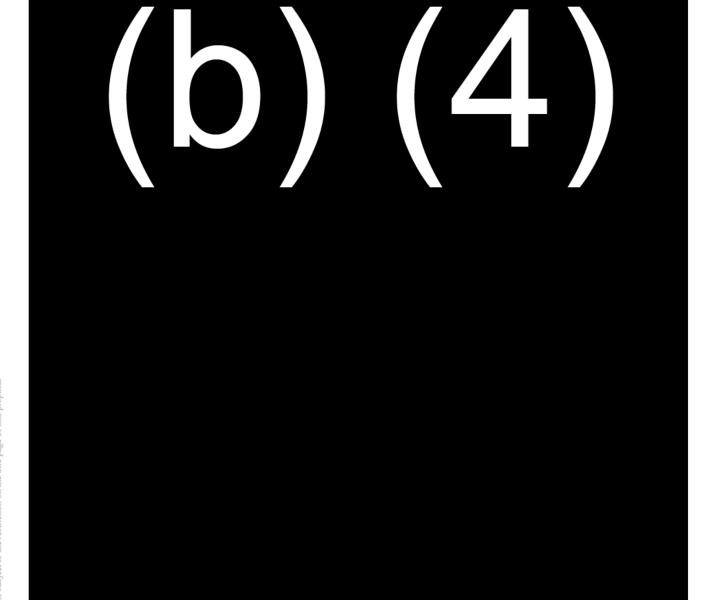


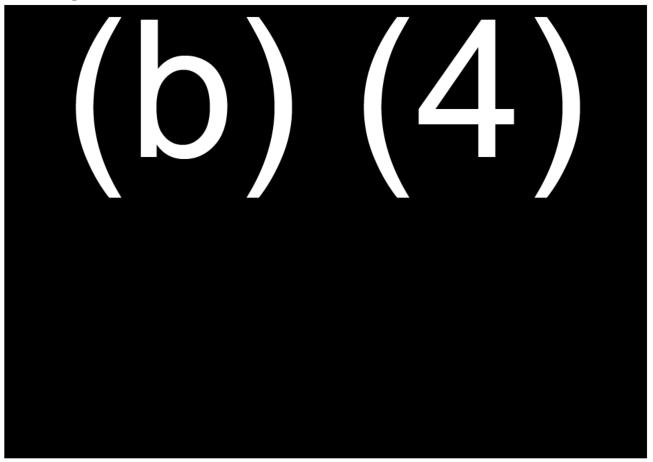
A.1.b Prioritize the use of publicly accessible application programming interfaces (APIs) to enhance data sharing and integration with the electronic health records (EHRs) and other tools used by OPTN members and patients.

OPTN must focus on seamlessly integrating data from member organizations and its own systems into the OPTN ecosystem for better visibility and efficiency. (b) (4)



A.1.c Enhance user interfaces to improve the ability of the OPTN IT system to conduct enhanced real-time tracking of donated organs, allocate organs more efficiently and support increased transplant center engagement with patients in organ acceptance decisions

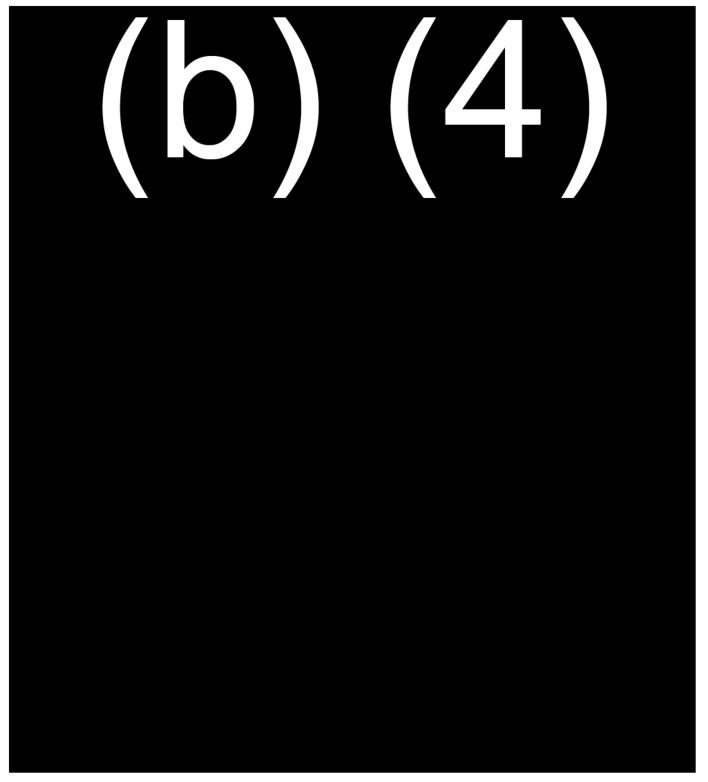


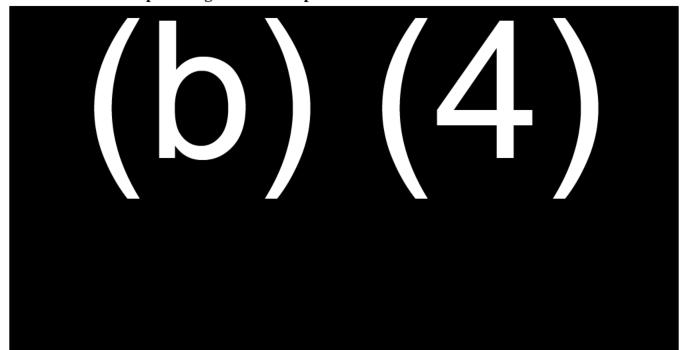


A.1.e Maximize these and other tools to save critical time in the organ allocation process, minimize errors, and improve patient outcomes.

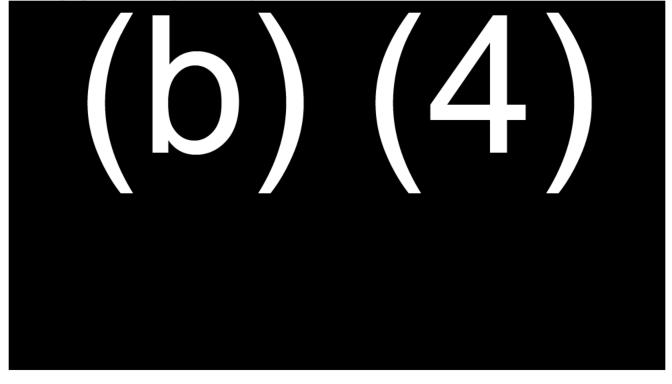


A.2 The current contract requires system availability uptime of 99.5%. HRSA is planning to target a 99.999% uptime for this lifesaving OPTN IT system. Is 99.999% uptime reasonable and achievable? If not, what is an appropriate uptime standard for an IT system of this importance?

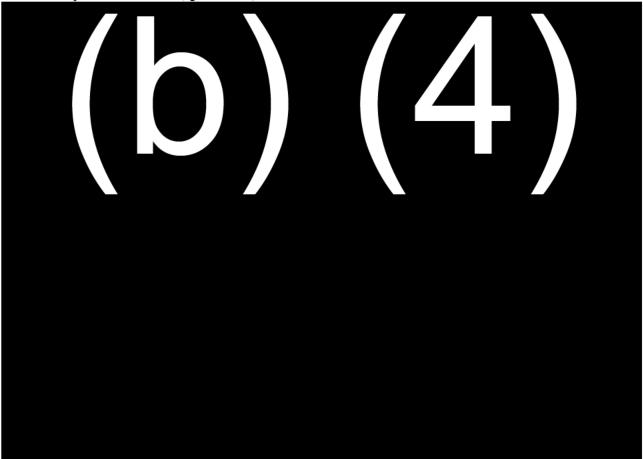




A.4 How would you/a vendor ensure ongoing security enhancements to protect against emerging and evolving IT security threats?



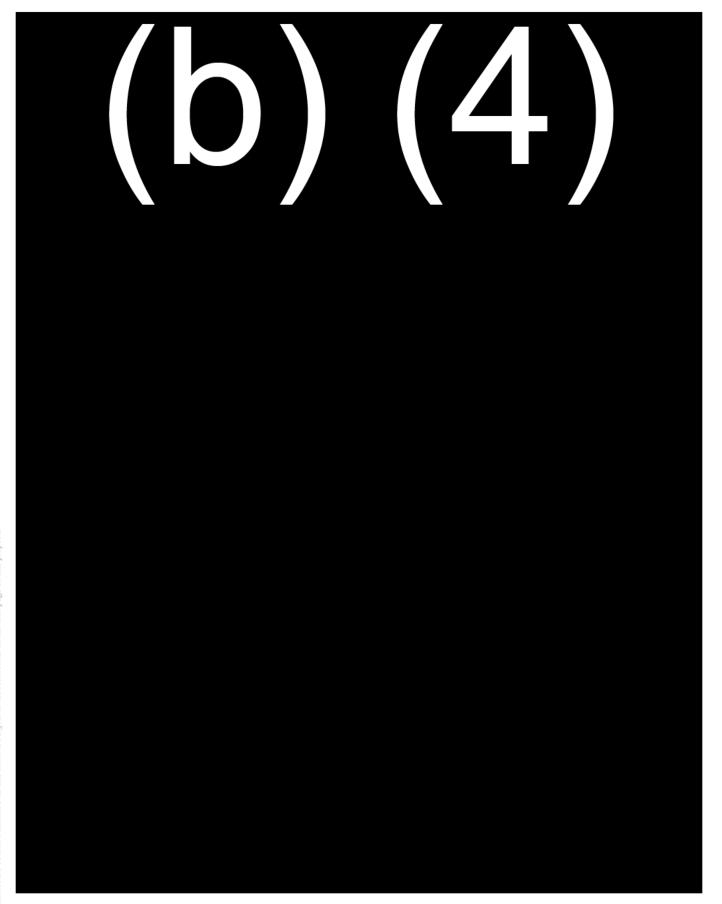
A.5 How would you/a vendor ensure adherence to the latest industry best practices for IT security infrastructure, practices, and standards?

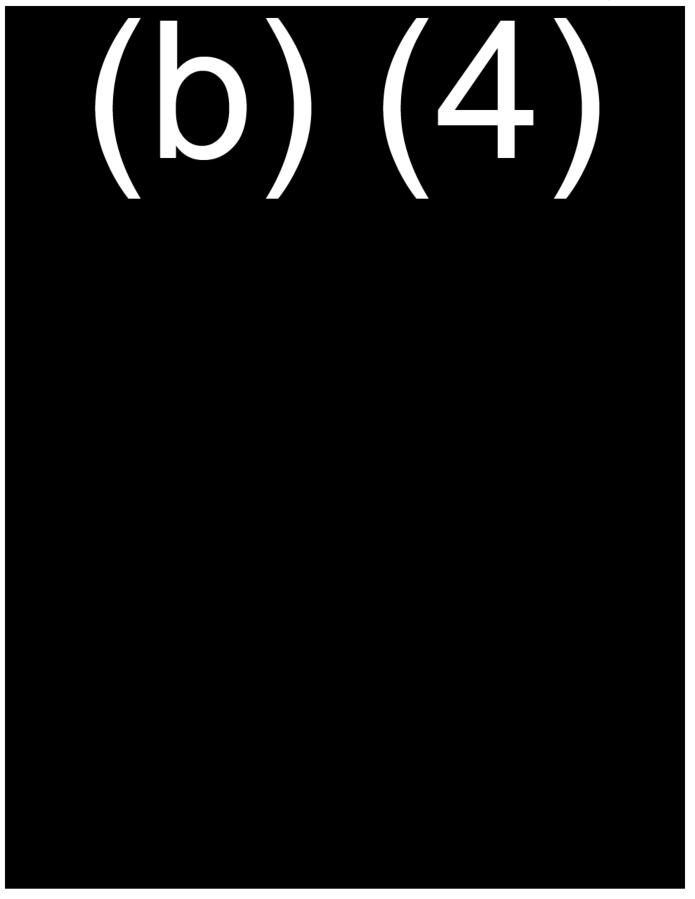


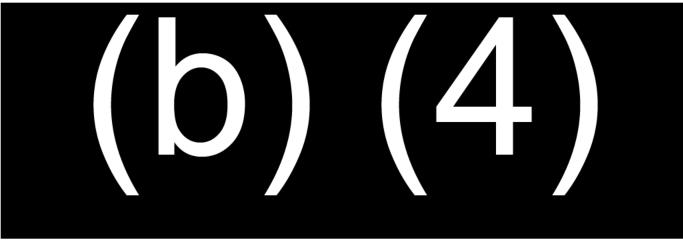
B Data Collection Activities

B.1 Describe how you would/how vendors could develop performance metrics and benchmarks for the organ donation, procurement, allocation, and transplant system, including through expert consultation, subcontracting, and engagement with transplant candidates, transplant recipients, organ donors and their families about the metrics they value.

(b) (4)

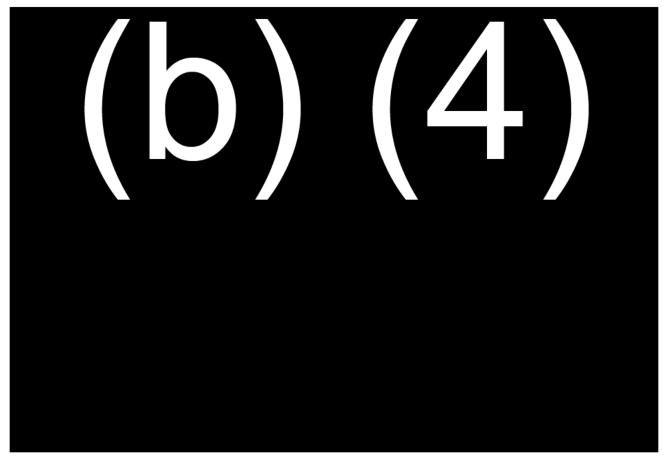






B.2.a Describe how you would/how vendors could structure data collection and reporting mechanisms for the system:

To report OPTN performance metrics including process, outcome, and patient engagement measures.

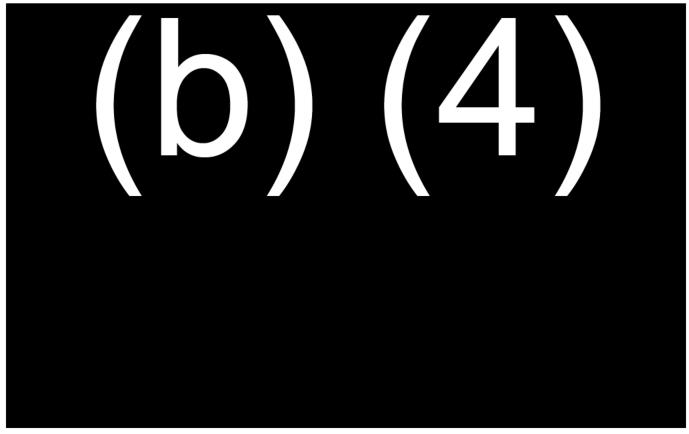


 $B.2.b \quad To\ establish\ OPTN\ member\ performance\ benchmarks.$

(b) (4)

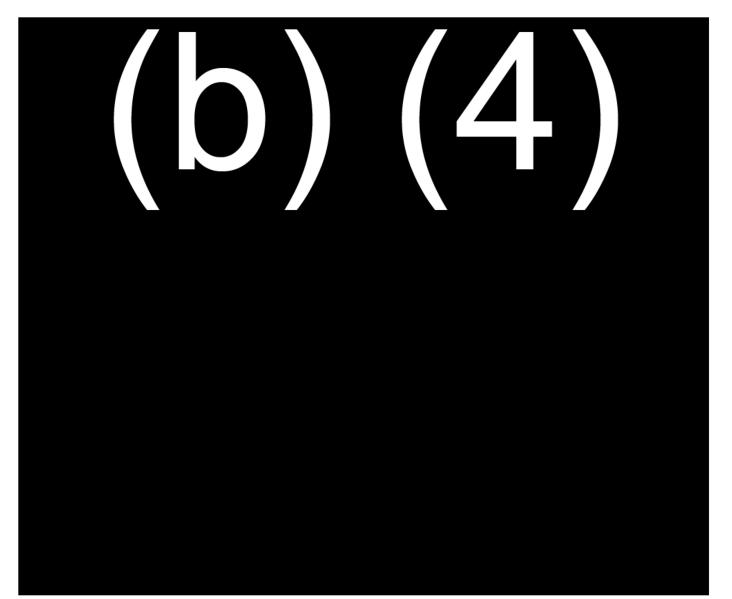


B.2.c To capture patient and donor demographics, including race, ethnicity, language, and socioeconomic factors.



B.2.d To create public OPTN national, regional, and local performance dashboards.

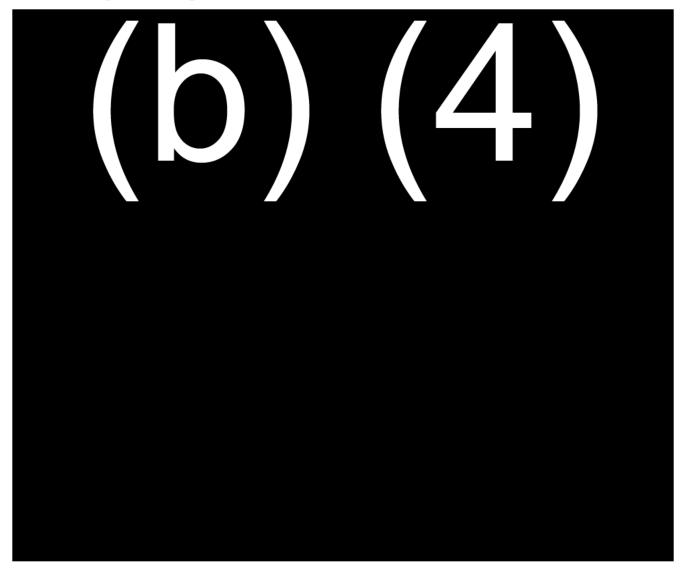
(b) (4)



B.2.e To track long-term patient outcomes and health and non-health-related factors that contribute to outcomes

To track long-term patient outcomes and non-health related factors, we will need to look at the

- C OPTN FINANCES No response provided for this section.
- D OPTN Governance No response provided for this section.
- E Increasing Organ Donation and Improving Procurement No response provided for this section.
- F Organ Usage
- F.1 Describe how you would/a vendor could support the OPO performance improvement activities to decrease discarded organs and further increase the use of organs.
- F.2 How can OPTN organ matching activities be modified to decrease non-usage (discards) of procured organs?



- F.3 Describe the steps you would/vendors could take to improve transparency around the organ matching and acceptance process for transplant candidates, transplant recipients, other affected patients, organ donors and family members served by the OPTN.
- **G** OPTN Operations and Policy Development Improvement No response provided for this section.
- H Statement of intent to supply a proposal on any future solicitation related to this requirement

